I

116TH CONGRESS
1ST SESSION

H. R. 1332

To address the high costs of health care services, prescription drugs, and health insurance coverage in the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2019

Mr. WESTERMAN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Judiciary, Oversight and Reform, Education and Labor, Rules, the Budget, Armed Services, and House Administration, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To address the high costs of health care services, prescription drugs, and health insurance coverage in the United States, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Fair Care Act of 2019''.

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

TITLE I—PRIVATE-SECTOR HEALTH INSURANCE REFORMS

Subtitle A—Commercial Health Insurance Provisions

SEC. 101. INVISIBLE HIGH RISK POOL REINSURANCE PROGRAM; TAX ON EXCHANGE PLANS.

(a) ESTABLISHMENT.—Not later than January 1, 2021, the Secretary of Health and Human Services shall establish the Invisible High Risk Pool Reinsurance Program (in this section referred to as the ''IHRPR program'').

(b) STATE GRANTS.—Under the IHRPR program, the Secretary shall, from amounts appropriated under subsection (f) for a fiscal year, award grants to States for such fiscal year, in amounts determined in accordance with the allocation methodology specified under subsection (d). Such grants shall be used for the purpose of establishing or maintaining a qualifying invisible high risk pool for the State.

(c) FEDERAL DEFAULT.—

(1) IN GENERAL.—In the case of a State that does not, by a date and in a manner specified by the Secretary, choose to be awarded a grant under subsection (b) for a fiscal year to operate a qualifying invisible high risk pool for the State, the Secretary shall, from amounts appropriated under subsection (f) for such fiscal year, use the allocation determined for the State under subsection (d) for participation of such State in the Federal default qualifying invisible high risk pool described in paragraph (2).

(2) FEDERAL DEFAULT QUALIFYING INVISIBLE HIGH RISK POOL.—The Federal default qualifying high risk pool is, with respect to each State that chooses not to be awarded a grant under subsection (b) with respect to a fiscal year for which funds are appropriated under subsection (f), an invisible high

risk pool under which health insurance issuers participating in the Exchange of such a State, with respect to designated individuals who are enrolled in health insurance coverage and are expected to experience higher than average health costs as determined by the insurer, cede risk to the pool, without affecting the premium paid by the designated individuals or their terms of coverage. With respect to such pool—

(A) high-risk individuals designated for cession to the pool shall be designated by the ceding issuer;

(B) the premium amount the ceding issuer shall pay to the reinsurance pool shall be 90 percent of the premium paid to the issuer for the coverage;

(C) the ceding issuer shall retain the same risk under the ceded policies as under any other policy of the issuer with respect to the first $10,000 of benefits for each ceded policy involved and will not retain any risk under ceded policies after such first $10,000 of benefits; and

(D) after a ceding issuer, with respect to a ceded policy, no longer retains risk under such policy pursuant to subparagraph (C), the

negotiated rate under such policy for items and services shall be payable at the reimbursement rate under the Medicare program under title XVIII of the Social Security Act for such items and services, or in the case of items and services for which payment is available under the policy but not the Medicare program, at a rate determined by the Secretary.

(d) ALLOCATION METHODOLOGY.—Not later than June 30, 2020, the Secretary shall specify an allocation methodology for determining the amount of funds appropriated under subsection (f) for a fiscal year to be allocated for each State for purposes of subsections (b) and (c). Such methodology shall be based on the number of residents of each State and the general health status of such residents.

(e) QUALIFYING INVISIBLE HIGH RISK POOL.—For purposes of this section, the term ''qualifying invisible high risk pool'' means, with respect to a State, a method of designation under which health insurance issuers identify individuals who experience higher than average health costs as determined by the State and are enrolled in health insurance coverage offered in the individual market, and cede the risk of spending more than $10,000 on health care services for a single individual to the pool without

affecting the premium paid by the designated individuals or their terms of coverage. With respect to such pool, the State, or an entity operating the pool on behalf of the State, shall establish—

(1) the premium amount the ceding issuer shall pay to the reinsurance pool;

(2) the applicable attachment points or coinsurance percentages if the ceding issuer retains any portion of the risk under ceded policies, except that the provisions of subparagraphs (C) and (D) of subsection (c)(2) shall apply to such high risk pool in the same manner as such clauses apply to the Federal default high risk pool; and

(3) the mechanism by which high-risk individuals are designated for cession to the pool, which may include a list of designated high-cost health conditions.

(f) APPROPRIATIONS.—There is appropriated to the Secretary of Health and Human Services $200,000,000,000 to carry out this section for the period of fiscal year 2020 through fiscal year 2029.

(g) TAX ON HEALTH INSURANCE PLANS SOLD ON EXCHANGES.—

(1) IN GENERAL.—Chapter 34 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subchapter:

"Subchapter C—Additional Tax on Health Insurance Plans Sold by Insurers Offering Plans on Exchanges

"SEC. 4401. ADDITIONAL TAX ON HEALTH INSURANCE PLANS SOLD BY INSURERS OFFERING PLANS ON EXCHANGES.

"(a) IMPOSITION OF TAX.—There is imposed a tax of $4 for each policy month of each health insurance policy sold by insurers offering plans through an Exchange established under the Patient Protection and Affordable Care Act.

"(b) LIABILITY.—The tax imposed by subsection (a) shall be paid by the plan sponsor.".

(2) CONFORMING AMENDMENT.—The table of subchapters for chapter 34 of the Internal Revenue Code of 1986 is amended by adding at the end the following item:

"SUBCHAPTER C—ADDITIONAL TAX ON HEALTH INSURANCE PLANS SOLD BY INSURERS OFFERING PLANS ON EXCHANGES".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to months beginning after the date of enactment of this Act.

SEC. 102. CHANGE IN PERMISSIBLE AGE VARIATION IN HEALTH INSURANCE PREMIUM RATES.

Section 2701(a)(1)(A)(iii) of the Public Health Service Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by inserting after ''(consistent with section 2707(c))'' the following: ''or, for plan years beginning on or after January 1, 2020, as the Secretary may implement through interim final regulation, 5 to 1 for adults (consistent with section 2707(c))''.

SEC. 103. EMPLOYER HEALTH INSURANCE MANDATE REPEAL.

(a) IN GENERAL.—Chapter 43 of the Internal Revenue Code of 1986 is amended by striking section 4980H.

(b) REPEAL OF RELATED REPORTING REQUIREMENTS.—Subpart D of part III of subchapter A of chapter 61 of such Code is amended by striking section 6056.

(c) CONFORMING AMENDMENTS.—

(1) Section 6724(d)(1)(B) of such Code is amended by inserting ''or'' at the end of clause (xxiii), by striking ''or'' at the end of clause (xxiv), and by striking clause (xxv).

(2) Section 6724(d)(2) of such Code is amended by inserting ''or'' at the end of subparagraph (GG) and by striking subparagraph (HH).

(3) The table of sections for chapter 43 of such Code is amended by striking the item relating to section 4980H.

(4) The table of sections for subpart D of part III of subchapter A of chapter 61 of such Code is amended by striking the item relating to section 6056.

(5) Section 1513 of the Patient Protection and Affordable Care Act is amended by striking subsection (c).

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall apply to months and other periods beginning after December 31, 2020.

(2) REPEAL OF STUDY AND REPORT.—The amendment made by subsection (c)(5) shall take effect on the date of the enactment of this Act.

SEC. 104. EMPLOYER BENEFITS REPORTS.

(a) IN GENERAL.—Subject to subsection (b), for each plan year beginning on or after January 1, 2021, a group health plan and a health insurance issuer offering group health insurance coverage shall provide to each individual enrolled in such plan or such coverage for such plan year a notification containing the following:

(1) The amount the sponsor of such group health plan expended with respect to such individual under such plan for such plan year (or, in the case of a health insurance issuer offering group health insurance coverage, the amount the employer of such individual contributed for such coverage for such individual for such plan year).

(2) The amount the sponsor of such group health plan expended with respect to such individual under such plan for each previous plan year (or, in the case of a health insurance issuer offering group health insurance coverage, the amount the employer of such individual contributed for such coverage for such individual for each previous plan year), if applicable.

(b) LIMITATION.—Subsection (a) shall not apply to a group health plan, or a health insurance issuer offering group health insurance coverage, for a plan year if, for such plan year, the number of individuals enrolled under such plan or such coverage was less than 100.

(c) PENALTY.—In the case that the Secretary of Health and Human Services determines that a group health plan or a health insurance issuer offering group health insurance failed to provide the notice required under subsection (a), the Secretary may impose a civil

monetary penalty on the sponsor of such plan or such issuer, as applicable, in an amount not to exceed $100 per individual enrolled in such plan or such coverage per day that such sponsor or issuer failed to provide such notification to such individual.

(d) DEFINITIONS.—In this section, the terms ''group health plan'', ''group health insurance coverage'', ''health insurance issuer'', and ''sponsor'' have the meaning given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91).

SEC. 105. WAIVERS FOR STATE INNOVATION.

(a) STREAMLINING THE STATE APPLICATION PROCESS.—Section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052) is amended—

(1) in subsection (a)(1)(C), by striking ''the law'' and inserting ''a law or has in effect a certification''; and

(2) in subsection (b)(2)—

(A) in the paragraph heading, by inserting ''OR CERTIFY'' after ''LAW'';

(B) in subparagraph (A)—

(i) by striking ''A law'' and inserting the following:

''(i) LAWS.—A law''; and

(ii) by adding at the end the following:

''(ii) CERTIFICATIONS.—A certification described in this paragraph is a document, signed by the Governor of the State, that certifies that such Governor has the authority under existing Federal and State law to take action under this section, including implementation of the State plan under subsection (a)(1)(B).''; and

(C) in subparagraph (B)—

(i) in the subparagraph heading, by striking ''OF OPT OUT''; and

(ii) by striking ''may repeal a law'' and all that follows through the period at the end and inserting the following: ''may terminate the authority provided under the waiver with respect to the State by—

''(i) repealing a law described in subparagraph (A)(i); or

''(ii) terminating a certification described in subparagraph (A)(ii), through a certification for such termination signed by the Governor of the State.''.

(b) PROVIDING EXPEDITED APPROVAL OF STATE WAIVERS.—Section 1332(d) of the Patient Protection and Affordable Care Act (42 U.S.C. 18052(d)) is amended—

(1) in paragraph (1) by striking ''180'' and inserting ''90''; and

(2) by adding at the end the following:

''(3) EXPEDITED DETERMINATION.—

''(A) IN GENERAL.—With respect to any application under subsection (a)(1) submitted on or after the date of this paragraph or any such application submitted prior to such date of enactment and under review by the Secretary on such date of enactment, the Secretary shall make a determination on such application, using the criteria for approval otherwise applicable under this section, not later than 45 days after the receipt of such application, and shall allow the public notice and comment at the State and Federal levels described under subsection (a)(4) to occur concurrently if such State application—

''(i) is submitted in response to an urgent situation, with respect to areas in the State that the Secretary determines are at risk for excessive premium increases or

having no health plans offered in the applicable health insurance market for the current or following plan year; or

''(ii) is for a waiver that is the same or substantially similar to a waiver that the Secretary already has approved for another State.

''(B) APPROVAL.—

''(i) URGENT SITUATIONS.—

''(I) PROVISIONAL APPROVAL.—A waiver approved under the expedited determination process under subparagraph (A)(i) shall be in effect for a period of 3 years, unless the State requests a shorter duration.

''(II) FULL APPROVAL.—Subject to the requirements for approval otherwise applicable under this section, not later than 1 year before the expiration of a provisional waiver period described in subclause (I) with respect to an application described in subparagraph (A)(i), the Secretary shall make a determination on whether to extend the approval of such waiver for

the full term of the waiver requested by the State, for a total approval period not to exceed 6 years. The Secretary may request additional information as the Secretary determines appropriate to make such determination.

''(ii) APPROVAL OF SAME OR SIMILAR APPLICATIONS.—An approval of a waiver under subparagraph (A)(ii) shall be subject to the terms of subsection (e).

''(C) GAO STUDY.—Not later than 5 years after the date of enactment of this paragraph, the Comptroller General of the United States shall conduct a review of all waivers approved pursuant to an application under subparagraph (A)(ii) to evaluate whether such waivers met the requirements of subsection (b)(1) and whether the applications should have qualified for such expedited process.''.

(c) PROVIDING CERTAINTY FOR STATE-BASED REFORMS.—Section 1332(e) of the Patient Protection and Affordable Care Act (42 U.S.C. 18052(e)) is amended by striking ''No waiver'' and all that follows through the pe-

riod at the end and inserting the following: ''A waiver under this section—

''(1) shall be in effect for a period of 6 years unless the State requests a shorter duration;

''(2) may be renewed, subject to the State meeting the criteria for approval otherwise applicable under this section, for unlimited additional 6-year periods upon application by the State; and

''(3) may not be suspended or terminated, in whole or in part, by the Secretary at any time before the date of expiration of the waiver period (including any renewal period under paragraph (2)), unless the Secretary determines that the State materially failed to comply with the terms and conditions of the waiver.''.

(d) ENSURING PATIENT ACCESS TO MORE FLEXIBLE HEALTH PLANS.—Section 1332(b)(1)(B) of the Patient Protection and Affordable Care Act (42 U.S.C. 18052(b)(1)(B)) is amended by striking ''at least as affordable'' and inserting ''of comparable affordability, including for low-income individuals, individuals with serious health needs, and other vulnerable populations,''.

(e) APPLICABILITY.—The amendments made by this Act to section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052)—

(1) with respect to applications for waivers under such section 1332 submitted after the date of enactment of this Act and applications for such waivers submitted prior to such date of enactment and under review by the Secretary on the date of enactment, shall take effect on the date of enactment of this Act; and

(2) with respect to applications for waivers approved under such section 1332 before the date of enactment of this Act, shall not require reconsideration of whether such applications meet the requirements of such section 1332, except that, at the request of a State, the Secretary shall recalculate the amount of funding provided under subsection (a)(3) of such section.

SEC. 106. STATE-OPERATED EXCHANGES FLEXIBILITY FOR OPEN ENROLLMENT PERIODS.

Section 1311(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(c)) is amended—

(1) in paragraph (6), by striking ''The Secretary'' and inserting ''Subject to paragraph (7), the Secretary''; and

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

''(7) FLEXIBILITY FOR ENROLLMENT PERIODS.—

''(A) STATE-OPERATED EXCHANGES OPEN ENROLLMENT PERIODS.—In the case of an Exchange operated by a State, beginning with plan year 2021, the Exchange may provide for open enrollment periods (after the initial enrollment period) every 12, 24, or 36 months, as determined by the State.''.

SEC. 107. ENROLLMENT PERIODS.

(a) EXCHANGES.—Paragraph (7) of section 1311(c) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(c)), as added by section 106, is amended by adding at the end the following new subparagraph:

''(B) ENROLLMENTS OTHER THAN DURING INITIAL, OPEN, AND SPECIAL ENROLLMENT PERIODS.—Beginning with plan year 2021, an Exchange may provide for enrollments during period in addition to open enrollment periods described in subparagraph (A) or paragraph (6) and special enrollment periods described in paragraph (6).''.

(b) HEALTH PLANS.—Subpart I of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

"SEC. 2710. ENROLLMENT OUTSIDE OF INITIAL, OPEN, AND SPECIAL ENROLLMENT PERIOD.

''Beginning with plan year 2021, a group health plan and a health insurance issuer offering group or individual health insurance coverage may provide for enrollment in such plan or coverage during periods in addition to initial, open, or special enrollment periods. In the case that an individual enrolls in such plan or coverage during a period pursuant to the previous sentence, the plan or issuer may charge the individual a one-time enrollment fee.''.

SEC. 108. SHORT-TERM LIMITED DURATION INSURANCE.

(a) DEFINITION.—Section 2791(b) of the Public Health Service Act (42 U.S.C. 300gg–91(b)) is amended by adding at the end the following:

''(6) SHORT-TERM LIMITED DURATION INSURANCE.—The term 'short-term limited duration insurance' means health insurance coverage provided pursuant to a contract with a health insurance issuer that has an expiration date specified in the contract (not taking into account any extensions that may be elected by the policyholder with or without the issuer's consent) that is less than 12 months after the original effective date of the contract.''.

(b) GUARANTEED RENEWABILITY.—Section 2703 of the Public Health Service Act (42 U.S.C. 300gg–2) is amended—

(1) in subsection (a), by inserting ''or offers short-term limited duration insurance'' after ''group market''; and

(2) by adding at the end the following:

''(f) APPLICATION TO SHORT-TERM LIMITED DURATION INSURANCE.—

''(1) IN GENERAL.—In applying this section in the case of short-term limited duration insurance—

''(A) a reference to 'health insurance coverage' with respect to such coverage offered in the individual market shall be deemed to include short-term limited duration insurance; and

''(B) a reference to 'health insurance issuer' with respect to health insurance coverage offered in the individual market shall be deemed to include an issuer of short-term limited duration insurance.

''(2) SPECIAL RULE FOR SHORT-TERM LIMITED DURATION INSURANCE.—In the case of short-term limited duration insurance, at the time of application for enrollment in such insurance coverage, an issuer of such insurance may offer renewability of such coverage, and an individual may decline renewability of such coverage in accordance with this section, and

the contract between such individual and the health insurance issuer shall specify whether the individual opted for renewability or no renewability.''.

(c) APPLICABILITY.—The amendments made by subsections (a) and (b) shall apply with respect to contracts for short-term limited duration insurance that take effect on or after January 1, 2020.

SEC. 109. PROMOTING HEALTH PLANS THAT COVER INDIVIDUALS IN MORE THAN ONE STATE.

There are appropriated, out of amounts in the Treasury not otherwise appropriated, $10,000,000 to be made available by December 31, 2020, to the Center for Medicare & Medicaid Innovation to fund new research or pilot programs dedicated to pursuing viable methods of enrolling individuals in health insurance programs that cross State lines.

SEC. 110. RESTORING THE APPLICATION OF ANTITRUST LAWS TO THE BUSINESS OF HEALTH INSURANCE.

(a) AMENDMENT TO MCCARRAN-FERGUSON ACT.—Section 3 of the Act of March 9, 1945 (15 U.S.C. 1013), commonly known as the McCarran-Ferguson Act, is amended by adding at the end the following:

''(c)(1) Nothing contained in this Act shall modify, impair, or supersede the operation of any of the antitrust

laws with respect to the business of health insurance (including the business of dental insurance and limited-scope dental benefits).

''(2) Paragraph (1) shall not apply with respect to making a contract, or engaging in a combination or conspiracy—

''(A) to collect, compile, or disseminate historical loss data;

''(B) to determine a loss development factor applicable to historical loss data;

''(C) to perform actuarial services if such contract, combination, or conspiracy does not involve a restraint of trade; or

''(D) to develop or disseminate a standard insurance policy form (including a standard addendum to an insurance policy form and standard terminology in an insurance policy form) if such contract, combination, or conspiracy is not to adhere to such standard form or require adherence to such standard form.

''(3) For purposes of this subsection—

''(A) the term 'antitrust laws' has the meaning given it in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12), except that such term includes section 5 of the Federal Trade Commission

Act (15 U.S.C. 45) to the extent that such section 5 applies to unfair methods of competition;

''(B) the term 'business of health insurance (including the business of dental insurance and limited-scope dental benefits)' does not include—

''(i) the business of life insurance (including annuities); or

''(ii) the business of property or casualty insurance, including but not limited to—

''(I) any insurance or benefits defined as 'excepted benefits' under paragraph (1), subparagraph (B) or (C) of paragraph (2), or paragraph (3) of section 9832(c) of the Internal Revenue Code of 1986 (26 U.S.C. 9832(c)) whether offered separately or in combination with insurance or benefits described in paragraph (2)(A) of such section; and

''(II) any other line of insurance that is classified as property or casualty insurance under State law;

''(C) the term 'historical loss data' means information respecting claims paid, or reserves held for claims reported, by any person engaged in the business of insurance; and

''(D) the term 'loss development factor' means an adjustment to be made to reserves held for losses incurred for claims reported by any person engaged in the business of insurance, for the purpose of bringing such reserves to an ultimate paid basis.''.

(b) RELATED PROVISION.—For purposes of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section applies to unfair methods of competition, section 3(c) of the McCarran-Ferguson Act shall apply with respect to the business of health insurance without regard to whether such business is carried on for profit, notwithstanding the definition of ''Corporation'' contained in section 4 of the Federal Trade Commission Act.

SEC. 111. HEALTH PLANS CREATED UNDER PPACA OR OFFERED THROUGH EXCHANGES TO BE ONLY HEALTH PLANS FEDERAL GOVERNMENT MAY MAKE AVAILABLE TO PRESIDENT, VICE PRESIDENT, MEMBERS OF CONGRESS, AND FEDERAL EMPLOYEES.

Section 1312(d)(3)(D) of the Patient Protection and Affordable Care Act (42 U.S.C. 18032(d)(3)(D)) is amended—

(1) in the subparagraph heading, by striking ''MEMBERS OF CONGRESS'' and inserting ''PRESI-

DENT, VICE PRESIDENT, MEMBERS OF CONGRESS, AND FEDERAL EMPLOYEES'';

(2) in clause (i), in the matter preceding subclause (I)—

(A) by striking ''Members of Congress and congressional staff'' and inserting ''the President, Vice President, Members of Congress, and Federal employees''; and

(B) by striking ''a Member of Congress or congressional staff'' and inserting ''the President, the Vice President, a Member of Congress, or a Federal employee''; and

(3) in clause (ii), by amending subclause (II) to read as follows:

''(II) FEDERAL EMPLOYEE.—The term 'Federal employee' means—

''(aa) an 'employee', as such term is defined in section 2105 of title 5, United States Code; and

''(bb) includes an individual to whom subsection (c) or (f) of such section 2105 pertains (whether or not such individual satisfies item (aa)).''.

SEC. 112. COST-SHARING REDUCTIONS.

(a) COST-SHARING REDUCTION PAYMENTS.—Section 1402 of the Patient Protection and Affordable Care Act (42 U.S.C. 18071) is amended by adding at the end the following new subsection:

''(g) FUNDING.—

''(1) APPROPRIATIONS.—There is appropriated, from any money in the Treasury not otherwise appropriated, such sums as may be necessary to, subject to paragraph (2), provide health benefits coverage through payment to issuers (under this section or through advance payment by the Secretary of the Treasury under section 1412(c)(3)) of the amounts computed under this section for each of plan years 2019 through 2022.

''(2) ADJUSTMENTS.—Notwithstanding any other provision of law, payments and other actions for adjustments to obligations incurred prior to December 31, 2020, may be made through December 31, 2021.

''(3) LIMITATION.—Amounts appropriated under paragraph (1) for each of plan years 2019 through 2022 are subject to the requirements and limitations under sections 506 and 507 of division H of Public Law 115–31 in the same manner and to

the same extent as if such amounts for each such year were appropriated under such division.''.

(b) ELECTION.—In the case of an election under this subsection by a State and a certification by the Secretary of Health and Human Services that such election will not result in an increase in Federal expenditures, in lieu of the amounts that would be paid to health insurance issuers in such State under section 1402 of the Patient Protection and Affordable Care Act, the Secretary may pay to such State an amount equal to such amounts. Prior to such payment, such State shall make such assurances as the Secretary deems necessary to ensure that such State shall redistribute such payments to health savings accounts of individuals—

(1) enrolled in qualified health plans (as defined in section 36B of the Internal Revenue Code of 1986) offered by such issuers, and

(2) whose income is less than 250 percent of the Federal poverty line.

SEC. 113. HEALTH SAVINGS ACCOUNTS.

(a) NO HIGH DEDUCTIBLE HEALTH PLANS REQUIRED FOR HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—

(1) IN GENERAL.—Section 223 of the Internal Revenue Code of 1986 is amended by inserting ''or

qualified health plan'' after ''high deductible health plan'' each place such term appears.

(2) QUALIFIED HEALTH PLAN DEFINED.—Section 223(c) of such Code is amended to read as follows:

''(c) ELIGIBLE INDIVIDUAL.—For purposes of this section—

''(1) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if such individual is covered under a qualified health plan as of the 1st day of such month.

''(2) QUALIFIED HEALTH PLAN.—The term 'qualified health plan' has the meaning given such term in section 36B.''.

(b) PREMIUMS FOR PLANS AS QUALIFIED MEDICAL EXPENSES; TREATMENT OF ABORTIONS.—

(1) IN GENERAL.—Section 223(d)(2)(B) of such Code is amended to read as follows:

''(B) ABORTIONS.—

''(i) PAYMENTS FOR HEALTH INSURANCE WITH ABORTION COVERAGE.—The term 'qualified medical expense' shall not include amounts paid for insurance that includes coverage for abortions.

''(ii) PAYMENTS FOR ABORTIONS.—The term 'qualified medical expense' shall not include amounts paid for an abortion.

''(iii) EXCEPTION.—Clauses (i) and (ii) shall not apply to an abortion, or to coverage for an abortion—

''(I) if the pregnancy is the result of an act of rape or incest, or

''(II) 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.''.

(2) CONFORMING AMENDMENT.—Subsection 223(d)(2) is amended by striking subparagraph (C).

SEC. 114. ADDING COPPER PLANS TO EXCHANGES.

(a) IN GENERAL.—Section 1302 of the Patient Protection and Affordable Care Act (42 U.S.C. 18022) is amended—

(1) in subsection (a)(3), by inserting ''copper,'' after ''either the'';

(2) in subsection (c), by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR COPPER PLANS.—A health plan in the copper level of coverage (as described in subsection (d)(1)(E)) shall be deemed to meet the requirements of this subsection.'';

(3) in subsection (d)—

(A) in paragraph (1), by adding at the end the following new subparagraph:

''(E) COPPER LEVEL.—A plan in the copper level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 50 percent of the full actuarial value of the benefits provided under the plan.''; and

(B) in paragraph (4)—

(i) by inserting ''copper,'' after ''any reference to a''; and

(ii) by inserting ''copper,'' after ''providing a''; and

(4) in subsection (e)(1), by inserting ''copper,'' after ''not providing a''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2020.

SEC. 115. ELIMINATING FEHBP ELIGIBILITY FOR ANNUITANTS.

Section 8905(b) of title 5, United States Code, is amended—

(1) in the matter preceding paragraph (1), by striking ''An'' and inserting ''Consistent with the last sentence of this subsection, an''; and

(2) by adding at the end the following: ''. An individual who is entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) by reason of section 226 or 226A of such Act (42 U.S.C. 426, 426–1), or otherwise eligible to enroll under such part pursuant to section 1818 or 1818A of such Act (42 U.S.C. 1395i–2, 1395i–2a), and who first becomes an annuitant after the date of enactment of this sentence may not continue enrollment in any health benefits plan under this chapter.''.

Subtitle B—Association Health Plans

SEC. 121. 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 re-

quirements 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 applicable 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 this section.

''(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.

''(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; whole-

saling/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 this section.

"(B) SOLE AUTHORITY.—The board has sole authority under the plan to approve applications for participation in the plan and to con-

tract 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 this section, 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 employers 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 ad-

ditional 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 authority 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 Sec-

retary 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 pur-

suant 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 Secretary 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 payment 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 pre-

scribe 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 this section, 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.

''(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 ac-

cordance 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 in-

come 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 stat-

ing 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 recovering 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 spon-

sor, 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 this section.

''(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 insur-

ance 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 this section, 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 Sec-

retary 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 (f)'';

(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 strik-

ing ''subsection (a)'' in subparagraph (B) and inserting ''subsection (a) of this section or subsection (a)(2)(B) or (b) of section 805''; and

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

''(f)(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 defined 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(d) of such Act (29 U.S.C. 1144(d)) 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 this paragraph 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, 2022, the Secretary of Labor shall report to the Committee on Education and Labor 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:

''PART 8. RULES GOVERNING ASSOCIATION HEALTH PLANS

''801. Association health plans.
''802. Certification of association health plans.
''803. Requirements relating to sponsors and boards of trustees.
''804. Participation and coverage requirements.
''805. Other requirements relating to plan documents, contribution rates, and benefit options.
''806. Maintenance of reserves and provisions for solvency for plans providing health benefits in addition to health insurance coverage.
''807. Requirements for application and related requirements.
''808. Notice requirements for voluntary termination.
''809. Corrective actions and mandatory termination.
''810. Trusteeship by the Secretary of insolvent association health plans providing health benefits in addition to health insurance coverage.
''811. State assessment authority.
''812. Definitions and rules of construction.''.

SEC. 122. 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. 123. 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 by adding at the end the following new subsection:

''(c) 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 the Employee Retirement Income Security Act of 1974 (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 the Employee Retirement Income Security

Act of 1974 (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. 124. 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 accord-

ance 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. 125. EFFECTIVE DATE AND TRANSITIONAL AND OTHER RULES.

(a) EFFECTIVE DATE.—The amendments made by this Act 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 Act 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.

(c) COORDINATION WITH EXISTING LAW.—Nothing in this Act shall require plans to become certified under section 802 of the Employee Retirement Income Security Act of 1974, as amended by this Act, or require plans that are not certified under such section to comply with the requirements under part 8 of such Act, except to the extent provided in section 809 of such Act.

Subtitle C—Tax-Related Provisions

SEC. 131. PREMIUM ASSISTANCE ADJUSTMENT TO REFLECT AGE.

(a) MODIFICATION OF APPLICABLE PERCENTAGE.—Section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended to read as follows:

''(A) APPLICABLE PERCENTAGE.—

"(i) IN GENERAL.—The applicable percentage for any taxable year shall be the percentage such that the applicable percentage for any taxpayer whose household income is within an income tier specified in the following table shall increase, on a sliding scale in a linear manner, from the initial percentage to the final percentage specified in such table for such income tier with respect to a taxpayer of the age involved:

"In the case of household income (expressed as a percent of the poverty line) within the following income tier:	Up to Age 29		Age 30–39		Age 40–49		Age 50–59		Over Age 59	
	Initial %	Final %	Initial %	Final %	Initial %	Final %	Initial %	Final %	Initial %	Final %
Up to 100%	0	0	0	0	0	0	0	0	0	0
100%–133%	2	2	2	2	2	2	2	2	2	2
133%–150%	3	4	3	4	3	4	3	4	3	4
150%–200%	4	4.3	4	5.3	4	6.3	4	7.3	4	8.3
200%–250%	4.3	4.3	5.3	5.9	6.3	8.05	7.3	9	8.3	10
250%–300%	4.3	4.3	5.9	5.9	8.05	8.35	9	10.5	10	11.5
300%–400%	4.3	4.3	5.9	5.9	8.35	8.35	10.5	10.5	11.5	11.5

"(ii) AGE DETERMINATIONS.—

"(I) IN GENERAL.—For purposes of clause (i), the age of the taxpayer taken into account under clause (i) with respect to any taxable year is the age attained by such taxpayer before the close of such taxable year.

"(II) JOINT RETURNS.—In the case of a joint return, the age of the older spouse shall be taken into account under clause (i).

"(iii) INDEXING.—In the case of any taxable year beginning after calendar year 2021, the initial and final percentages contained in clause (i) shall be adjusted to reflect—

"(I) the excess (if any) of the rate of premium growth for the period beginning with calendar year 2013 and ending with calendar year 2020, over the rate of income growth for such period, and

"(II) in addition to any adjustment under subclause (I), the excess (if any) of the rate of premium growth for calendar year 2020, over the rate of growth in the consumer price index for calendar year 2020.

"(iv) FAILSAFE.—Clause (iii)(II) shall apply only if the aggregate amount of premium tax credits under this section and cost-sharing reductions under section 1402

of the Patient Protection and Affordable Care Act for calendar year 2018 exceeds an amount equal to 0.504 percent of the gross domestic product for such calendar year.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2020.

SEC. 132. REPEAL OF ANNUAL FEE ON HEALTH INSURANCE PROVIDERS.

(a) IN GENERAL.—The Patient Protection and Affordable Care Act is amended by striking section 9010.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to calendar years beginning after December 31, 2019.

SEC. 133. REPEAL OF MEDICAL DEVICE EXCISE TAX.

(a) IN GENERAL.—Chapter 32 of the Internal Revenue Code of 1986 is amended by striking subchapter E.

(b) CONFORMING AMENDMENTS.—

(1) Subsection (a) of section 4221 of such Code is amended by striking the last sentence.

(2) Paragraph (2) of section 6416(b) of such Code is amended by striking the last sentence.

(c) CLERICAL AMENDMENT.—The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to sales after December 31, 2017.

SEC. 134. INCLUSION IN INCOME OF CERTAIN COSTS OF EMPLOYER-PROVIDED COVERAGE UNDER HEALTH PLANS.

(a) IN GENERAL.—Section 106 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(h) LIMITATION.—

''(1) IN GENERAL.—Subsection (a) shall not apply to the extent that employer-provided coverage under health plans for an employee for a taxable year exceeds—

''(A) $10,200 for self-only coverage, and

''(B) $27,500 for all other coverage.

''(2) IN GENERAL.—In the case of any calendar year after 2021, the dollar amounts in paragraph (1) shall each be increased by an amount equal to—

''(A) such dollar amount, multiplied by—

''(B) the cost-of-living adjustment determined under section 1(f)(3) for such calendar year, determined

"(i) by substituting 'calendar year 2020' for 'calendar year 2016' in subparagraph (A)(ii) thereof, and

"(ii) by substituting for the C–CPI–U referred to in section 1(f)(3)(A) the amount that such CPI would have been if the annual percentage increase in CPI with respect to each year after 2020 and before 2031 had been one percentage point greater.

"(3) TERMS RELATED TO CPI.—

"(A) ANNUAL PERCENTAGE INCREASE.—For purposes of subparagraph (B)(ii)(II), the term 'annual percentage increase' means the percentage (if any) by which C–CPI–U for any year exceeds the C–CPI–U for the prior year.

"(B) OTHER TERMS.—Terms used in this paragraph which are also used in section 1(f)(3) shall have the same meanings as when used in such section.".

(b) REPEAL OF EMPLOYER-SPONSORED HEALTH COVERAGE EXCISE TAX.—The Internal Revenue Code of 1986 is amended by striking section 4980I.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to taxable years beginning after December 31, 2020.

SEC. 135. INCLUSION OF CERTAIN OVER-THE-COUNTER MEDICAL PRODUCTS AS QUALIFIED MEDICAL EXPENSES.

(a) HSAS.—Section 223(d)(2) of the Internal Revenue Code of 1986 is amended—

(1) by striking the last sentence of subparagraph (A) and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products shall be treated as paid for medical care.'', and

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

''(D) MENSTRUAL CARE PRODUCT.—For purposes of this paragraph, the term 'menstrual care product' means a tampon, pad, liner, cup, sponge, or similar product used by women with respect to menstruation or other genital-tract secretions.''.

(b) ARCHER MSAS.—Section 220(d)(2)(A) of such Code is amended by striking the last sentence and inserting the following: ''For purposes of this subparagraph, amounts paid for menstrual care products (as defined in

section 223(d)(2)(D)) shall be treated as paid for medical care.''.

(c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Section 106 of such Code is amended by striking subsection (f) and inserting the following new subsection:

''(f) REIMBURSEMENTS FOR MENSTRUAL CARE PRODUCTS.—For purposes of this section and section 105, expenses incurred for menstrual care products (as defined in section 223(d)(2)(D)) shall be treated as incurred for medical care.''.

(d) EFFECTIVE DATES.—

(1) DISTRIBUTIONS FROM HEALTH SAVINGS ACCOUNTS.—The amendments made by subsections (a) and (b) shall apply to amounts paid after December 31, 2020.

(2) REIMBURSEMENTS.—The amendment made by subsection (c) shall apply to expenses incurred after December 31, 2020.

SEC. 136. REPEAL OF LIMITATION ON HEALTH FLEXIBLE SPENDING ARRANGEMENTS.

(a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986 is amended by striking subsection (i).

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2018.

SEC. 137. MEDICARE PART D TAX DEDUCTION.

(a) IN GENERAL.—Section 139A of the Internal Revenue Code of 1986 is amended by adding at the end the following: ''This section shall not be taken into account for purposes of determining whether any deduction is allowable with respect to any cost taken into account in determining such payment.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2018.

SEC. 138. REPEAL OF NET INVESTMENT INCOME TAX.

(a) IN GENERAL.—Subtitle A of the Internal Revenue Code of 1986 is amended by striking chapter 2A.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2019.

SEC. 139. BASIS FOR PURPOSES OF DETERMINING GAIN OR LOSS.

Nothing in the Internal Revenue Code of 1986 shall be construed to prevent the Secretary of the Treasury (or any designee of the Secretary) from providing that the

basis for determining gain or loss (whether on the basis of cost or otherwise) is adjusted on the basis of inflation.

SEC. 140. DEDUCTION FOR QUALIFIED CHARITY CARE.

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

"SEC. 199B. QUALIFIED CHARITY CARE.

''(a) IN GENERAL.—There shall be allowed as a deduction for the taxable year an amount equal to—

''(1) in the case of a direct primary care physician, an amount equal to the sum of—

''(A) the fee (as published on a publicly available website of such physician) for physicians' services that are qualified charity care furnished by such taxpayer during such year, and

''(B) for each visit by a patient to such physician during which qualified charity care is furnished, half of so much of the lowest subscription fee of such physician that is attributable to a month, and

''(2) in the case of any other individual, the unreimbursed Medicare-based value of qualified charity care furnished by such taxpayer during such year.

''(b) DEFINITIONS.—For purposes of this section:

"(1) UNREIMBURSED MEDICARE-BASED VALUE.—The term 'unreimbursed Medicare-based value' means, with respect to physicians' services, the amount payable for such services under the physician fee schedule established under section 1848 of the Social Security Act.

"(2) QUALIFIED CHARITY CARE.—The term 'qualified charity care' means physicians' services that are furnished—

"(A) without expectation of reimbursement, and

"(B) to an individual enrolled—

"(i) under a State plan under title XIX of the Social Security Act (or a waiver of such plan), or

"(ii) under a State child health plan under title XXI of the Social Security Act (or a waiver of such plan).

"(3) DIRECT PRIMARY CARE PHYSICIAN.—The term 'direct primary care physician' means a physician (as defined in section 1861(r) of the Social Security Act) who provides primary care—

"(A) to individuals who have paid a periodic subscription fee, and

''(B) in exchange for a fee that is published on a publicly available website of such physician.

''(4) PHYSICIANS' SERVICES.—The term 'physicians' services' has the meaning given such term by section 1861(q) of the Social Security Act.

''(c) LIMITATION.—The amount allowed as a deduction under subsection (a) for a taxable year shall not exceed the gross receipts attributable to physicians' services furnished by the taxpayer during the taxable year.''.

(b) CLERICAL AMENDMENT.—The table of sections for part VI of subchapter B of chapter 1 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 199B. Qualified charity care.''.

SEC. 141. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

(a) IN GENERAL.—Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by inserting after section 224 the following:

''SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS.

''(a) LIMITATION ON LIABILITY.—A physician shall not be liable under Federal or State law in any civil action for any harm caused by an act or omission of such physi-

cian, or attending medical personnel supporting such physician, if such act or omission—

''(1) occurs in the course of furnishing qualified charity care (as such term is defined in section 199B of the Internal Revenue Code of 1986); and

''(2) was not grossly negligent.

''(b) PREEMPTION.—This section preempts the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability for a defendant.

''(c) DEFINITIONS.—In this section:

''(1) PHYSICIAN.—The term 'physician' has the meaning given such term by section 1861(r) of the Social Security Act.

''(2) ATTENDING MEDICAL PERSONNEL.—The term 'attending medical personnel' means an individual who is licensed to directly support a physician in furnishing medical services.''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to any claim filed to the extent that it is with respect to acts or omissions occurring after the date of the enactment of this Act.

TITLE II—MEDICARE AND MEDICAID REFORMS

Subtitle A

SEC. 201. FLEXIBLE BLOCK GRANT OPTION FOR STATES.

Title XIX of the Social Security Act is amended—

(1) in section 1903 (42 U.S.C. 1396b)—

(A) in subsection (a), in the matter before paragraph (1), by inserting ''and section 1903A(a)'' after ''except as otherwise provided in this section''; and

(B) in subsection (d)(1), by striking ''to which'' and inserting ''to which, subject to section 1903A(a),''; and

(2) by inserting after such section 1903 the following new section:

''SEC. 1903A. FLEXIBLE BLOCK GRANT OPTION FOR STATES.

''(a) IN GENERAL.—In the case of a State that elects the option of applying this section for a 10-fiscal-year period (beginning no earlier than fiscal year 2020 and, at the State option, for any succeeding 10-fiscal-year period) and that has a plan approved by the Secretary under subsection (b) to carry out the option for such period—

''(1) the State shall receive, instead of amounts otherwise payable to the State under this title for medical assistance for block grant individuals within

the applicable block grant category (as defined in subsection (f)) for the State during the period in which the election is in effect, the amount specified in subsection (d);

''(2) the payment under this section may only be used consistent with the State plan under subsection (b) for block grant health care assistance (as defined in subsection (g)); and

''(3) with respect to block grant individuals within the applicable block grant category for the State for which block grant health care assistance is made available under this section, such assistance shall be instead of medical assistance otherwise provided to the individual under this title.

''(b) STATE PLAN FOR ADMINISTERING BLOCK GRANT OPTION.—

''(1) IN GENERAL.—No payment shall be made under this section to a State pursuant to an election for a 10-fiscal-year period under subsection (a) unless the State has a plan, approved under paragraph (2), for such period that specifies—

''(A) the applicable block grant category with respect to which the State will apply the option under this section for such period;

''(B) the conditions for eligibility of block grant individuals within such applicable block grant category for block grant health care assistance under the option, which shall be instead of other conditions for eligibility under this title, except that in the case of a State that has elected the applicable block grant category described in—

''(i) paragraph (1) of subsection (f), the plan must provide for eligibility for pregnant women and children required to be provided medical assistance under subsections (a)(10)(A)(i) and (e)(4) of section 1902; or

''(ii) paragraph (2) of subsection (f), the plan must provide for eligibility for pregnant women required to be provided medical assistance under subsection (a)(10)(A)(i); and

''(C) the types of items and services, the amount, duration, and scope of such services, the cost-sharing with respect to such services, and the method for delivery of block grant health care assistance under this section, which shall be instead of the such types, amount, du-

ration, and scope, cost-sharing, and methods of delivery for medical assistance otherwise required under this title, except that the plan must provide for assistance for—

"(i) hospital care;

"(ii) surgical care and treatment;

"(iii) medical care and treatment;

"(iv) obstetrical and prenatal care and treatment;

"(v) prescribed drugs, medicines, and prosthetic devices;

"(vi) other medical supplies and services; and

"(vii) health care for children under 18 years of age.

"(2) REVIEW AND APPROVAL.—A plan described in paragraph (1) shall be deemed approved by the Secretary unless the Secretary determines, within 30 days after the date of the Secretary's receipt of the plan, that the plan is incomplete or actuarially unsound and, with respect to such plan and its implementation under this section, the requirements of paragraphs (1), (10)(B), (17), and (23) of section 1902(a) shall not apply.

"(c) AMOUNT OF BLOCK GRANT FUNDS.—

''(1) FOR INITIAL FISCAL YEAR.—The block grant amount under this subsection for a State for the initial fiscal year in the first 10-fiscal-year period is equal to an amount determined by the Secretary to equal the per capita spending on the population covered by the State plan established in subsection (b) of section 1903A.

''(2) FOR ANY SUBSEQUENT FISCAL YEAR.—The block grant amount under this section for a State for each succeeding fiscal year (in any 10-fiscal-year period) is equal to the block grant amount under paragraph (1) (or this paragraph) for the State for the previous fiscal year increased by the annual increase in the consumer price index for all urban consumers (all items; U.S. city average) for the fiscal year involved.

''(3) AVAILABILITY OF ROLLOVER FUNDS.—The block grant amount under this subsection for a State for a fiscal year shall remain available to the State for expenditures under this section for the succeeding fiscal year but only if an election is in effect under this section for the State in such succeeding fiscal year.

''(d) FEDERAL PAYMENT AND STATE RESPONSIBILITY.—The Secretary shall pay to each State with an

election in effect under this section for a fiscal year, from its block grant amount under subsection (c) available for such fiscal year, an amount for each quarter of such fiscal year equal to the enhanced FMAP described in the first sentence of section 2105(b) of the total amount expended under the State plan under this section during such quarter, and the State is responsible for the balance of funds to carry out such plan.

''(e) BLOCK GRANT INDIVIDUAL DEFINED.—In this section, the term 'block grant individual' means, with respect to a State for a 10-fiscal-year period, an individual who is within an applicable block grant category for the State and such period.

''(f) APPLICABLE BLOCK GRANT CATEGORY DEFINED.—In this section, the term 'applicable block grant category' means with respect to a State for a 10-fiscal-year period, either of the following as specified by the State for such period in its plan under subsection (b)(1)(A):

''(1) ELDERLY, BLIND, DISABLED.—Both of the following categories:

''(A) ELDERLY.—Individuals who are 65 years of age or older.

''(B) BLIND AND DISABLED.—Individuals (not described in the previous subparagraph)

who are eligible for medical assistance under this title on the basis of being blind or disabled.

''(2) ELDERLY, BLIND, DISABLED, AND OTHERS.—All of the following categories:

''(A) ELDERLY.—Individuals who are 65 years of age or older.

''(B) BLIND AND DISABLED.—Individuals (not described in the previous subparagraph) who are eligible for medical assistance under this title on the basis of being blind or disabled.

''(C) CHILDREN.—Individuals (not described in a previous subparagraph) who are children under 19 years of age.

''(D) EXPANSION ENROLLEES.—Individuals (not described in a previous subparagraph) for whom the amounts expended for medical assistance are subject to an increase or change in the Federal medical assistance percentage under subsection (y) or (z)(2), respectively, of section 1905.

''(E) OTHER NONELDERLY, NONDISABLED, NON-EXPANSION ADULTS.—Individuals who are not described in any of the previous subparagraphs and whose income does not exceed 60 percent of the poverty line (as defined in section

2110(c)(5)) applicable to a family of the size involved.

''(g) BLOCK GRANT HEALTH CARE ASSISTANCE.—In this section, the term 'block grant health care assistance' means assistance for health-care-related items and medical services for block grant individuals within the applicable block grant category for the State and 10-fiscal-year period involved who are low-income individuals (as defined by the State).

''(h) AUDITING.—As a condition of receiving funds under this section, a State shall contract with an independent entity to conduct audits of its expenditures made with respect to activities funded under this section for each fiscal year for which the State elects to apply this section to ensure that such funds are used consistent with this section and shall make such audits available to the Secretary upon the request of the Secretary.''.

SEC. 202. MEDICAID ELIGIBILITY DETERMINATIONS.

(a) STATE FLEXIBILITY TO USE CONTRACTORS TO MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF STATE.—Section 1902(a)(5) of the Social Security Act (42 U.S.C. 1396a(a)(5)) is amended by inserting before the semicolon at the end the following: '', but such determinations of eligibility may be made, at the option of a State, under a contract with another State or local agency

or a contractor so long as the contract does not provide incentives for the agency or contractor to delay eligibility determinations or to deny eligibility for individuals otherwise eligible for medical assistance''.

(b) FREQUENCY OF ELIGIBILITY REDETERMINATIONS.—Section 1902(e)(14) of the Social Security Act (42 U.S.C. 1396a(e)(14)) is amended by adding at the end the following:

''(L) FREQUENCY OF ELIGIBILITY REDETERMINATIONS.—Beginning on October 1, 2019, and notwithstanding subparagraph (H), in the case of an individual whose eligibility for medical assistance under the State plan under this title (or a waiver of such plan) is determined based on the application of modified adjusted gross income under subparagraph (A) and who is so eligible on the basis of clause (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection (a)(10)(A), at the option of the State, the State plan may provide that the individual's eligibility shall be redetermined every 6 months (or such shorter number of months as the State may elect).''.

SEC. 203. LOWERING SAFE HARBOR THRESHOLD WITH RESPECT TO STATE TAXES ON HEALTH CARE PROVIDERS.

Section 1903(w)(4)(C)(ii) of the Social Security Act (42 U.S.C. 1396b(w)(4)(C)(ii)) is amended—

(1) by striking ''of fiscal years beginning'' and inserting ''of fiscal years—

''(I) beginning''; and

(2) by striking ''it appears.'' and inserting the following: ''it appears;

''(II) beginning on or after January 1, 2020, and before January 1, 2030, '4 percent' shall be substituted for '6 percent' each place it appears;

''(III) beginning on or after January 1, 2030, and before January 1, 2035, '3 percent' shall be substituted for '6 percent' each place it appears;

''(IV) beginning on or after January 1, 2035, and before January 1, 2040, '2 percent' shall be substituted for '6 percent' each place it appears;

''(V) beginning on or after January 1, 2040, and before January 1, 2045, '1 percent' shall be substituted for '6 percent' each place it appears; and

''(VI) beginning on or after January 1, 2045, '0 percent' shall be substituted for '6 percent' each place it appears.''.

SEC. 204. INCOME LIMITATIONS FOR REFUNDABLE CREDITS FOR COVERAGE UNDER A QUALIFIED HEALTH PLAN.

(a) IN GENERAL.—Subparagraphs (A) and (B) of section 36B(c)(1) of the Internal Revenue Code of 1986 are amended by inserting after ''100 percent'' each place such term appears the following: ''(60 percent in the case of an individual enrolled through an Exchange utilized by a State that makes the election described in section 1903A of the Social Security Act)''.

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

Subtitle B—Medicare

SEC. 221. OFF-CAMPUS PROVIDER-BASED DEPARTMENT MEDICARE SITE NEUTRAL PAYMENT.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(x) OFF-CAMPUS PROVIDER-BASED DEPARTMENT SITE NEUTRAL PAYMENT.—

''(1) IN GENERAL.—With respect to items and services furnished in an off-campus provider-based department, payment under this section for such items and services shall be the amount determined under the fee schedule under section 1848 for such items and services furnished if furnished in a physician office setting.

''(2) OFF-CAMPUS PROVIDER-BASED DEPARTMENT.—For purposes of this subsection, the term 'off-campus provider-based department' has such meaning as specified by the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to items and services furnished on or after January 1, 2021.

SEC. 222. ELIMINATION OF MEDICARE ELIGIBILITY FOR CERTAIN INDIVIDUALS.

(a) ENROLLMENT PROHIBITION.—

(1) PART B.—Section 1836 of the Social Security Act (42 U.S.C. 1395o) is amended by striking the period at the end and inserting '', except that an individual who attains age 65 on or after January 1, 2030, and is an individual who, upon attaining such age, has earned $10,000,000 or more in lifetime wages, shall not be eligible to so enroll.''.

(2) PART D.—Section 1860D–1(a)(3)(A) of such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amended by striking the period at the end and inserting ", excluding an individual who, upon attaining age 65, has earned $10,000,000 or more in lifetime wages.".

(b) MEDIGAP.—Section 1882 of the Social Security Act (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

"(aa) ADDITIONAL LIMITATION ON NEWLY ELIGIBLE BENEFICIARIES.—

"(1) IN GENERAL.—Notwithstanding any other provision of this section, on or after January 1, 2030, a medicare supplemental policy may not be sold or issued to a targeted newly eligible Medicare beneficiary.

"(2) TARGETED NEWLY ELIGIBLE MEDICARE BENEFICIARY.—For purposes of this subsection, the term 'targeted newly eligible Medicare beneficiary' means an individual who, upon attaining the age of 65, has earned $10,000,000 or more in lifetime wages.".

SEC. 223. MEDICARE COVERAGE OF BAD DEBT.

Section 1861(v)(1) of the Social Security Act (42 U.S.C. 1395(v)(1)) is amended—

(1) in subparagraph (T)—

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

(B) in clause (v)—

(i) by striking ''during fiscal year'' and inserting ''during fiscal years'';

(ii) by striking ''or a subsequent fiscal year'' and inserting ''through 2020''; and

(iii) by striking the period at the end and inserting '', and''; and

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

''(vi) for cost reporting periods beginning during fiscal year 2021 or a subsequent fiscal year, by the percent applicable for cost reporting periods beginning during the previous fiscal year, increased (through fiscal year 2024) by 10 percentage points.'';

(2) in subparagraph (V)—

(A) in clause (i)—

(i) in subclause (III), by striking ''and'' at the end;

(ii) in subclause (IV)—

(I) by striking ''during fiscal year'' and inserting ''during fiscal years 2015 through 2020''; and

(II) by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following new subclause:

''(V) for cost reporting periods beginning during fiscal year 2021 or a subsequent fiscal year, the percent applicable for cost reporting periods beginning during the previous fiscal year, increased (through fiscal year 2024) by 10 percentage points.''; and

(B) in clause (ii)—

(i) in subclause (III), by striking ''and'' at the end; and

(ii) in subclause (IV)—

(I) by striking ''a subsequent fiscal year'' and inserting ''fiscal years 2015 through 2020'';

(II) by striking the period at the end and inserting ''; and''; and

(III) by adding at the end the following new subclause:

''(V) for cost reporting periods beginning during fiscal year 2021 or a subsequent fiscal year, shall be reduced by the percent applicable for cost reporting periods beginning during the previous fiscal year, increased (through fiscal year 2024) by 10 percentage points.''; and

(3) in subparagraph (W)(i)—

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

(B) in subclause (III)—

(i) by striking ''during a subsequent fiscal year'' and inserting ''during fiscal years 2015 through 2020''; and

(ii) by striking the period at the end and inserting ''; and''; and

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

''(IV) for cost reporting periods beginning during fiscal year 2021 or a subsequent fiscal year, by the percent applicable for cost reporting periods beginning during the previous fiscal year, increased (through fiscal year 2024) by 10 percentage points.''.

Subtitle C—Medical Malpractice Reform

SEC. 231. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

(a) STATUTE OF LIMITATIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the time for the commencement of a health care lawsuit shall be, whichever occurs first of the following:

(A) Three years after the date of the occurrence of the breach or tort.

(B) Three years after the date the medical or health care treatment that is the subject of the claim is completed.

(C) One year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury.

(2) TOLLING.—In no event shall the time for commencement of a health care lawsuit exceed 3 years after the date of the occurrence of the breach or tort or 3 years after the date the medical or health care treatment that is the subject of the claim is completed (whichever occurs first) unless tolled for any of the following—

(A) upon proof of fraud;

(B) intentional concealment; or

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

(3) ACTIONS BY A MINOR.—Actions by a minor shall be commenced within 3 years after the date of the occurrence of the breach or tort or 3 years after the date of the medical or health care treatment that is the subject of the claim is completed (whichever occurs first) except that actions by a minor under the full age of 6 years shall be commenced within 3 years after the date of the occurrence of the breach or tort, 3 years after the date of the medical or health care treatment that is the subject of the claim is completed, or 1 year after the injury is discovered, or through the use of reasonable diligence should have been discovered, 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 have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

(b) STATE FLEXIBILITY.—No provision of subsection (a) shall be construed to preempt any State law (whether

effective before, on, or after the date of the enactment of this Act) that—

(1) specifies a time period of less than 3 years after the date of injury or less than 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, for the filing of a health care lawsuit;

(2) that specifies a different time period for the filing of lawsuits by a minor;

(3) that triggers the time period based on the date of the alleged negligence; or

(4) establishes a statute of repose for the filing of a health care lawsuit.

SEC. 232. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this Act 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, shall not exceed $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 propor-

tion of responsibility of each party for the claimant's harm.

(e) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of economic or noneconomic 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 section.

SEC. 233. 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 particular, 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) Forty percent of the first $50,000 recovered by the claimant(s).

(2) Thirty-three and one-third percent of the next $50,000 recovered by the claimant(s).

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

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

(c) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a lesser percentage or lesser total value of damages which may be claimed by an attorney representing a claimant in a health care lawsuit.

SEC. 234. 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 accordance with 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 Act.

(c) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies periodic payments for future damages at any amount other than $50,000 or that mandates such payments absent the request of either party.

SEC. 235. PRODUCT LIABILITY FOR HEALTH CARE PROVIDERS.

A health care provider who prescribes, or who dispenses pursuant to a prescription, a medical product ap-

proved, licensed, or cleared by the Food and Drug Administration shall not be named as a party to a product liability lawsuit involving such product and shall not be liable to a claimant in a class action lawsuit against the manufacturer, distributor, or seller of such product.

SEC. 236. DEFINITIONS.

In this Act:

(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) 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.

(5) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision or use of (or failure to provide or use) 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, unless otherwise defined under applicable State law. In no circumstances shall damages for health care services or medical products exceed the amount actually paid or incurred by or on behalf of the claimant.

(6) FUTURE DAMAGES.—The term ''future damages'' means any damages that are incurred after the date of judgment, settlement, or other resolution (including mediation, or any other form of alternative dispute resolution).

(7) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of goods or services for which coverage was provided in whole or in part via a Federal program, subsidy or tax benefit, or any health care liability action concerning the provision of goods or services for which coverage was provided in whole or in part via a Federal program, subsidy or tax benefit, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider 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 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, including, but not limited to, third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision or use of (or the failure to provide or use) health care services or medical products, re-

gardless 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 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, as well as any other individual or entity defined as a health care provider, health care professional, or health care institution under State law.

(11) HEALTH CARE SERVICES.—The term ''health care services'' means the provision of any goods or services (including safety, professional, or administrative services directly related to health care) by a health care 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.

(12) 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)), respectively, including any component or raw material used therein, but excluding health care services.

(13) 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 incurred as a result of the provision or use of (or failure to provide or use) health care services or medical products, unless otherwise defined under applicable State law.

(14) 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.

(15) REPRESENTATIVE.—The term ''representative'' means a legal guardian, attorney, person designated to make decisions on behalf of a patient under a medical power of attorney, or any person recognized in law or custom as a patient's agent.

(16) 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. 237. 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 Act does not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this subtitle 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 subtitle or otherwise applicable law (as determined under this subtitle) will apply to such aspect of such action.

(b) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this subtitle 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. 238. RULES OF CONSTRUCTION.

(a) HEALTH CARE LAWSUITS.—Unless otherwise specified in this subtitle, the provisions governing health care lawsuits set forth in this subtitle 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 subtitle. The provisions governing health care lawsuits set forth in this subtitle 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 subtitle; 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.—Any issue that is not governed by any provision of law established by or under this subtitle (including State standards of negligence) shall be governed by otherwise applicable State or Federal law.

(c) STATE FLEXIBILITY.—No provision of this subtitle shall be construed to preempt any defense available to a party in a health care lawsuit under any other provision of State or Federal law.

SEC. 239. EFFECTIVE DATE.

This subtitle 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 subtitle, except that any health care lawsuit arising from an injury occurring prior to the date of the enactment of this subtitle shall

be governed by the applicable statute of limitations provisions in effect at the time the cause of action accrued.

SEC. 240. LIMITATION ON EXPERT WITNESS TESTIMONY.

(a) IN GENERAL.—No person in a health care profession requiring licensure under the laws of a State shall be competent to testify in any court of law to establish the following facts—

(1) the recognized standard of acceptable professional practice and the specialty thereof, if any, that the defendant practices, which shall be the type of acceptable professional practice recognized in the defendant's community or in a community similar to the defendant's community that was in place at the time the alleged injury or wrongful action occurred;

(2) that the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with the recognized standard; and

(3) that as a proximate result of the defendant's negligent act or omission, the claimant suffered injuries which would not otherwise have occurred,

unless the person was licensed to practice, in the State or a contiguous bordering State, a profession or specialty which would make the person's expert testimony relevant to the issues in the case and had practiced this profession

or specialty in one of these States during the year preceding the date that the alleged injury or wrongful act occurred.

(b) APPLICABILITY.—The requirements set forth in subsection (a) shall also apply to expert witnesses testifying for the defendant as rebuttal witnesses.

(c) WAIVER AUTHORITY.—The court may waive the requirements in this subsection if it determines that the appropriate witnesses otherwise would not be available.

SEC. 241. COMMUNICATIONS FOLLOWING UNANTICIPATED OUTCOME.

(a) PROVIDER COMMUNICATIONS.—In any health care liability action, any and all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence which are made by a health care provider or an employee of a health care provider to the patient, a relative of the patient, or a representative of the patient and which relate to the discomfort, pain, suffering, injury, or death of the patient as the result of the unanticipated outcome of medical care shall be inadmissible for any purpose as evidence of an admission of liability or as evidence of an admission against interest.

(b) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether

effective before, on, or after the date of the enactment of this Act) that makes additional communications inadmissible as evidence of an admission of liability or as evidence of an admission against interest.

SEC. 242. EXPERT WITNESS QUALIFICATIONS.

(a) IN GENERAL.—In any health care lawsuit, an individual shall not give expert testimony on the appropriate standard of practice or care involved unless the individual is licensed as a health professional in one or more States and the individual meets the following criteria:

(1) If the party against whom or on whose behalf the testimony is to be offered is or claims to be a specialist, the expert witness shall specialize at the time of the occurrence that is the basis for the lawsuit in the same specialty or claimed specialty as the party against whom or on whose behalf the testimony is to be offered. If the party against whom or on whose behalf the testimony is to be offered is or claims to be a specialist who is board certified, the expert witness shall be a specialist who is board certified in that specialty or claimed specialty.

(2) During the 1-year period immediately preceding the occurrence of the action that gave rise to the lawsuit, the expert witness shall have devoted a

majority of the individual's professional time to one or more of the following:

(A) The active clinical practice of the same health profession as the defendant and, if the defendant is or claims to be a specialist, in the same specialty or claimed specialty.

(B) The instruction of students in an accredited health professional school or accredited residency or clinical research program in the same health profession as the defendant and, if the defendant is or claims to be a specialist, in an accredited health professional school or accredited residency or clinical research program in the same specialty or claimed specialty.

(3) If the defendant is a general practitioner, the expert witness shall have devoted a majority of the witness's professional time in the 1-year period preceding the occurrence of the action giving rise to the lawsuit to one or more of the following:

(A) Active clinical practice as a general practitioner.

(B) Instruction of students in an accredited health professional school or accredited residency or clinical research program in the same health profession as the defendant.

(b) LAWSUITS AGAINST ENTITIES.—If the defendant in a health care lawsuit is an entity that employs a person against whom or on whose behalf the testimony is offered, the provisions of subsection (a) apply as if the person were the party or defendant against whom or on whose behalf the testimony is offered.

(c) POWER OF COURT.—Nothing in this subsection shall limit the power of the trial court in a health care lawsuit to disqualify an expert witness on grounds other than the qualifications set forth under this subsection.

(d) LIMITATION.—An expert witness in a health care lawsuit shall not be permitted to testify if the fee of the witness is in any way contingent on the outcome of the lawsuit.

(e) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that places additional qualification requirements upon any individual testifying as an expert witness.

SEC. 243. AFFIDAVIT OF MERIT.

(a) REQUIRED FILING.—Subject to subsection (b), the plaintiff in a health care lawsuit alleging negligence or, if the plaintiff is represented by an attorney, the plaintiff's attorney shall file simultaneously with the health care lawsuit an affidavit of merit signed by a health pro-

fessional who meets the requirements for an expert witness under section 242 of this Act. The affidavit of merit shall certify that the health professional has reviewed the notice and all medical records supplied to him or her by the plaintiff's attorney concerning the allegations contained in the notice and shall contain a statement of each of the following:

(1) The applicable standard of practice or care.

(2) The health professional's opinion that the applicable standard of practice or care was breached by the health professional or health facility receiving the notice.

(3) The actions that should have been taken or omitted by the health professional or health facility in order to have complied with the applicable standard of practice or care.

(4) The manner in which the breach of the standard of practice or care was the proximate cause of the injury alleged in the notice.

(5) A listing of the medical records reviewed.

(b) FILING EXTENSION.—Upon motion of a party for good cause shown, the court in which the complaint is filed may grant the plaintiff or, if the plaintiff is represented by an attorney, the plaintiff's attorney an additional 28

days in which to file the affidavit required under subsection (a).

(c) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that establishes additional requirements for the filing of an affidavit of merit or similar pre-litigation documentation.

SEC. 244. NOTICE OF INTENT TO COMMENCE LAWSUIT.

(a) ADVANCE NOTICE.—A person shall not commence a health care lawsuit against a health care provider unless the person has given the health care provider 90 days written notice before the action is commenced.

(b) EXCEPTIONS.—A health care lawsuit against a health care provider filed within 6 months of the statute of limitations expiring as to any claimant, or within 1 year of the statute of repose expiring as to any claimant, shall be exempt from compliance with this section.

(c) STATE FLEXIBILITY.—No provision of this section shall be construed to preempt any State law (whether effective before, on, or after the date of the enactment of this Act) that establishes a different time period for the filing of written notice.

TITLE III—PRESCRIPTION DRUG COMPETITION

Subtitle A—Eliminating Delays of Generic Drugs and Biosimilar Products

SEC. 301. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term ''covered product''—

(A) means—

(i) any drug approved under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to demonstrate sameness, biosimilarity, or interchangeability for purposes of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42

U.S.C. 262), as applicable, any product, including any device, that is marketed or intended for use with such drug or biological product; and

(B) does not include any drug or biological product that the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(2) the term ''device'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(3) the term ''eligible product developer'' means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under sec-

tion 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(4) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(5) the term ''REMS'' means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(6) the term ''REMS with ETASU'' means a REMS that contains elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term ''Secretary'' means the Secretary of Health and Human Services;

(8) the term ''single, shared system of elements to assure safe use'' means a single, shared system of elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1); and

(9) the term ''sufficient quantities'' means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application—

(i) for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) for licensing under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to such an application for approval or licensing.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization

issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 90 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms; or

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its

agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with

sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the

date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered

product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different approved risk evaluation and mitigation strategies for a reference drug product and a drug that is the subject of an abbreviated new drug application.''; and

(2) in subsection (i)(1), by striking subparagraph (B) and inserting the following:

''(B) Elements to assure safe use, if required under subsection (f) for the listed drug in accordance with the following:

''(i) Subject to clause (ii), a drug that is the subject of an abbreviated new drug application may use—

''(I) a single, shared system with the listed drug under subsection (f); or

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an abbreviated new drug application and the listed drug to

use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).''.

Subtitle B—Increasing Access to Drugs and Biosimilar Products

SEC. 311. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.

''(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide priority review under section 505(j) for, generic complex drug products.

''(b) REQUEST FOR DESIGNATION.—A sponsor of a generic complex drug product may request that the Secretary designate such product for expedited development and priority review under this section.

''(c) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the product that is the subject of the request meets the criteria under subsection (e) to be considered a generic complex drug product. If the Secretary determines that the product meets the criteria, the Secretary shall designate the product for expedited development and priority review.

''(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

''(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (e) no longer applying because of the subsequent clearance or approval of any other product.

''(d) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW GUIDANCE.—

''(1) CONTENT.—Not later than December 31, 2021, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

"(A) set forth the process by which a person may seek a designation under subsection (c);

"(B) provide a template for requests under subsection (b);

"(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

"(D) identify the criteria and processes the Secretary will use to expedite the development and review of products designated under this section.

"(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a draft version of that guidance.

"(e) GENERIC COMPLEX DRUG PRODUCT DEFINED.—In this section, the term 'generic complex drug product' means a product that represents a complex therapy that consists of or includes a drug for approval under section 505(j) and that—

"(1)(A) contains complex active ingredients (such as peptides, polymeric compounds, complex mixtures of active ingredients, and naturally sourced ingredients);

''(B) is composed of complex formulations (such as liposomes or colloids);

''(C) requires a complex route of delivery (such as locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions, or gels); or

''(D) involves a complex dosage form (such as transdermals, metered dose inhalers, or extended release injectables);

''(2) presents as a complex drug-device combination product (such as auto injectors or metered dose inhalers); or

''(3) is a product that would benefit from early scientific engagement due to complexity or uncertainty concerning the approval pathway under section 505(j).''.

SEC. 312. INCREASING PHARMACEUTICAL OPTIONS TO TREAT AN UNMET MEDICAL NEED.

Subsection (b) of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) is amended by adding at the end the following:

''(4) UNMET MEDICAL NEED.—For purposes of paragraph (1), a drug shall be deemed to address an unmet medical need for a disease or condition if

fewer than 3 available drugs exist for the treatment of such disease or condition.''.

SEC. 313. PREEMPTION OF STATE BARRIERS TO THE SUBSTITUTION OF BIOSIMILAR PRODUCTS.

No State, or any political subdivision thereof, may, under any circumstances, prohibit a pharmacy or pharmacist from dispensing, in place of a biological reference product, any biosimilar that the Food and Drug Administration has designated as an interchangeable product for that biological reference product.

Subtitle C—Limiting Exclusivity Periods Delaying Competition

SEC. 321. LIMITING EXCLUSIVITY PERIODS FOR DRUGS TREATING RARE DISEASES AND CONDITIONS.

(a) IN GENERAL.—Subsection (a) of section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended to read as follows:

''(a) EXCLUSIVITY.—

''(1) IN GENERAL.—Except as provided in subsection (b), if the Secretary approves an application filed pursuant to section 505, or issues a license under section 351 of the Public Health Service Act, for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve an application filed pursuant to section 505, or issue

a license under section 351 of the Public Health Service Act, for the same drug for the same disease or condition for a person who is not the holder of such approved application or of such license until the expiration of the exclusivity period described in paragraph (2).

''(2) EXCLUSIVITY PERIOD DESCRIBED.—The exclusivity period described in this paragraph, with respect to a drug designated under section 526 for a rare disease or condition, is—

''(A) a single 7-year period of exclusivity with respect to the first designation of such drug under such section for that rare disease or condition; or

''(B) in the case of a drug that has previously received a period of exclusivity under paragraph (1), a single 3-year period of exclusivity with respect to any subsequent designation of such drug under such section for any other rare disease or condition.

''(3) LIMITATION.—In the case of a drug that has received two periods of exclusivity pursuant to paragraph (1), no additional exclusivity period under this section is available with respect to such drug, regardless of whether such drug has been designated

under section 526 for a rare disease or condition that is distinct from the rare disease or condition for which such exclusivity periods were granted.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 505(j)(5)(B)(iv)(II)(dd)(AA) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by striking ''7-year period'' and inserting ''exclusivity period''.

(2) Section 505A(b)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by striking ''rather than seven years;'' and inserting '', or three years and six months, rather than seven years or three years, respectively;''.

(3) Section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by striking ''rather than seven years;'' and inserting '', or three years and six months, rather than seven years or three years, respectively;''.

(4) Section 505E(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by striking ''7-year period'' and inserting ''exclusivity periods''.

(5) Section 527(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended by

striking ''the 7-year period'' and inserting ''any exclusivity period''.

(6) Section 351(m)(2)(B) of the Public Health Service Act (42 U.S.C. 262) is amended by striking ''rather than 7 years'' and inserting ''or 3 years and 6 months, rather than 7 years or 3 years, respectively''.

(7) Section 351(m)(3)(B) of the Public Health Service Act (42 U.S.C. 262) is amended by striking ''rather than 7 years'' and inserting ''or 3 years and 6 months, rather than 7 years or 3 years, respectively''.

SEC. 322. LIMITING EXCLUSIVITY FOR BIOSIMILAR PRODUCTS.

Paragraph (7) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended in subparagraph (A), by striking ''12'' and inserting ''5''.

Subtitle D—Congressional Review of Agency Rulemaking

SEC. 331. CONGRESSIONAL REVIEW OF THE FOOD AND DRUG ADMINISTRATION RULEMAKING.

(a) CONGRESSIONAL REVIEW.—Part I of title 5, United States Code, is amended by adding at the end the following:

"CHAPTER 10—CONGRESSIONAL REVIEW OF FOOD AND DRUG ADMINISTRATION RULEMAKING

"§ 920. Applicability

''This chapter applies in lieu of chapter 8 with respect to the Food and Drug Administration.

"§ 921. Congressional review

''(a)(1)(A) Before a rule may take effect, the Food and Drug Administration shall satisfy the requirements of section 928 and shall publish in the Federal Register a list of information on which the rule is based, including data, scientific and economic studies, and cost-benefit analyses, and identify how the public can access such information online, and shall submit to each House of the Congress and to the Comptroller General a report containing—

''(i) a copy of the rule;

''(ii) a concise general statement relating to the rule;

''(iii) a classification of the rule as a major or nonmajor rule, including an explanation of the classification specifically addressing each criteria for a major rule contained within sections 924(2)(A), 924(2)(B), and 924(2)(C);

''(iv) a list of any other related regulatory actions intended to implement the same statutory provision or regulatory objective as well as the individual and aggregate economic effects of those actions; and

''(v) the proposed effective date of the rule.

''(B) On the date of the submission of the report under subparagraph (A), the Food and Drug Administration shall submit to the Comptroller General and make available to each House of Congress—

''(i) a complete copy of the cost-benefit analysis of the rule, if any, including an analysis of any jobs added or lost, differentiating between public and private sector jobs;

''(ii) the Food and Drug Administration's actions pursuant to sections 603, 604, 605, 607, and 609 of this title;

''(iii) the Food and Drug Administration's actions pursuant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

''(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

''(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

''(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction by the end of 15 calendar days after the submission or publication date. The report of the Comptroller General shall include an assessment of the Food and Drug Administration's compliance with procedural steps required by paragraph (1)(B) and an assessment of whether the major rule imposes any new limits or mandates on private-sector activity.

''(B) The Food and Drug Administration shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

''(3) A major rule relating to a report submitted under paragraph (1) shall take effect upon enactment of

a joint resolution of approval described in section 922 or as provided for in the rule following enactment of a joint resolution of approval described in section 922, whichever is later.

''(4) A nonmajor rule shall take effect as provided by section 923 after submission to Congress under paragraph (1).

''(5) If a joint resolution of approval relating to a major rule is not enacted within the period provided in subsection (b)(2), then a joint resolution of approval relating to the same rule may not be considered under this chapter in the same Congress by either the House of Representatives or the Senate.

''(b)(1) A major rule shall not take effect unless the Congress enacts a joint resolution of approval described under section 922.

''(2) If a joint resolution described in subsection (a) is not enacted into law by the end of 70 session days or legislative days, as applicable, beginning on the date on which the report referred to in section 921(a)(1)(A) is received by Congress (excluding days either House of Congress is adjourned for more than 3 days during a session of Congress), then the rule described in that resolution shall be deemed not to be approved and such rule shall not take effect.

''(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a major rule may take effect for one 90-calendar-day period if the President makes a determination under paragraph (2) and submits written notice of such determination to the Congress.

''(2) Paragraph (1) applies to a determination made by the President by Executive order that the major rule should take effect because such rule is—

''(A) necessary because of an imminent threat to health or safety or other emergency;

''(B) necessary for the enforcement of criminal laws;

''(C) necessary for national security; or

''(D) issued pursuant to any statute implementing an international trade agreement.

''(3) An exercise by the President of the authority under this subsection shall have no effect on the procedures under section 922.

''(d)(1) In addition to the opportunity for review otherwise provided under this chapter, in the case of any rule for which a report was submitted in accordance with subsection (a)(1)(A) during the period beginning on the date occurring—

''(A) in the case of the Senate, 60 session days; or

''(B) in the case of the House of Representatives, 60 legislative days,

before the date the Congress is scheduled to adjourn a session of Congress through the date on which the same or succeeding Congress first convenes its next session, sections 922 and 923 shall apply to such rule in the succeeding session of Congress.

''(2)(A) In applying sections 922 and 923 for purposes of such additional review, a rule described under paragraph (1) shall be treated as though—

''(i) such rule were published in the Federal Register on—

''(I) in the case of the Senate, the 15th session day; or

''(II) in the case of the House of Representatives, the 15th legislative day,

after the succeeding session of Congress first convenes; and

''(ii) a report on such rule were submitted to Congress under subsection (a)(1) on such date.

''(B) Nothing in this paragraph shall be construed to affect the requirement under subsection (a)(1) that a

report shall be submitted to Congress before a rule can take effect.

''(3) A rule described under paragraph (1) shall take effect as otherwise provided by law (including other subsections of this section).

"§ 922. Congressional approval procedure for major rules

''(a)(1) For purposes of this section, the term 'joint resolution' means only a joint resolution addressing a report classifying a rule as major pursuant to section 921(a)(1)(A)(iii) that—

''(A) bears no preamble;

''(B) bears the following title (with blanks filled as appropriate): 'Approving the rule submitted by _____ relating to _____.';

''(C) includes after its resolving clause only the following (with blanks filled as appropriate): 'That Congress approves the rule submitted by _____ relating to _____.'; and

''(D) is introduced pursuant to paragraph (2).

''(2) After a House of Congress receives a report classifying a rule as major pursuant to section 921(a)(1)(A)(iii), the majority leader of that House (or his or her respective designee) shall introduce (by request,

if appropriate) a joint resolution described in paragraph (1)—

''(A) in the case of the House of Representatives, within 3 legislative days; and

''(B) in the case of the Senate, within 3 session days.

''(3) A joint resolution described in paragraph (1) shall not be subject to amendment at any stage of proceeding.

''(b) A joint resolution described in subsection (a) shall be referred in each House of Congress to the committees having jurisdiction over the provision of law under which the rule is issued.

''(c) In the Senate, if the committee or committees to which a joint resolution described in subsection (a) has been referred have not reported it at the end of 15 session days after its introduction, such committee or committees shall be automatically discharged from further consideration of the resolution and it shall be placed on the calendar. A vote on final passage of the resolution shall be taken on or before the close of the 15th session day after the resolution is reported by the committee or committees to which it was referred, or after such committee or committees have been discharged from further consideration of the resolution.

''(d)(1) In the Senate, when the committee or committees to which a joint resolution is referred have reported, or when a committee or committees are discharged (under subsection (c)) from further consideration of a joint resolution described in subsection (a), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for a motion to proceed to the consideration of the joint resolution, and all points of order against the joint resolution (and against consideration of the joint resolution) are waived. The motion is not subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the joint resolution is agreed to, the joint resolution shall remain the unfinished business of the Senate until disposed of.

''(2) In the Senate, debate on the joint resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 2 hours, which shall be divided equally between those favoring and those opposing the joint resolution. A motion to further limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the

consideration of other business, or a motion to recommit the joint resolution is not in order.

''(3) In the Senate, immediately following the conclusion of the debate on a joint resolution described in subsection (a), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the Senate, the vote on final passage of the joint resolution shall occur.

''(4) Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a joint resolution described in subsection (a) shall be decided without debate.

''(e) In the House of Representatives, if any committee to which a joint resolution described in subsection (a) has been referred has not reported it to the House at the end of 15 legislative days after its introduction, such committee shall be discharged from further consideration of the joint resolution, and it shall be placed on the appropriate calendar. On the second and fourth Thursdays of each month it shall be in order at any time for the Speaker to recognize a Member who favors passage of a joint resolution that has appeared on the calendar for at least 5 legislative days to call up that joint resolution for immediate consideration in the House without intervention of any point of order. When so called up a joint resolution

shall be considered as read and shall be debatable for 1 hour equally divided and controlled by the proponent and an opponent, and the previous question shall be considered as ordered to its passage without intervening motion. It shall not be in order to reconsider the vote on passage. If a vote on final passage of the joint resolution has not been taken by the third Thursday on which the Speaker may recognize a Member under this subsection, such vote shall be taken on that day.

''(f)(1) If, before passing a joint resolution described in subsection (a), one House receives from the other a joint resolution having the same text, then—

''(A) the joint resolution of the other House shall not be referred to a committee; and

''(B) the procedure in the receiving House shall be the same as if no joint resolution had been received from the other House until the vote on passage, when the joint resolution received from the other House shall supplant the joint resolution of the receiving House.

''(2) This subsection shall not apply to the House of Representatives if the joint resolution received from the Senate is a revenue measure.

''(g) If either House has not taken a vote on final passage of the joint resolution by the last day of the period

described in section 921(b)(2), then such vote shall be taken on that day.

''(h) This section and section 923 are enacted by Congress—

''(1) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and as such is deemed to be part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of a joint resolution described in subsection (a) and superseding other rules only where explicitly so; and

''(2) with full recognition of the Constitutional right of either House to change the rules (so far as they relate to the procedure of that House) at any time, in the same manner and to the same extent as in the case of any other rule of that House.

''§ 923. Congressional disapproval procedure for nonmajor rules

''(a) For purposes of this section, the term 'joint resolution' means only a joint resolution introduced in the period beginning on the date on which the report referred to in section 921(a)(1)(A) is received by Congress and ending 60 days thereafter (excluding days either House of Congress is adjourned for more than 3 days during a

session of Congress), the matter after the resolving clause of which is as follows: 'That Congress disapproves the nonmajor rule submitted by the _____ relating to _____, and such rule shall have no force or effect.' (The blank spaces being appropriately filled in).

''(b) A joint resolution described in subsection (a) shall be referred to the committees in each House of Congress with jurisdiction.

''(c) In the Senate, if the committee to which is referred a joint resolution described in subsection (a) has not reported such joint resolution (or an identical joint resolution) at the end of 15 session days after the date of introduction of the joint resolution, such committee may be discharged from further consideration of such joint resolution upon a petition supported in writing by 30 Members of the Senate, and such joint resolution shall be placed on the calendar.

''(d)(1) In the Senate, when the committee to which a joint resolution is referred has reported, or when a committee is discharged (under subsection (c)) from further consideration of a joint resolution described in subsection (a), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for a motion to proceed to the consideration of the joint resolution, and all points of order against the joint resolu-

tion (and against consideration of the joint resolution) are waived. The motion is not subject to amendment, or to a motion to postpone, or to a motion to proceed to the consideration of other business. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the joint resolution is agreed to, the joint resolution shall remain the unfinished business of the Senate until disposed of.

''(2) In the Senate, debate on the joint resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 10 hours, which shall be divided equally between those favoring and those opposing the joint resolution. A motion to further limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommit the joint resolution is not in order.

''(3) In the Senate, immediately following the conclusion of the debate on a joint resolution described in subsection (a), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the Senate, the vote on final passage of the joint resolution shall occur.

''(4) Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a joint resolution described in subsection (a) shall be decided without debate.

''(e) In the Senate, the procedure specified in subsection (c) or (d) shall not apply to the consideration of a joint resolution respecting a nonmajor rule—

''(1) after the expiration of the 60 session days beginning with the applicable submission or publication date; or

''(2) if the report under section 921(a)(1)(A) was submitted during the period referred to in section 921(d)(1), after the expiration of the 60 session days beginning on the 15th session day after the succeeding session of Congress first convenes.

''(f) If, before the passage by one House of a joint resolution of that House described in subsection (a), that House receives from the other House a joint resolution described in subsection (a), then the following procedures shall apply:

''(1) The joint resolution of the other House shall not be referred to a committee.

''(2) With respect to a joint resolution described in subsection (a) of the House receiving the joint resolution—

''(A) the procedure in that House shall be the same as if no joint resolution had been received from the other House; but

''(B) the vote on final passage shall be on the joint resolution of the other House.

''§ 924. Definitions

''For purposes of this chapter:

''(1) The term 'major rule' means any rule of the Food and Drug Administration, including an interim final rule, that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in—

''(A) an annual cost on the economy of $100,000,000 or more, adjusted annually for inflation;

''(B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

''(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

''(2) The term 'nonmajor rule' means any rule of the Food and Drug Administration that is not a major rule.

''(3) The term 'rule' has the meaning given such term in section 551, except that such term does not include—

''(A) any rule of particular applicability;

''(B) any rule relating to agency management or personnel; or

''(C) any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties.

''(4) The term 'submission date or publication date', except as otherwise provided in this chapter, means—

''(A) in the case of a major rule, the date on which the Congress receives the report submitted under section 921(a)(1); and

''(B) in the case of a nonmajor rule, the later of—

''(i) the date on which the Congress receives the report submitted under section 921(a)(1); and

''(ii) the date on which the nonmajor rule is published in the Federal Register, if so published.

''§ 925. Judicial review

''(a) No determination, finding, action, or omission under this chapter shall be subject to judicial review.

''(b) Notwithstanding subsection (a), a court may determine whether the Food and Drug Administration has completed the necessary requirements under this chapter for a rule to take effect.

''(c) The enactment of a joint resolution of approval under section 922 shall not be interpreted to serve as a grant or modification of statutory authority by Congress for the promulgation of a rule, shall not extinguish or affect any claim, whether substantive or procedural, against any alleged defect in a rule, and shall not form part of the record before the court in any judicial proceeding concerning a rule except for purposes of determining whether or not the rule is in effect.

''§ 926. Exemption for monetary policy

''Nothing in this chapter shall apply to rules that concern monetary policy proposed or implemented by the Board of Governors of the Federal Reserve System or the Federal Open Market Committee.

"§ 927. Effective date of certain rules

''Notwithstanding section 921, any rule other than a major rule which the Food and Drug Administration for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Food and Drug Administration determines.

"§ 928. Regulatory cut-go requirement

''In making any new rule, the Food and Drug Administration shall identify a rule or rules that may be amended or repealed to completely offset any annual costs of the new rule to the United States economy. Before the new rule may take effect, the Food and Drug Administration shall make each such repeal or amendment. In making such an amendment or repeal, the Food and Drug Administration shall comply with the requirements of subchapter II of chapter 5, but the Food and Drug Administration may consolidate proceedings under subchapter with proceedings on the new rule.

"§ 929. Review of rules currently in effect

''(a) ANNUAL REVIEW.—Beginning on the date that is 6 months after the date of enactment of this section and annually thereafter for the 9 years following, the Food and Drug Administration shall designate not less than 10

percent of eligible rules made by the Food and Drug Administration for review, and shall submit a report including each such eligible rule in the same manner as a report under section 921(a)(1). Section 921, section 922, and section 923 shall apply to each such rule, subject to subsection (c) of this section. No eligible rule previously designated may be designated again.

''(b) SUNSET FOR ELIGIBLE RULES NOT EXTENDED.—Beginning after the date that is 10 years after the date of enactment of this section, if Congress has not enacted a joint resolution of approval for that eligible rule, that eligible rule shall not continue in effect.

''(c) CONSOLIDATION; SEVERABILITY.—In applying sections 921, 922, and 923 to eligible rules under this section, the following shall apply:

''(1) The words 'take effect' shall be read as 'continue in effect'.

''(2) Except as provided in paragraph (3), a single joint resolution of approval shall apply to all eligible rules in a report designated for a year, and the matter after the resolving clause of that joint resolution is as follows: 'That Congress approves the rules submitted by the ____ for the year ____.' (The blank spaces being appropriately filled in).

''(3) It shall be in order to consider any amendment that provides for specific conditions on which the approval of a particular eligible rule included in the joint resolution is contingent.

''(4) A member of either House may move that a separate joint resolution be required for a specified rule.

''(d) DEFINITION.—In this section, the term 'eligible rule' means a rule that is in effect as of the date of enactment of this section.''.

(b) BUDGETARY EFFECTS OF RULES SUBJECT TO SECTION 922 OF TITLE 5, UNITED STATES CODE.—Section 257(b)(2) of the Balanced Budget and Emergency Deficit Control Act of 1985 is amended by adding at the end the following new subparagraph:

''(E) BUDGETARY EFFECTS OF RULES SUBJECT TO SECTION 922 OF TITLE 5, UNITED STATES CODE.—Any rules subject to the congressional approval procedure set forth in section 922 of chapter 8 of title 5, United States Code, affecting budget authority, outlays, or receipts shall be assumed to be effective unless it is not approved in accordance with such section.''.

(c) GOVERNMENT ACCOUNTABILITY OFFICE STUDY OF RULES.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine, as of the date of the enactment of this Act—

(A) how many rules (as such term is defined in section 924 of title 5, United States Code) of the Food and Drug Administration were in effect;

(B) how many major rules (as such term is defined in section 924 of title 5, United States Code) of the Food and Drug Administration were in effect; and

(C) the total estimated economic cost imposed by all such rules.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to Congress that contains the findings of the study conducted under paragraph (1).

(d) EFFECTIVE DATE.—Subsections (a) and (b), and the amendments made by such sections, shall take effect beginning on the date that is 1 year after the date of enactment of this Act.

SEC. 332. GOVERNMENT ACCOUNTABILITY OFFICE STUDY OF RULES.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine, as of the date of the enactment of this Act—

(1) how many rules (as such term is defined in section 804 of title 5, United States Code) were in effect;

(2) how many major rules (as such term is defined in section 804 of title 5, United States Code) were in effect; and

(3) the total estimated economic cost imposed by all such rules.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit a report to Congress that contains the findings of the study conducted under subsection (a).

Subtitle E—Medicare Prescription Drug Competition

SEC. 341. MEDICARE DRUG COVERAGE.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may alter the reimbursement mechanism for prescription drugs provided through the Medicare Part B program by reimbursing at

a rate that, based on ASP+6% in the year of implementation of this Act, grows at CPI.

SEC. 342. PBM TRANSPARENCY AND ELIMINATION OF DIR FEES.

(a) PROHIBITING MEDICARE PDP SPONSORS AND MA–PD ORGANIZATIONS FROM RETROACTIVELY REDUCING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHARMACIES.—

(1) IN GENERAL.—Section 1860D–12(b)(4)(A) of the Social Security Act (42 U.S.C. 1395w–112(b)(4)(A)) is amended by adding at the end the following new clause:

"(iv) PROHIBITING RETROACTIVE REDUCTIONS IN PAYMENTS ON CLEAN CLAIMS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that after the date of receipt of a clean claim submitted by a pharmacy, the PDP sponsor (or an agent of the PDP sponsor) may not retroactively reduce payment on such claim directly or indirectly through aggregated effective rate or otherwise except in the case such claim is found to not be a clean

claim (such as in the case of a claim lacking required substantiating documentation) during the course of a routine audit as permitted pursuant to written agreement between the PDP sponsor (or such an agent) and such pharmacy. The previous sentence shall not prohibit any retroactive increase in payment to a pharmacy pursuant to a written agreement between a PDP sponsor (or an agent of such sponsor) and such pharmacy.''.

(2) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to contracts entered into on or after January 1, 2021.

(b) ELIMINATION OF DIR FEES.—

(1) PHARMACY BENEFITS MANAGER STANDARDS UNDER THE MEDICARE PROGRAM FOR PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—

(A) IN GENERAL.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

''(7) PHARMACY BENEFITS MANAGER TRANSPARENCY REQUIREMENTS.—Each contract entered into with a PDP sponsor under this part with re-

spect to a prescription drug plan offered by such sponsor or with an MA organization offering an MA–PD plan under part C shall provide that the sponsor or organization, respectively, may not enter into a contract with any pharmacy benefits manager (referred to in this paragraph as a 'PBM') to manage the prescription drug coverage provided under such plan, or to control the costs of the prescription drug coverage under such plan, unless the PBM adheres to the following criteria when handling personally identifiable utilization and claims data or other sensitive patient data:

''(A) The PBM may not transmit any personally identifiable utilization, protected health information, or claims data, with respect to a plan enrollee, to a pharmacy owned by a PBM if the plan enrollee has not voluntarily elected in writing or via secure electronic means to fill that particular prescription at the PBM-owned pharmacy.

''(B) The PBM may not require that a plan enrollee use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or

that has an ownership interest in the PBM, or provide an incentive to a plan enrollee to encourage the enrollee to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM, if the incentive is applicable only to such pharmacies.''.

(B) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Paragraph (6) of section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended to read as follows:

''(6) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—

''(A) IN GENERAL.—If the PDP sponsor of a prescription drug plan (or MA organization offering an MA–PD plan) uses a standard for reimbursement (as described in subparagraph (B)) of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part (or organization under part C) with respect to the plan shall provide that the sponsor (or organization) shall—

''(i) update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug;

''(ii) disclose to applicable pharmacies and the contracting entities of such pharmacies the sources used for making any such update immediately without requirement of request;

''(iii) if the source for such a standard for reimbursement is not publicly available, disclose to the applicable pharmacies and the respective contracting entities of such pharmacies all individual drug prices to be so updated in advance of the use of such prices for the reimbursement of claims;

''(iv) establish a process to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price for such drug, which must be adjudicated within 7 days of the pharmacy filing its appeal; and

''(v) provide all such pricing data in an .xml spreadsheet format or a com-

parable easily accessible and complete spreadsheet format.

''(B) PRESCRIPTION DRUG PRICING STANDARD DEFINED.—For purposes of subparagraph (A), a standard for reimbursement of a pharmacy is any methodology or formula for varying the pricing of a drug or drugs during the term of the pharmacy reimbursement contract that is based on the cost of the drug involved, including drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost (MAC), or other costs, whether publicly available or not.''.

(C) EFFECTIVE DATE.—The amendments made by this section shall apply to plan years beginning on or after January 1, 2020.

(2) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD UNDER TRICARE RETAIL PHARMACY PROGRAM.—Section 1074g(d) of title 10, United States Code, is amended by adding at the end the following new paragraph:

''(3) To the extent practicable, with respect to the TRICARE retail pharmacy program described in sub-

section (a)(2)(E)(ii), the Secretary shall ensure that a contract entered into with a TRICARE managed care support contractor includes requirements described in section 1860D–12(b)(6) of the Social Security Act (42 U.S.C. 1395w–112(b)(6)) to ensure the provision of information regarding the pricing standard for prescription drugs.''.

(3) PRESCRIPTION DRUG TRANSPARENCY IN THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.—

(A) IN GENERAL.—Section 8902 of title 5, United States Code, is amended by adding at the end the following new subsections:

''(p) A contract may not be made or a plan approved under this chapter under which a carrier has an agreement with a pharmacy benefits manager (in this subsection referred to as a 'PBM') to manage prescription drug coverage or to control the costs of the prescription drug coverage unless the carrier and PBM adhere to the following criteria:

''(1) The PBM may not transmit any personally identifiable utilization, protected health information, or claims data with respect to an individual enrolled under such contract or plan to a pharmacy owned by the PBM if the individual has not voluntarily elected

in writing or via secure electronic means to fill that particular prescription at such a pharmacy.

''(2) The PBM may not require that an individual enrolled under such contract or plan use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM or provide an incentive to a plan enrollee to encourage the enrollee to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM, if the incentive is applicable only to such pharmacies.

''(q)(1) If a contract made or plan approved under this chapter provides for a standard for reimbursement (as described in paragraph (2)) with respect to a prescription drug plan, such contract or plan shall provide that the applicable carrier—

''(A) update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug;

''(B) disclose to applicable pharmacies and the contracting entities of such pharmacies the sources used for making any such update immediately without requirement of request;

''(C) if the source for such a standard for reimbursement is not publicly available, disclose to the applicable pharmacies and contracting entities of such pharmacies all individual drug prices to be so updated in advance of the use of such prices for the reimbursement of claims;

''(D) establish a process to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price for such drug, which must be adjudicated within 7 days of the pharmacy filing its appeal; and

''(E) provide all such pricing data in an .xml spreadsheet format or a comparable easily accessible and complete spreadsheet format.

''(2) For purposes of paragraph (1), a standard for reimbursement of a pharmacy is any methodology or formula for varying the pricing of a drug or drugs during the term of the pharmacy reimbursement contract that is based on the cost of the drug involved, including drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufac-

turer price, average sales price, maximum allowable cost, or other costs, whether publicly available or not.''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall apply to any contract entered into under section 8902 of title 5, United States Code, on or after the date of enactment of this section.

SEC. 343. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.

Section 1927(c)(2)(D) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(D)) is amended by inserting after ''December 31, 2009,'' the following: ''and before December 31, 2024,''.

SEC. 344. REGULATION OF MANUFACTURER-SPONSORED COPAY CONTRIBUTIONS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may establish a mechanism prohibiting drug manufacturers from contributing financially to patient copays, and establish a system of penalizing such behavior.

SEC. 345. DATA REPORTING TO IMPROVE THE TRANSPARENCY REGARDING HOW 340B HOSPITAL COVERED ENTITIES PROVIDE CARE FOR PATIENTS.

Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following new subsection:

''(f) DATA REPORTING TO IMPROVE THE TRANSPARENCY REGARDING HOW HOSPITAL COVERED ENTITIES PROVIDE CARE FOR PATIENTS.—

''(1) IN GENERAL.—Beginning on the date that is 14 months after the date of the enactment of this subsection, and annually thereafter, subject to subparagraph (C), a covered entity described in subparagraph (L) or (M) of subsection (a)(4), unless otherwise indicated, shall report on the following, with respect to the previous year, in such a manner and form as specified by the Secretary:

''(A) The following information:

''(i) With respect to such covered entity and with respect to each child site of such entity (as referenced in paragraph (11)), the number and percentage of individuals who are dispensed or administered drugs that are subject to an agreement under this section, organized by form of

health insurance coverage of such individuals (including at least by the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, health insurance coverage offered in the individual or group market or a group health plan (as such terms are defined in section 2791), and uninsured).

''(ii) With respect to each such child site of such entity, the total costs incurred at each such site and the cost incurred at each such site for charity care as defined in line 23 of worksheet S–10 to the Medicare cost report or in any successor form.

''(B) The aggregate amount of gross reimbursement received by each such covered entity (including child sites of such entity) described in such subparagraph (L) or (M) for all drugs purchased that are subject to an agreement under this section and the entity's aggregate acquisition cost for such drugs.

''(C) In the case of covered entity described in subparagraph (L) of subsection (a)(4), at the time of application and recertifi-

cation (and at least annually thereafter), the contract that is the basis for eligibility under the requirement under clause (i) of such subparagraph and any modifications to such contract for purposes of review by the Secretary.

''(D) With respect to such covered entity and with respect to each child site of such entity, the name of all third-party vendors or other similar entities that the covered entity contracts with to provide services associated with the program under this section.

''(2) AVAILABILITY OF INFORMATION.—

''(A) IN GENERAL.—The Secretary shall make data reported by covered entities under subparagraphs (A), (C), and (D) of paragraph (1) available on the public website of the Department of Health and Human Services in an electronic and searchable format, which may include the 340B Office of Pharmacy Affairs Information System or a successor to such system.

''(B) FORMAT.—Data made available under subparagraph (A) shall be made available in a manner that shows each category of data reported both in the aggregate and identified by

covered entities described in subparagraphs (L) and (M) of subsection (a)(4) and child sites of such covered entities. In carrying out this paragraph, with respect to data reported pursuant to paragraph (1)(C), the Secretary shall ensure that any proprietary information shall be redacted from contracts submitted pursuant to such paragraph (1)(C) before posting such data.

''(3) INTERIM FINAL REGULATIONS.—The Secretary shall issue interim final regulations no later than the date that is 6 months after the date of the enactment of this subsection, to carry out this subsection and shall finalize such regulations prior to the end of the moratorium period to which subsection (a)(11) applies.

''(4) REPORTS TO CONGRESS.—

''(A) OIG REPORT.—Not later than 2 years after the date of the enactment of this subsection, the Office of the Inspector General shall submit to Congress a final report on the level of charity care provided by covered entities described in subparagraphs (L) and (M) of subsection (a)(4) and separately by child sites of

such covered entities, as reported in paragraph (1)(A).

"(B) GAO REPORTS.—

"(i) INITIAL REPORT.—Not later than 1 year after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a report—

"(I) analyzing the State and local government contracts intended to satisfy the requirement under subsection (a)(4)(L)(i) for a covered entity to qualify as an entity described in subparagraph (L) of subsection (a)(4);

"(II) assessing the amount of care such contracts obligate such entity to provide to low-income individuals ineligible for Medicare under title XVIII of the Social Security Act and Medicaid under title XIX of such Act; and

"(III) analyzing how these contracts define low-income individuals and whether the Secretary reviews such determinations.

''(ii) SUBSEQUENT REPORT.—Not later than 2 years after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a final report on the information collected under paragraph (1)(B) regarding the difference between the aggregate gross reimbursement and aggregate acquisition costs received by each such covered entity (including child sites of such entity) for drugs subject to an agreement under this section.''.

SEC. 346. REQUIRING 340B DRUG DISCOUNT PROGRAM REPORTS BY DSH HOSPITAL COVERED ENTITIES ON LOW-INCOME UTILIZATION RATE OF OUTPATIENT HOSPITAL SERVICES.

(a) IN GENERAL.—Section 340B(d)(2) of the Public Health Service Act (42 U.S.C. 256b(d)(2)) is amended—

(1) in subparagraph (B)(i), by inserting before the period at the end the following: '', including, with respect to such updates made on or after January 1, 2020, by requiring covered entities described in subsection (a)(4)(L) to submit (and to so regularly update) information described in subparagraph (C)''; and

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

"(C) INFORMATION ON LOW-INCOME UTILIZATION RATE OF OUTPATIENT HOSPITAL SERVICES.—

"(i) IN GENERAL.—For purposes of subparagraph (B)(i), the information described in this subparagraph, with respect to a covered entity described in subsection (a)(4)(L) and an update under such subparagraph (B)(i), is—

"(I) the low-income outpatient utilization rate of such covered entity for the most recent fiscal year; and

"(II) the low-income outpatient utilization rate of off-site outpatient facilities, clinics, eligible off-site locations, and associated sites of such entity identified as child sites of such entity pursuant to the identification system under subparagraph (B)(iv) for the most recent fiscal year.

"(ii) LOW-INCOME OUTPATIENT UTILIZATION RATE DEFINED.—In this subparagraph, the term 'low-income outpatient

utilization rate' has the meaning given the term 'low-income utilization rate' under paragraph (3) of section 1923(b) of the Social Security Act, except that—

"(I) clauses (i) and (ii) of subparagraph (A) of such paragraph shall be applied as if—

"(aa) each reference to 'patient services' were a reference to 'patient services furnished on an outpatient basis'; and

"(bb) for purposes of clause (i)(II) of this subparagraph, each reference to 'hospital' were a reference to 'off-site outpatient facilities, clinics, eligible off-site locations, and associated sites of the hospital that are identified as child sites of the hospital pursuant to the identification system under section 340B(d)(2)(B)(iv) of the Public Health Service Act'; and

"(II) clauses (i) and (ii) of subparagraph (B) of such paragraph shall be applied as if—

"(aa) each reference to 'inpatient hospital services' were a reference to 'outpatient hospital services'; and

"(bb) for purposes of clause (i)(II) each reference to 'hospital's charges' were a reference to 'charges of the off-site outpatient facilities, clinics, eligible off-site locations, and associated sites of the hospital that are identified as child sites of the hospital pursuant to the identification system under section 340B(d)(2)(B)(iv) of the Public Health Service Act'.".

(b) ANNUAL REPORTS.—Not later than January 1, 2021, and annually thereafter, the Administrator of the Health Resources and Services Administration shall submit to Congress a report on information submitted by covered entities for the previous year pursuant to the amendments made by subsection (a).

TITLE IV—PROVIDER COMPETITION

SEC. 401. HOSPITAL CONSOLIDATION.

(a) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $160,000,000 to the Federal Trade Commission to hire staff to investigate, as consistent with the Sherman Antitrust Act and other relevant Federal laws, anti-competitive mergers and practices under such laws to the extent such mergers and practices relate to providers of inpatient and outpatient health care services, as defined by the Secretary of Health and Human Services.

(b) MEDICARE RATES APPLIED TO CERTAIN HHI HOSPITALS.—

(1) IN GENERAL.—Section 1866(a) of the Social Security Act (42 U.S.C. 1395cc(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (X), by striking ''and'' at the end;

(ii) in subparagraph (Y), by striking the period at the end and inserting ''; and''; and

(iii) by inserting after subparagraph (Y) the following new subparagraph:

''(Z) subject to paragraph (4), in the case of a hospital in an urban area and with respect to which there is a Herfindahl-Hirschman Index (HHI) of greater than 4,000 and in the case of a hospital in a rural area and with respect to which there is Herfindahl-Hirschman Index (HHI) of greater than 5,000, to apply the reimbursement rate with respect to individuals (regardless of whether such an individual is entitled to or eligible for benefits under this title, but excluding individuals eligible for medical assistance under a State plan under title XIX) furnished items and services at such hospital that would be billable under this title for such items and services if furnished by such hospital to an individual entitled to or enrolled for benefits under this title.''; and

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

''(4)(A) The requirement under paragraph (1)(Z) shall not apply in the case of a hospital in a hospital referral region if the HRR market share of such hospital (as determined under subparagraph (B)) is less than 0.15.

''(B) For purposes of subparagraph (A), the HRR market share of a hospital in a hospital referral region is equal to—

''(i) the total revenue of the hospital, divided by

''(ii) the total revenue of all hospital in the hospital referral region.''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to items and services furnished on or after January 1, 2021.

(c) GRANTS FOR HOSPITAL INFRASTRUCTURE IMPROVEMENT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out a grant program under which the Secretary shall provide grants to eligible States, in accordance with this subsection.

(2) USES.—An eligible State receiving a grant under this subsection may use such grant to improve the State hospital infrastructure and to supplement any other funds provided for a purpose authorized under a State or local hospital grant programs under State law.

(3) ELIGIBILITY.—

(A) IN GENERAL.—An eligible State may receive not more than one grant under this sub-

section with respect to each qualifying criterion described in subparagraph (B) that is met by the State.

(B) ELIGIBLE STATE.—For purposes of this subsection, the term ''eligible State'' means a State that meets any one or more of the following qualifying criteria:

(i) The State does not have in effect any State certificate of need law that requires a health care provider to provide to a regulatory body a certification that the community needs the services provided by the health care provider.

(ii) The State has in effect State scope of practice laws that—

(I) allow advanced practice providers (such as nurse practitioners, advanced practice registered nurses, clinical nurse specialists, and physician assistants) to evaluate patients; diagnose, order, and interpret diagnostic tests; and initiate and manage treatments; or

(II) provide that the only justification for limiting the scope of

practice of a health care provider is safety to the public.

(iii) The State does not have in effect any State laws that require managed care plans to accept into the network of such plan any qualified provider who is willing to accept the terms and conditions of the managed care plan.

(4) FUNDING.—There is authorized to be appropriated to carry out this subsection $1,000,000,000 for each of the fiscal years 2019 through 2028. Funds appropriated under this paragraph shall remain available until expended.

SEC. 402. PRICE TRANSPARENCY.

Section 1866 of the Social Security Act (42 U.S.C. 1395cc), as amended by section 401, is further amended—

(1) in subsection (a)(1)—

(A) in subparagraph (Y), by striking ''and'' at the end;

(B) in subparagraph (Z), by striking the period at the end and inserting ''; and''; and

(C) by inserting after subparagraph (Z) the following new subparagraph:

''(AA) in the case of a hospital, to comply with the requirement under subsection (l).''; and

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

''(l) REQUIREMENT RELATING TO PUBLISHING CERTAIN HOSPITAL PRICES.—

''(1) IN GENERAL.—For purposes of subsection (a)(1)(AA), the requirement described in this subsection is, with respect to a hospital and year (beginning with 2021), for the hospital to publicly post, through the system established under paragraph (3), for each service included in the list published under paragraph (2) for such year, the volume-weighted average price charged by the hospital to—

''(A) individuals enrolled during such year in group health plans or health insurance coverage offered in the individual or group market (as such terms are defined in section 2791 of the Public Health Service Act); and

''(B) individuals who are not enrolled in any health insurance coverage or health benefits plan and individuals who are enrolled in such coverage or plan but such coverage or plan does not provide benefits for the service.

''(2) SERVICES.—For purposes of subsection (a)(1)(AA) and this subsection, the Secretary shall, for 2021 and each subsequent year, publish a list of

the 100 services that are the most highly utilized in a hospital-based setting.

''(3) STANDARDIZED DIGITAL REPORTING SYSTEM.—Not later than January 1, 2021, the Secretary shall establish a standardized digital system for purposes of paragraph (1).''.

SEC. 403. REPEALING SHARED SAVINGS INCENTIVES FROM MEDICARE SHARED SAVINGS PROGRAM.

(a) IN GENERAL.—Section 1899 of the Social Security Act (42 U.S.C. 1395jjj) is amended—

(1) in subsection (a)(1)—

(A) by striking subparagraph (B); and

(B) by striking ''such program—

''(A) groups of providers'' and inserting ''such program, groups of providers'';

(2) in subsection (b)(2)—

(A) in subparagraph (C), by striking ''that would allow the organization to receive and distribute payments for shared savings under subsection (d)(2) to participating providers of services and suppliers''; and

(B) in subparagraph (E)—

(i) by striking ''the implementation'' and inserting ''and the implementation''; and

(ii) by striking ", and the determination of payments for shared savings under subsection (d)(2)";

(3) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "except" and all that follows through "subparagraph (B)(i)."; and

(ii) by striking subparagraph (B); and

(B) by striking paragraph (2); and

(4) in subsection (g), by striking paragraph (4) and redesignating paragraphs (5) and (6) as paragraphs (4) and (5), respectively.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on January 1, 2021.

SEC. 404. REPEAL OF HEALTH CARE REFORM PROVISIONS LIMITING MEDICARE EXCEPTION TO THE PROHIBITION ON CERTAIN PHYSICIAN REFERRALS FOR HOSPITALS.

Sections 6001 and 10601 of the Patient Protection and Affordable Care Act (Public Law 111–148; 124 Stat. 684, 1005) and section 1106 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152; 124 Stat. 1049) are repealed and the provisions of law

amended by such sections are restored as if such sections had never been enacted.

SEC. 405. ADVISORY GROUP ON REDUCING BURDEN OF HOSPITAL ADMINISTRATIVE REQUIREMENTS.

(a) IN GENERAL.—Not later than January 1, 2021, the Secretary of Health and Human Services shall convene an advisory group to provide, in accordance with this section, recommendations on ways the Federal Government could reduce the burden of administrative requirements on hospitals.

(b) RECOMMENDATIONS.—Not later than January 1, 2022, the advisory board convened under this section shall—

(1) submit to the Secretary of Health and Human Services recommendations described under subsection (a) for executive action and any recommendations for State actions for potential consideration in making grants under section 2(c) to States; and

(2) submit to Congress recommendations described under subsection (a) for legislative proposals.

(c) MEMBERSHIP.—The advisory board under this section shall consist of the following members:

(1) Three representatives of companies that have—

(A) geographically distributed workforces;

(B) at least 10,000 employees; and

(C) no more than 10 percent of such employees in any single State.

(2) Three representatives of health insurance issuers and health plans, consisting of—

(A) one representative of for-profit health insurance issuers and health plans with at least 20,000,000 enrollees in the employer-sponsored market;

(B) one representative of non-profit health insurance issuers and health plans operating in at least 5 States; and

(C) one representative of non-profit health insurance issuers and health plans operating in a rural State (as defined by the Census Bureau).

(3) Seven public policy experts in the field of hospital consolidation.

SEC. 406. AUTHORITY OF FEDERAL TRADE COMMISSION OVER CERTAIN TAX-EXEMPT ORGANIZATIONS.

Section 4 of the Federal Trade Commission Act (15 U.S.C. 44) is amended, in the undesignated paragraph relating to the definition of the term ''Corporation''—

(1) by striking ‘‘, and any’’ and inserting ‘‘, any’’; and

(2) by inserting before the period at the end the following: ‘‘, and any organization described in section 501(c)(3) of the Internal Revenue Code of 1986 that is exempt from taxation under section 501(a) of such Code’’.

TITLE V—DIGITAL HEALTH CARE

SEC. 501. ACCESS OF INDIVIDUALS TO PROTECTED HEALTH INFORMATION.

The provisions of section 164.524 of title 45, Code of Federal Regulations, as in effect on the day before the date of the enactment of this Act, shall have the force and effect of law.

SEC. 502. EXPANSION OF COVERAGE OF TELEHEALTH SERVICES.

(a) COVERED SERVICES.—Section 1834(m)(4)(F)(i) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)(i)) is amended—

(1) by striking ‘‘and office’’ and inserting ‘‘office’’; and

(2) by inserting: ‘‘respiratory services, audiology services (as defined in section 1861(ll)), outpatient therapy services (including physical therapy, occupa-

tional therapy, and speech-language pathology services)'' after ''the Secretary)),''.

(b) PROVIDERS.—Subsection (m) of section 1834 of such Act (42 U.S.C. 1395m) is amended—

(1) in paragraph (1), by striking ''or a practitioner (described in section 1842(b)(18)(C))'' and inserting '', a practitioner (described in section 1842(b)(18)(C)), or an applicable professional (as defined in paragraph (4)(G))'';

(2) by striking ''physician or practitioner'' each time it appears in such subsection and inserting ''physician, practitioner, or applicable professional'';

(3) in paragraph (3)(A)—

(A) in the heading, by striking ''PHYSICIAN AND PRACTITIONER'' and inserting ''PHYSICIAN, PRACTITIONER, AND APPLICABLE PROFESSIONAL''; and

(B) by striking ''physicians or practitioners'' and inserting ''physicians, practitioners, or applicable professionals''; and

(4) in paragraph (4), by adding at the end the following new subparagraph:

''(G) APPLICABLE PROFESSIONAL.—The term 'applicable professional' means, with respect to services furnished on or after the date

that is 6 months after the date of the enactment of this subparagraph, a certified diabetes educator or licensed—

"(i) respiratory therapist;

"(ii) audiologist;

"(iii) occupational therapist;

"(iv) physical therapist; or

"(v) speech language pathologist.".

(c) HOME-BASED MONITORING SERVICES FOR CONGESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE.—

(1) COVERAGE OF REMOTE PATIENT MONITORING SERVICES FOR CERTAIN CHRONIC HEALTH CONDITIONS.—

(A) IN GENERAL.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(i) in subparagraph (GG), by striking "and" at the end;

(ii) in subparagraph (HH), by inserting "and" at the end; and

(iii) by inserting after subparagraph (HH) the following new subparagraph:

''(II) applicable remote patient monitoring services (as defined in paragraph (1)(A) of subsection (iii));''.

(2) SERVICES DESCRIBED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

''(kkk) REMOTE PATIENT MONITORING SERVICES FOR CHRONIC HEALTH CONDITIONS.—

''(1)(A) The term 'applicable remote patient monitoring services' means remote patient monitoring services (as defined in subparagraph (B)) furnished to provide for the monitoring, evaluation, and management of an individual with a covered chronic condition (as defined in paragraph (2)), insofar as such services are for the management of such chronic condition.

''(B) The term 'remote patient monitoring services' means services furnished through remote patient monitoring technology (as defined in subparagraph (C)).

''(C) The term 'remote patient monitoring technology' means a coordinated system that uses one or more home-based or mobile monitoring devices that automatically transmit vital sign data or information

on activities of daily living and may include responses to assessment questions collected on the devices wirelessly or through a telecommunications connection to a server that complies with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, as part of an established plan of care for that patient that includes the review and interpretation of that data by a health care professional.

''(2) For purposes of paragraph (1), the term 'covered chronic health condition' means applicable conditions (as defined in and applied under section 1886(q)(5)) when under chronic care management (identified as of July 1, 2015, by HCPCS code 99490 (and as subsequently modified by the Secretary)).

''(3)(A) Payment may be made under this part for applicable remote patient monitoring services provided to an individual during a period of up to 90 days and such additional period as provided for under subparagraph (B).

''(B) The 90-day period described in subparagraph (A), with respect to an individual, may be re-

newed by the physician who provides chronic care management to such individual if the individual continues to qualify for such management.''.

(3) PAYMENT UNDER THE PHYSICIAN FEE SCHEDULE.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended—

(A) in subsection (c)—

(i) in paragraph (2)(B)—

(I) in clause (ii)(II), by striking ''and (v)'' and inserting ''(v), and (vii)''; and

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

''(vii) BUDGETARY TREATMENT OF CERTAIN SERVICES.—The additional expenditures attributable to services described in section 1861(s)(2)(II) shall not be taken into account in applying clause (ii)(II).''; and

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

''(7) TREATMENT OF APPLICABLE REMOTE PATIENT MONITORING SERVICES.—

''(A) In determining relative value units for applicable remote patient monitoring serv-

ices (as defined in section 1861(iii)(1)(A)), the Secretary, in consultation with appropriate physician groups, practitioner groups, and supplier groups, shall take into consideration—

"(i) physician or practitioner resources, including physician or practitioner time and the level of intensity of services provided, based on—

"(I) the frequency of evaluation necessary to manage the individual being furnished the services;

"(II) the complexity of the evaluation, including the information that must be obtained, reviewed, and analyzed; and

"(III) the number of possible diagnoses and the number of management options that must be considered;

"(ii) practice expense costs associated with such services, including the direct costs associated with installation and information transmission, costs of remote patient monitoring technology (including equipment and software), device delivery costs, and resource costs necessary for pa-

tient monitoring and followup (but not including costs of any related item or nonphysician service otherwise reimbursed under this title); and

''(iii) malpractice expense resources.

''(B) Using the relative value units determined in subparagraph (A), the Secretary shall provide for separate payment for such services and shall not adjust the relative value units assigned to other services that might otherwise have been determined to include such separately paid remote patient monitoring services.''; and

(B) in subsection (j)(3), by inserting ''(2)(II),'' after ''health risk assessment),''.

SEC. 503. STARK AND AKS EXEMPTIONS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may exempt value-based arrangements, alternative payment models, and technologies (as defined by the Secretary) from any provision of section 1128B or 1877 of the Social Security Act for purposes of maintaining, analyzing, or transferring electronic health records.

SEC. 504. STARK TECHNICAL PENALTY.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may institute a civil

monetary penalty for technical, nonegregious violations of section 1877 of the Social Security Act in lieu of any penalty otherwise applicable for such violations under such section.

○