I

116TH CONGRESS
2D SESSION

H. R. 8527

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

OCTOBER 2, 2020

Mr. WESTERMAN (for himself, Mr. BURCHETT, Mr. SMUCKER, and Mr. RIGGLEMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, the Judiciary, Oversight and Reform, House Administration, Rules, the Budget, and Armed Services, 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 2020''.

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

TITLE I—MEDISAVE

Subtitle A—Medisave Accounts and Contributions

SEC. 101. ESTABLISHMENT OF MEDISAVE ACCOUNTS.

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

"SEC. 530A. MEDISAVE ACCOUNTS.

''(a) MEDISAVE ACCOUNT.—For purposes of this section—

''(1) IN GENERAL.—The term 'Medisave account' means a trust created or organized in the United States as a Medisave account exclusively for the purpose of paying the qualified medical expenses of the account beneficiary, but only if the written governing instrument creating the trust meets the following requirements:

''(A) Except in the case of a rollover contribution described in subparagraph (A) or (B) of subsection (e)(5), no contribution will be accepted—

''(i) unless it is in cash,

''(ii) to the extent such contribution, when added to previous contributions to the trust for the calendar year, exceeds the

limitation amount specified in subsection (b)(1), or

''(iii) to the extent such contribution, when added to the balance of the account, exceeds the limitation amount specified in subsection (b)(2).

''(B) The trustee is a bank (as defined in section 408(n)), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

''(C) No part of the trust assets will be invested in life insurance contracts.

''(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

''(E) The interest of an individual in the balance in his account is nonforfeitable.

''(2) QUALIFIED MEDICAL EXPENSES.—

''(A) IN GENERAL.—The term 'qualified medical expenses' means, with respect to an account beneficiary, amounts paid by such bene-

ficiary for medical care, but only to the extent such amounts are not compensated for by insurance or otherwise—

"(i) for—

"(I) such individual,

"(II) the spouse of such individual,

"(III) any dependent (as defined in section 152, determined without regard to subsections (b)(1), (b)(2), and (d)(1)(B) thereof) of such individual, and

"(IV) any individual who bears a relationship to the account beneficiary that is described in subparagraph (C) or (D) of section 152(d) if the account beneficiary is or was a dependent of such individual for any taxable year ending before or with the taxable year in which the individual attained 18 years of age, and

"(ii) if, on the date such medical care was provided, such individual, spouse or dependent to whom such care was provided

was covered under the qualified health insurance of the account beneficiary.

''(B) MODIFIED DEFINITION OF MEDICAL CARE.—For purposes of subparagraph (A), the term 'medical care' has the meaning given such term by section 213(d), except that such term includes—

''(i) a direct primary care service arrangement, and

''(ii) predetermined level of access to care from an integrated health plan.

''(3) ACCOUNT BENEFICIARY.—The term 'account beneficiary' means the individual on whose behalf the Medisave account was established.

''(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

''(A) Section 219(d)(2) (relating to no deduction for rollovers).

''(B) Section 219(f)(3) (relating to time when contributions deemed made).

''(C) Except as provided in section 106(d), section 219(f)(5) (relating to employer payments).

"(D) Section 408(g) (relating to community property laws).

"(E) Section 408(h) (relating to custodial accounts).

"(b) LIMITATIONS.—

"(1) ANNUAL LIMITATION.—

"(A) IN GENERAL.—The limitation amount specified in this paragraph is—

"(i) $5,000 in the case of a qualified health plan with an actuarial value of less than 40 percent,

"(ii) $4,300 in the case of a qualified health plan with an actuarial value that is 40 percent or more and less than 75 percent, and

"(iii) $3,600 in the case of a qualified health plan with an actuarial value that is 75 percent or more.

"(B) ACTUARIAL VALUE OF QUALIFIED HEALTH PLAN.—For purposes of subparagraph (A), the actuarial value of a qualified health plan is the percentage of the total average costs of covered benefits under the health plan.

''(2) ACCOUNT ACCUMULATION LIMITATION.—The limitation amount specified in this paragraph is $50,000.

''(3) INDEXING.—

''(A) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 2020, each dollar amount contained in paragraph (1)(A) shall be increased by the medical care cost adjustment of such amount for such calendar year.

''(B) MEDICAL CARE COST ADJUSTMENT.—For purposes of subparagraph (A), the medical care cost adjustment for any calendar year is the percentage (if any) by which—

''(i) the medical care component of the C–CPI–U (as defined in section 1(f)(6)) for August of the preceding calendar year, exceeds

''(ii) such component of the C–CPI–U (as so defined) for August of 2019.

''(C) ROUNDING.—

''(i) ANNUAL LIMITATION.—If any increase in a dollar amount contained in paragraph (1)(A) determined under subparagraph (A) is not a multiple of $100,

such increase shall be rounded to the nearest multiple of $100.

''(ii) ACCOUNT LIMITATION.—If any increase in the dollar amount contained in paragraph (2) determined under subparagraph (A) is not a multiple of $1,000, such increase shall be rounded to the nearest multiple of $1,000.

''(4) COORDINATION WITH OTHER CONTRIBUTIONS.—The limitation which would (but for this paragraph) apply under paragraphs (1) and (2) to an individual for any taxable year shall be reduced (but not below zero) by the sum of—

''(A) the aggregate amount contributed to Medisave accounts of such individual which is excludable from the taxpayer's gross income for such taxable year under section 106(d), and

''(B) the aggregate amount contributed to Medisave accounts of such individual for such taxable year under section 408(d)(9).

''(5) DEPOSIT OF ADVANCE PREMIUM TAX CREDIT.—An account beneficiary who is eligible for an advance payment of the premium tax credit under section 36B may elect to have the Secretary

deposit the advance payment into the Medisave account of the account beneficiary.

''(c) DEFINITIONS AND SPECIAL RULES.—For purposes of this section—

''(1) ELIGIBLE INDIVIDUAL.—

''(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month—

''(i) any individual who is covered under a qualified health plan as of the 1st day of such month; and

''(ii) any individual whose household income is greater than 250 percent of the Federal poverty level—

''(I) if such individual is covered under a qualified health plan with an actuarial value not more than 80 percent; or

''(II) if—

''(aa) such individual is covered under a high deductible health plan as of the 1st day of such month; and

''(bb) such individual is not, while covered under a high de-

ductible health plan, covered under any health plan—

"(AA) which is not a high deductible health plan; and

"(BB) which provides coverage for any benefit which is covered under the high deductible health plan.

"(B) CERTAIN COVERAGE DISREGARDED.—Subparagraph (A) shall be applied without regard to—

"(i) coverage for any benefit provided by permitted insurance, and

"(ii) coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

"(C) SPECIAL RULE FOR INDIVIDUALS ELIGIBLE FOR CERTAIN VETERANS BENEFITS.—An individual shall not fail to be treated as an eligible individual for any period merely because the individual receives hospital care or medical services under any law administered by the Secretary of Veterans Affairs for a service-con-

nected disability (within the meaning of section 101(16) of title 38, United States Code).

''(2) QUALIFIED HEALTH PLAN.—

''(A) IN GENERAL.—The term 'qualified health plan' means a health plan that offers health insurance coverage. Such term includes entitlement to benefits under title XVIII or title XIX of the Social Security Act.

''(B) EXCLUSION OF CERTAIN PLANS.—Such term does not include a health plan if substantially all of its coverage is disregarded under paragraph (1)(B).

''(C) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

''(D) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' means an insurance company, insurance service, or insurance

organization (including a health maintenance organization) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(2))).

''(E) HEALTH MAINTENANCE ORGANIZATION.—The term 'health maintenance organization' means—

''(i) a Federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a))),

''(ii) an organization recognized under State law as a health maintenance organization, or

''(iii) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

''(3) PERMITTED INSURANCE.—The term 'permitted insurance' means—

''(A) insurance if substantially all of the coverage provided under such insurance relates to—

''(i) liabilities incurred under workers' compensation laws,

''(ii) tort liabilities,

''(iii) liabilities relating to ownership or use of property, or

''(iv) such other similar liabilities as the Secretary may specify by regulations,

''(B) insurance for a specified disease or illness, and

''(C) insurance paying a fixed amount per day (or other period) of hospitalization.

''(4) FAMILY COVERAGE.—The term 'family coverage' means any coverage other than self-only coverage.

''(d) TAX TREATMENT OF ACCOUNTS.—

''(1) IN GENERAL.—A Medisave account is exempt from taxation under this subtitle unless such account has ceased to be a Medisave account. Notwithstanding the preceding sentence, any Medisave account is subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc. organizations).

''(2) ACCOUNT TERMINATIONS.—Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to Medisave accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

''(e) TAX TREATMENT OF DISTRIBUTIONS.—

''(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a Medisave account which is used exclusively to pay qualified medical expenses of any account beneficiary shall not be includible in gross income.

''(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a Medisave account which is not used exclusively to pay the qualified medical expenses of the account beneficiary shall be included in the gross income of such beneficiary.

''(3) EXCESS CONTRIBUTIONS RETURNED BEFORE DUE DATE OF RETURN.—

''(A) IN GENERAL.—If any excess contribution is contributed for a taxable year to any Medisave account of an individual, paragraph (2) shall not apply to distributions from the Medisave accounts of such individual (to the

extent such distributions do not exceed the aggregate excess contributions to all such accounts of such individual for such year) if—

''(i) such distribution is received by the individual on or before the last day prescribed by law (including extensions of time) for filing such individual's return for such taxable year, and

''(ii) such distribution is accompanied by the amount of net income attributable to such excess contribution.

Any net income described in clause (ii) shall be included in the gross income of the individual for the taxable year in which it is received.

''(B) EXCESS CONTRIBUTION.—For purposes of subparagraph (A), the term excess contribution means any contribution (other than a rollover contribution described in paragraph (5)) which exceeds the limitations specified in subsection (b).

''(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—

''(A) IN GENERAL.—The tax imposed by this chapter on the account beneficiary for any taxable year in which there is a payment or dis-

tribution from a Medisave account of such beneficiary which is includible in gross income under paragraph (2) shall be increased by 20 percent of the amount which is so includible.

''(B) EXCEPTION FOR DISABILITY OR DEATH.—Subparagraph (A) shall not apply if the payment or distribution is made after the account beneficiary becomes disabled within the meaning of section 72(m)(7) or dies.

''(5) ROLLOVER CONTRIBUTION.—

''(A) IN GENERAL.—An amount is described in this subparagraph as a rollover contribution if it meets the requirements of clauses (i) and (ii).

''(i) IN GENERAL.—Paragraph (2) shall not apply to any amount paid or distributed from a Medisave account to the account beneficiary to the extent the amount received is paid into a Medisave account for the benefit of such beneficiary not later than the 60th day after the day on which the beneficiary receives the payment or distribution.

''(ii) LIMITATION.—This paragraph shall not apply to any amount described in

clause (i) received by an individual from a Medisave account if, at any time during the 1-year period ending on the day of such receipt, such individual received any other amount described in clause (i) from a Medisave account which was not includible in the individual's gross income because of the application of this paragraph.

"(B) ROLLOVER FROM FSA, ARCHER MSA, AND HSA.—An amount is described in this subparagraph for a calendar year as a rollover contribution if the amount is the remaining balance in a flexible spending account, Archer MSA, or health savings account that is contributed to the Medisave account for a taxable year ending on or before one year after the date of the enactment of the Fair Care Act of 2020.

"(6) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a Medisave account for qualified medical expenses shall not be treated as an expense paid for medical care.

"(7) TRANSFER OF ACCOUNT INCIDENT TO DIVORCE.—The transfer of an individual's interest in

a Medisave account to an individual's spouse or former spouse under a divorce or separation instrument described in clause (i) of section 121(d)(3)(C) shall not be considered a taxable transfer made by such individual notwithstanding any other provision of this subtitle, and such interest shall, after such transfer, be treated as a Medisave account with respect to which such spouse is the account beneficiary.

''(8) TREATMENT AFTER DEATH OF ACCOUNT BENEFICIARY.—

''(A) TREATMENT IF DESIGNATED BENEFICIARY IS SPOUSE.—If the account beneficiary's surviving spouse acquires such beneficiary's interest in a Medisave account by reason of being the designated beneficiary of such account at the death of the account beneficiary, such Medisave account shall be treated as if the spouse were the account beneficiary.

''(B) OTHER CASES.—

''(i) IN GENERAL.—If, by reason of the death of the account beneficiary, any person acquires the account beneficiary's interest in a Medisave account in a case to which subparagraph (A) does not apply—

''(I) such account shall cease to be a Medisave account as of the date of death, and

''(II) an amount equal to the fair market value of the assets in such account on such date shall be includible if such person is not the estate of such beneficiary, in such person's gross income for the taxable year which includes such date, or if such person is the estate of such beneficiary, in such beneficiary's gross income for the last taxable year of such beneficiary.

''(ii) SPECIAL RULES.—

''(I) REDUCTION OF INCLUSION FOR PREDEATH EXPENSES.—The amount includible in gross income under clause (i) by any person (other than the estate) shall be reduced by the amount of qualified medical expenses which were incurred by the decedent before the date of the decedent's death and paid by such person within 1 year after such date.

"(II) DEDUCTION FOR ESTATE TAXES.—An appropriate deduction shall be allowed under section 691(c) to any person (other than the decedent or the decedent's spouse) with respect to amounts included in gross income under clause (i) by such person.

"(f) REPORTS.—The Secretary may require—

"(1) the trustee of a Medisave account to make such reports regarding such account to the Secretary and to the account beneficiary with respect to contributions, distributions, the return of excess contributions, and such other matters as the Secretary determines appropriate, and

"(2) any person who provides an individual with a qualified health plan to make such reports to the Secretary and to the account beneficiary with respect to such plan as the Secretary determines appropriate.

The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.

''(g) REGULATIONS AND GUIDANCE.—For purposes of this section, the Secretary shall prescribe such regulations or other guidance as the Secretary determines necessary or appropriate to carry out this section, including regulations or guidance on the methods acceptable to the Secretary for determining qualified health plan actuarial value.''.

(b) CLERICAL AMENDMENTS.—The table of sections for part VIII of subchapter F of chapter 1 of such Code is amended by adding at the end the following new item:

''Sec. 530A. Medisave accounts.''.

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

SEC. 102. CONSOLIDATION OF HSAS, HRAS, FSAS, AND MSAS INTO MEDISAVE ACCOUNTS.

(a) TREATMENT OF EMPLOYER PAYMENTS.—

(1) EXCLUSION LIMITED TO SELF-FUNDED MAJOR MEDICAL PLAN OF EMPLOYERS.—Section 105(b) of the Internal Revenue Code of 1986 is amended by striking ''paid,'' and inserting ''paid under a self-funded major medical plan of the employer''.

(2) EXCLUSION NOT APPLICABLE TO HEALTH REIMBURSEMENT ARRANGEMENTS.—Subsection (h) of such Code is amended to read as follows:

"(h) EXCLUSION NOT APPLICABLE TO HEALTH REIMBURSEMENT ARRANGEMENTS.—Subsection (b) shall not apply to health reimbursement arrangements.".

(3) REPEAL OF EXCLUSIONS FROM INCOME FOR ARCHER MSAS, FSAS, AND HSAS.—

(A) IN GENERAL.—Section 106 of such Code is amended—

(i) by striking subsections (b), (d), and (e), and

(ii) by redesignating subsections (f) and (g) as subsections (d) and (e), respectively.

(B) EXCLUSION FROM INCOME FOR MEDISAVE ACCOUNTS.—Section 106 of such Code, as amended by subparagraph (A), is amended by inserting after subsection (a) the following:

"(b) CONTRIBUTIONS TO MEDISAVE ACCOUNTS.—

"(1) IN GENERAL.—In the case of an employee who is an eligible individual (as defined in section 530A(c)(1)), amounts contributed by such employee's employer to any Medisave account (as defined in section 530A(a)) of such employee shall be treated as employer-provided coverage for medical expenses under an accident or health plan to the extent such

amounts do not exceed the limitations specified in clauses (ii) and (iii) of section 530A(a)(1)(A) (determined without regard to this subsection) which is applicable to such employee for such taxable year unless such employee is receiving and advance payment of the premium tax credit under section, then such amounts shall not be treated as employer-provided coverage for medical expense under an accident or health plan and are subject to taxation as personal income.

''(2) NO CONSTRUCTIVE RECEIPT.—No amount shall be included in the gross income of any employee solely because the employee may choose between the contributions referred to in paragraph (1) and employer contributions to another health plan of the employer.

''(3) SPECIAL RULE FOR DEDUCTION OF EMPLOYER CONTRIBUTIONS.—Any employer contribution to a Medisave account, if otherwise allowable as a deduction under this chapter, shall be allowed only for the taxable year in which paid.

''(4) EMPLOYER MEDISAVE ACCOUNT CONTRIBUTIONS REQUIRED TO BE SHOWN ON RETURN.—Every individual required to file a return under section 6012 for the taxable year shall include

on such return the aggregate amount contributed by employers to the Medisave accounts of such individual or such individual's spouse for such taxable year.

"(5) MEDISAVE ACCOUNT CONTRIBUTIONS NOT PART OF COBRA COVERAGE.—Paragraph (1) shall not apply for purposes of section 4980B.

"(6) CROSS REFERENCE.—For penalty on failure by employer to make comparable contributions to the Medisave accounts of comparable employees, see section 4980G.".

(4) DISTRIBUTION FROM CERTAIN RETIREMENT ACCOUNTS FOR MEDISAVE ACCOUNT FUNDING.—Section 408(d)(9) of such Code is amended to read as follows:

"(9) DISTRIBUTION FOR MEDISAVE ACCOUNT FUNDING.—

"(A) IN GENERAL.—In the case of an individual who is an eligible individual (as defined in section 530A(c)(1)) and who elects the application of this paragraph for a taxable year, gross income of the individual for the taxable year does not include a qualified Medisave account funding distribution to the extent such

distribution is otherwise includible in gross income.

''(B) QUALIFIED MEDISAVE ACCOUNT FUNDING DISTRIBUTION.—For purposes of this paragraph, the term 'qualified Medisave account funding distribution' means a distribution from an individual retirement plan (other than a plan described in subsection (k) or (p)) of the employee to the extent that—

''(i) such distribution is contributed to the Medisave account of the individual in a direct trustee-to-trustee transfer, and

''(ii) such distribution—

''(I) when added to previous contributions to the Medisave account for the calendar year does not exceed the limitation amount specified in section 530A(b)(1), and

''(II) when added to the balance of the Medisave account, exceeds the limitation amount specified in section 530A(b)(2).

''(C) ONE-TIME TRANSFER.—An individual may make an election under subparagraph (A) only for one qualified Medisave account funding

distribution during the lifetime of the individual. Such an election, once made, shall be irrevocable.

''(D) APPLICATION OF SECTION 72.—Notwithstanding section 72, in determining the extent to which an amount is treated as otherwise includible in gross income for purposes of subparagraph (A), the aggregate amount distributed from an individual retirement plan shall be treated as includible in gross income to the extent that such amount does not exceed the aggregate amount which would have been so includible if all amounts from all individual retirement plans were distributed. Proper adjustments shall be made in applying section 72 to other distributions in such taxable year and subsequent taxable years.''.

(5) FAILURE OF EMPLOYER TO MAKE COMPARABLE CONTRIBUTIONS.—

(A) Section 4980G(a) of such Code is amended by striking ''health savings account'' and inserting ''Medisave account''.

(B) Section 4980G(c) of such Code is amended by striking ''Archer MSAs and health

savings accounts'' and inserting ''Medisave accounts''.

(6) W–2 STATEMENTS.—Section 6051(a) of such Code is amended—

(A) by striking paragraph (11) and redesignating paragraphs (12) through (17) as paragraphs (11) through (16), respectively, and

(B) by amending paragraph (11), as so redesignated, to read as follows:

''(11) the amount contributed to any Medisave account (as defined in section 530A) of such employee or such employee's spouse,''.

(b) OTHER CONFORMING AMENDMENTS.—

(1) ARCHER MSAS.—Section 220(a) of such Code is amended by adding at the end the following: ''No amount is allowed as a deduction under the preceding sentence for any taxable year beginning after one year after the date of the enactment of the Fair Care Act of 2020.''.

(2) HEALTH SAVINGS ACCOUNTS.—Section 223(a) of such Code is amended by adding at the end the following: ''No amount is allowed as a deduction under the preceding sentence for any taxable year beginning after one year after the date of the enactment of the Fair Care Act of 2020.''.

(c) ROLLOVER OF FSA, ARCHER MSA, HSA TO MEDISAVE ACCOUNT.—Notwithstanding any other provision of law, if the remaining balance in a health flexible spending arrangement, Archer MSA, or health savings account is transferred to a Medisave account before the end of any taxable year ending on or before one year after the date of the enactment of the Fair Care Act of 2020, such transfer shall be treated as a rollover to the Medisave account under section 530A(e)(5)(B) of the Internal Revenue Code of 1986 and the distribution from the health flexible spending arrangement, Archer MSA, or health savings account shall not be includible in gross income.

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

SEC. 103. HEALTH REIMBURSEMENT ARRANGEMENTS AND OTHER ACCOUNT-BASED GROUP HEALTH PLANS.

The rule published by the Internal Revenue Service, the Employee Benefits Security Administration, and the Health and Human Services Department relating to ''Health Reimbursement Arrangements and Other Account-Based Group Health Plans'' (June 20, 2019) shall have the force and effect of law. Health Reimbursement

Arrangements as described in this rule are subject to all sections in this title.

SEC. 104. COST-SHARING REDUCTION PAYMENTS AS ELIGIBLE CONTRIBUTIONS.

(a) ALTERNATIVE WAIVER FOR STATE INNOVATION.—Section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052) is amended by adding at the end the following new subsection:

''(f) ALTERNATIVE WAIVER FOR STATE INNOVATION.—

''(1) IN GENERAL.—Notwithstanding any preceding provision of this section, a State may apply to the Secretary for the waiver of any requirement of subsection (a)(2) with respect to health insurance coverage within that State for plan years beginning on or after January 1, 2022, if instead of complying with section 1402 the State provides for the distribution of funding received under paragraph (2) to Medisave accounts of qualifying individuals with respect to such State. Such application shall be filed at such time and in such manner as the Secretary may require, and shall include such information as the Secretary may require (including a 10-year budget plan for such plan that is budget neutral for the Federal Government).

''(2) PASS-THROUGH FUNDING.—With respect to a State waiver under paragraph (1), under which, due to the structure of such waiver, individuals in the State would not qualify for cost-sharing reductions under section 1402 for which they would otherwise be eligible, the Secretary shall provide for an alternative means by which an amount is transferred to the State equal to the aggregate amount of such reductions that would have been paid on behalf of the participants in the Exchanges established under this title—

''(A) had the State not received such waiver;

''(B) had references to 'eligible insureds' under section 1402 referred to 'qualifying insureds (as defined in section 1332(f))';

''(C) had, after application of clause (ii), in the case of a qualifying insured enrolled in the bronze level of coverage—

''(i) the percentages specified in subclauses (I), (II), and (III) of section 1402(c)(1)(B) were references to 84 percent, 77 percent, and 63 percent, respectively; and

"(ii) the references in subparagraphs (A), (B), and (C) of section 1402(c)(2) to 94 percent, 87 percent, and 73 percent, respectively, were references to 84 percent, 77 percent, and 63 percent, respectively; and

"(D) had, after application of clause (ii), in the case of a qualifying insured enrolled in the copper level of coverage—

"(i) the percentages specified in subclauses (I), (II), and (III) of section 1402(c)(1)(B) were references to 74 percent, 67 percent, and 53 percent, respectively; and

"(ii) the references in subparagraphs (A), (B), and (C) of section 1402(c)(2) to 94 percent, 87 percent, and 73 percent, respectively, were references to 74 percent, 67 percent, and 53 percent, respectively.

The amount transferred pursuant to the previous sentence shall be determined annually by the Secretary, taking into consideration the experience of other States with respect to participation in an Exchange and reductions provided under such provisions to residents of the other States, and shall be

paid to the State for purposes of implementing such waiver.

''(3) WAIVER CONSIDERATION AND TRANSPARENCY.—The provisions of paragraph (4) of subsection (a) shall apply to an application for a waiver under paragraph (1) in the same manner as such provisions apply with respect to an application for a waiver under subsection (a)(1), except that, for purposes of this paragraph, the provisions of subsection (a)(4)(B)(ii) shall not apply.

''(4) DETERMINATIONS; TERM OF WAIVER.—The provisions of subsections (d) and (e) shall apply with respect to a determination with respect to an application under paragraph (1), and with respect to the term of a waiver under such paragraph, in the same manner as such provisions apply with respect to a determination with respect to an application under subsection (a)(1), and with respect to the term of a waiver under such subsection.

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

''(A) MEDISAVE ACCOUNT.—The term 'Medisave account' has the meaning given such term in section 530A(a) of the Internal Revenue Code of 1986.

"(B) QUALIFYING INSURED.—The term 'qualifying insured' means, with respect to a State and a year, an individual—

"(i) who is enrolled in a Medisave account;

"(ii) who is enrolled for such year in a silver, bronze, or copper level coverage offered through an Exchange; and

"(iii) whose household income is not more than 250 percent of the Federal poverty line for a family of the size involved.".

(b) ADDITIONAL AMENDMENTS.—Section 1402 of the Patient Protection and Affordable Care Act (42 U.S.C. 18071) is amended by striking "not less than 100 percent but" and "exceeds 100 percent but" and "more than 100 percent but" each place such phrases appear.

(c) CONFORMING AMENDMENTS.—Section 1332 of the Patient Protection and Affordable Care Act (42 U.S.C. 18052), as amended by subsection (a), is further amended in subsection (a)(4)—

(1) in subparagraph (A) by striking the period and inserting ", except in the case of a waiver described in subsection (f)."; and

(2) in subparagraph (B)(ii) by inserting after ''an application'' the following: ''(except in the case of a waiver described in subsection (f))''.

(d) APPROPRIATION FOR COST-SHARING 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.—Out of any funds in the Treasury not otherwise appropriated, there is 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 2022 through 2026.

''(2) ADJUSTMENTS.—Notwithstanding any other provision of law, payments and other actions for adjustments to obligations incurred prior to December 31, 2022, may be made through December 31, 2022.

''(3) LIMITATION.—Amounts appropriated under paragraph (1) for each of plan years 2022 through 2026 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.''.

SEC. 105. DIRECT PRIMARY CARE.

(a) IN GENERAL.—Section 223(c)(1) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

''(D) TREATMENT OF DIRECT PRIMARY CARE SERVICE ARRANGEMENTS.—

''(i) IN GENERAL.—A direct primary care service arrangement shall not be treated as a health plan for purposes of subparagraph (A)(ii).

''(ii) DIRECT PRIMARY CARE SERVICE ARRANGEMENT.—For purposes of this paragraph—

''(I) IN GENERAL.—The term 'direct primary care service arrangement' means, with respect to any individual, an arrangement under which such individual is provided medical care (as defined in section 213(d)) consisting solely of primary care services provided by primary care practi-

tioners (as defined in section 1833(x)(2)(A) of the Social Security Act, determined without regard to clause (ii) thereof), if the sole compensation for such care is a fixed periodic fee.

''(II) LIMITATION.—With respect to any individual for any month, such term shall not include any arrangement if the aggregate fees for all direct primary care service arrangements (determined without regard to this subclause) with respect to such individual for such month exceed $150 (twice such dollar amount in the case of an individual with any direct primary care service arrangement (as so determined) that covers more than one individual).

''(iii) CERTAIN SERVICES SPECIFICALLY EXCLUDED FROM TREATMENT AS PRIMARY CARE SERVICES.—For purposes of this paragraph, the term 'primary care services' shall not include—

''(I) procedures that require the use of general anesthesia, and

''(II) laboratory services not typically administered in an ambulatory primary care setting.

The Secretary, after consultation with the Secretary of Health and Human Services, shall issue regulations or other guidance regarding the application of this clause.''.

(b) DIRECT PRIMARY CARE SERVICE ARRANGEMENT FEES TREATED AS MEDICAL EXPENSES.—Section 223(d)(2)(C) is amended by striking ''or'' at the end of clause (iii), by striking the period at the end of clause (iv) and inserting '', or'', and by adding at the end the following new clause:

''(v) any direct primary care service arrangement.''.

(c) INFLATION ADJUSTMENT.—Section 223(g)(1) of such Code is amended—

(1) by inserting '', (c)(1)(D)(ii)(II),'' after ''(b)(2),'' each place such term appears, and

(2) in subparagraph (B), by inserting ''and (iii)'' after ''clause (ii)'' in clause (i), by striking ''and'' at the end of clause (i), by striking the period at the end of clause (ii) and inserting '', and'', and

by inserting after clause (ii) the following new clause:

"(iii) in the case of the dollar amount in subsection (c)(1)(D)(ii)(II) for taxable years beginning in calendar years after 2020, calendar year 2019.".

(d) REPORTING OF DIRECT PRIMARY CARE SERVICE ARRANGEMENT FEES ON W–2.—Section 6051(a) of such Code is amended by striking "and" at the end of paragraph (16), by striking the period at the end of paragraph (17) and inserting ", and", and by inserting after paragraph (17) the following new paragraph:

"(18) in the case of a direct primary care service arrangement (as defined in section 223(c)(1)(D)(ii)) which is provided in connection with employment, the aggregate fees for such arrangement for such employee.".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to months beginning after December 31, 2019, in taxable years ending after such date.

Subtitle B—Assistance to Medisave Accounts

SEC. 111. SUPPORT IN IMPLEMENTATION.

(a) IN GENERAL.—In the case of an individual who makes a contribution to a Medisave account before the end

of the 1-year period beginning on the date of the enactment of this Act, there shall be allowed as a credit against the tax imposed by subtitle A of the Internal Revenue Code of 1986 for the taxable year in which the contribution is made an amount equal to the aggregate of $1 for every $3 contributed to the account (other than a rollover contribution under section 530A(e)(5) of such Code) for such taxable year.

(b) LIMITATION.—The aggregate amount allowed to an individual as a credit under subsection (a) for all taxable years shall not exceed $1,000.

(c) PORTION OF CREDIT REFUNDABLE.—For purposes of this section—

(1) IN GENERAL.—For purposes of the Internal Revenue Code of 1986, in the case of an eligible individual—

(A) INCREASE IN CREDIT RATE.—Subsection (a) shall be applied by substituting ''$1 for every $1 contributed'' for ''$1 for every $3 contributed''.

(B) CREDIT REFUNDABLE.—The credit allowed under this section shall be treated in the same manner as a credit allowed under subpart C of part IV of subchapter A of chapter 1 of such Code.

(2) ELIGIBLE INDIVIDUAL.—

(A) IN GENERAL.—The term ''eligible individual'' means, with respect to any taxable year, a taxpayer whose household income for the taxable year does not exceed 400 percent of an amount equal to the poverty line for a family of the size involved.

(B) MARRIED COUPLES MUST FILE JOINT RETURN.—If the taxpayer is married (within the meaning of section 7703 of such Code) at the close of the taxable year—

(i) the taxpayer shall be treated as an eligible individual only if the taxpayer and the taxpayer's spouse file a joint return for the taxable year, and

(ii) paragraph (1) shall be applied separately to each spouse.

(3) FAMILY SIZE, HOUSEHOLD INCOME, MODIFIED ADJUSTED GROSS INCOME, POVERTY LINE.—The terms ''family size'', ''household income'', ''modified adjusted gross income'', and ''poverty line'' have the meaning given such terms by section 36B(d) of such Code.

(d) DENIAL OF CREDIT TO DEPENDENTS.—No credit shall be allowed under this section to any individual with

respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

SEC. 112. NEW CORPORATIONS REQUIRED TO USE MEDISAVE.

Notwithstanding any other provision of law, a corporation incorporated after December 31, 2021, may not receive tax benefits for offering employees health insurance. The previous sentence shall not apply to Medisave contributions offered by such a corporation.

SEC. 113. FEDERAL EMPLOYEE HEALTH BENEFITS AND MEDISAVE.

(a) IN GENERAL.—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 ''PRESIDENT, 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 Presi-

dent, 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)).''.

(b) CONVERSION TO MEDISAVE ACCOUNTS.—Each plan offered under chapter 89 of title 5, United States Code, shall be converted into a Medisave account deposit and funded at the level of the second-least expensive silver plan available through the Exchange where the applicable individual resides.

SEC. 114. GRANTS TO STATES FOR CONSUMER ASSISTANCE.

(a) IN GENERAL.—The Administrator shall establish a grant program to provide assistance to eligible entities to carry out the activities described in subsection (c) for the 5-year period beginning on the date of the enactment of this section.

(b) APPLICATION.—An eligible entity shall submit an application to the Administrator in such time and in such manner as the Administrator may require, providing that such application requires a demonstration of the existence of a relationship with, or the ability to establish a relationship with, an employer, employee, self-employed individual, or consumer eligible to enroll in a Medisave account.

(c) USE OF FUNDS.—An eligible entity receiving a grant under this section shall use such funds to—

(1) distribute fair and impartial information to consumers about Medisave accounts, including the availability of such accounts and how such accounts may be utilized;

(2) conduct activities to raise public awareness of Medisave accounts;

(3) facilitate enrollment in Medisave accounts; and

(4) refer individuals enrolled in a Medisave account to the appropriate official, organization, or

State agency for the purpose of addressing a complaint, grievance, or other question with respect to such Medisave account.

(d) AMOUNT.—The Administrator may distribute up to $5,000,000 annually for each year occurring during the period described in subsection (a) to be divided among grant recipients under this section.

(e) REPORT.—Not later than one year after the date on which the last of the grant periods awarded under this section ends, the Administrator shall submit a report to the Congress on the effectiveness of the grants provided under this section.

(f) DEFINITIONS.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Centers for Medicare & Medicaid Services.

(2) CONSUMER.—The term ''consumer'' means an individual enrolled in, or seeking to enroll in, a Medisave account.

(3) ELIGIBLE ENTITY.—The term ''eligible entity'' includes the following:

(A) A State.

(B) Trade.

(C) Industry.

(D) Professional associations.

(E) Commercial fishing industry organizations.

(F) Ranching and farming organizations.

(G) Community and consumer-focused nonprofit groups.

(H) Chambers of Commerce.

(I) Unions.

(J) Small business development centers (as defined in section 21 of the Small Business Act (15 U.S.C. 648)).

(K) Other entities capable of carrying out the activities described under subsection (b).

(4) MEDISAVE ACCOUNT.—The term ''Medisave account'' has the meaning given such term in section 530A(a) of the Internal Revenue Code of 1986 (as added by section 2(a)).

(5) STATE.—The term ''State'' means each of the several States, the District of Columbia, each territory and possession of the United States, and each federally recognized Indian Tribe.

TITLE II—IMPROVING PRIVATE HEALTH INSURANCE

Subtitle A—Maintaining Protections for Patients With Pre-existing Conditions

SEC. 201. GUARANTEED AVAILABILITY OF COVERAGE; PROHIBITING DISCRIMINATION.

(a) IN GENERAL.—Subtitle C of title I of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) is amended by adding at the end the following:

"SEC. 196. GUARANTEED AVAILABILITY OF COVERAGE.

''(a) GUARANTEED ISSUANCE OF COVERAGE IN THE INDIVIDUAL AND GROUP MARKET.—Subject to subsections (b) through (d), each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

''(b) ENROLLMENT.—

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

''(2) ESTABLISHMENT.—A health insurance issuer described in subsection (a) shall, in accord-

ance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 603 of the Employee Retirement Income Security Act of 1974).

''(3) REGULATIONS.—The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).

''(c) SPECIAL RULES FOR NETWORK PLANS.—

''(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may—

''(A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and

''(B) within the service area of such plan, deny such coverage to such employers and individuals if the issuer has demonstrated, if required, to the applicable State authority that—

''(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees; and

''(ii) it is applying this paragraph uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents), or any health status-related factor relating to such individuals, employees, and dependents.

''(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the group or individual market within such service area for a period of 180 days after the date such coverage is denied.

''(d) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

''(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated, if required, to the applicable State authority that—

''(A) it does not have the financial reserves necessary to underwrite additional coverage; and

"(B) it is applying this paragraph uniformly to all employers and individuals in the group or individual market in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

"(2) 180-DAY SUSPENSION UPON DENIAL OF COVERAGE.—A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the group or individual market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

"(e) DEFINITIONS.—In this section and in sections 197 through 199A:

''(1) The term 'Secretary' means the Secretary of Health and Human Services.

''(2) The terms 'genetic information', 'genetic test', 'group health plan', 'group market', 'health insurance coverage', 'health insurance issuer', 'group health insurance coverage', 'individual health insurance coverage', 'individual market', and 'underwriting purpose' have the meanings given such terms in section 2791 of the Public Health Service Act.

''SEC. 197. FAIR HEALTH INSURANCE PREMIUMS.

''(a) PROHIBITING DISCRIMINATORY PREMIUM RATES.—

''(1) IN GENERAL.—With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

''(A) such rate shall vary with respect to the particular plan or coverage involved only by—

''(i) whether such plan or coverage covers an individual or family;

''(ii) rating area, as established in accordance with paragraph (2);

"(iii) age, except that such rate shall not vary by more than 5 to 1 for adults; and

"(iv) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and

"(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A).

"(2) RATING AREA.—

"(A) IN GENERAL.—Each State shall establish 1 or more rating areas within that State for purposes of applying the requirements of this title.

"(B) SECRETARIAL REVIEW.—The Secretary shall review the rating areas established by each State under subparagraph (A) to ensure the adequacy of such areas for purposes of carrying out the requirements of this title. If the Secretary determines a State's rating areas are not adequate, or that a State does not establish such areas, the Secretary may establish rating areas for that State.

"(3) PERMISSIBLE AGE BANDS.—The Secretary, in consultation with the National Association of Insurance Commissioners, shall define the permissible age bands for rating purposes under paragraph (1)(A)(iii).

"(4) APPLICATION OF VARIATIONS BASED ON AGE OR TOBACCO USE.—With respect to family coverage under a group health plan or health insurance coverage, the rating variations permitted under clauses (iii) and (iv) of paragraph (1)(A) shall be applied based on the portion of the premium that is attributable to each family member covered under the plan or coverage.

"SEC. 198. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

"(1) Health status.

''(2) Medical condition (including both physical and mental illnesses).

''(3) Claims experience.

''(4) Receipt of health care.

''(5) Medical history.

''(6) Genetic information.

''(7) Evidence of insurability (including conditions arising out of acts of domestic violence).

''(8) Disability.

''(9) Any other health status-related factor determined appropriate by the Secretary.

''(b) IN PREMIUM CONTRIBUTIONS.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

''(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to restrict the amount that an employer or individual may be charged for coverage under a group health plan except as provided in paragraph (3) or individual health coverage, as the case may be; or

"(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

"(3) NO GROUP-BASED DISCRIMINATION ON BASIS OF GENETIC INFORMATION.—

"(A) IN GENERAL.—For purposes of this section, a group health plan, and health insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

"(B) RULE OF CONSTRUCTION.—Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering

group or individual health insurance coverage to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.

''(c) GENETIC TESTING.—

''(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

''(2) RULE OF CONSTRUCTION.—Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

''(3) RULE OF CONSTRUCTION REGARDING PAYMENT.—

''(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offer-

ing health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act and section 264 of this Act, as may be revised from time to time) consistent with subsection (a).

''(B) LIMITATION.—For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

''(4) RESEARCH EXCEPTION.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

''(A) The request is made pursuant to research that complies with part 46 of title 45,

Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

''(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

''(i) compliance with the request is voluntary; and

''(ii) noncompliance will have no effect on enrollment status or premium or contribution amounts.

''(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

''(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

''(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

''(d) PROHIBITION ON COLLECTION OF GENETIC INFORMATION.—

''(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes.

''(2) PROHIBITION ON COLLECTION OF GENETIC INFORMATION PRIOR TO ENROLLMENT.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment.

''(3) INCIDENTAL COLLECTION.—If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, require-

ment, or purchase is not in violation of paragraph (1).

''(e) GENETIC INFORMATION OF A FETUS OR EMBRYO.—Any reference in this part to genetic information concerning an individual or family member of an individual shall—

''(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

''(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

''(f) PROGRAMS OF HEALTH PROMOTION OR DISEASE PREVENTION.—

''(1) GENERAL PROVISIONS.—

''(A) GENERAL RULE.—For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a 'wellness program') shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.

"(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

"(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

"(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.—If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying

a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

"(A) A program that reimburses all or part of the cost for memberships in a fitness center.

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

"(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

"(D) A program that reimburses individuals for the costs of smoking cessation pro-

grams without regard to whether the individual quits smoking.

''(E) A program that provides a reward to individuals for attending a periodic health education seminar.

''(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

''(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any de-

pendents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

''(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for

discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.

''(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

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

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

''(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

''(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the

reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

''(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

''(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

"SEC. 199. PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS OR OTHER DISCRIMINATION BASED ON HEALTH STATUS.

''(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.

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

''(1) PREEXISTING CONDITION EXCLUSION.—

''(A) IN GENERAL.—The term 'preexisting condition exclusion' means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

''(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

''(2) ENROLLMENT DATE.—The term 'enrollment date' means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in

the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

''(3) LATE ENROLLEE.—The term 'late enrollee' means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

''(A) the first period in which the individual is eligible to enroll under the plan; or

''(B) a special enrollment period under subsection (f).

''(4) WAITING PERIOD.—The term 'waiting period' means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

''(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

''(1) CREDITABLE COVERAGE DEFINED.—For purposes of this title, the term 'creditable coverage' means, with respect to an individual, coverage of the individual under any of the following:

''(A) A group health plan.

''(B) Health insurance coverage.

"(C) Part A or part B of title XVIII of the Social Security Act.

"(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

"(E) Chapter 55 of title 10, United States Code.

"(F) A medical care program of the Indian Health Service or of a tribal organization.

"(G) A State health benefits risk pool.

"(H) A health plan offered under chapter 89 of title 5, United States Code.

"(I) A public health plan (as defined in regulations).

"(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 2791(c)).

"(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

"(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group or in-

dividual health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

''(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group or individual health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

''(C) TAA-ELIGIBLE INDIVIDUALS.—In the case of plan years beginning before January 1, 2014—

''(i) TAA PRE-CERTIFICATION PERIOD RULE.—In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified

health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of the Internal Revenue Code of 1986 shall not be taken into account in determining the continuous period under subparagraph (A).

''(ii) DEFINITIONS.—The terms 'TAA-eligible individual' and 'TAA-related loss of coverage' have the meanings given such terms in section 2205(b)(4).

''(3) METHOD OF CREDITING COVERAGE.—

''(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

''(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group or individual health insurance, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified

in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group or individual health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

''(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

''(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election; and

''(ii) include in such statements a description of the effect of this election.

''(D) ISSUER NOTICE.—In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the individual or group market, the issuer—

''(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election; and

''(ii) shall include in such statements a description of the effect of such election.

''(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

''(d) EXCEPTIONS.—

''(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

''(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage,

may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

''(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

''(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

''(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

''(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

''(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group or

individual health insurance coverage, shall provide the certification described in subparagraph (B)—

"(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision;

"(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision; and

"(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

"(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

"(i) the period of creditable coverage of the individual under such plan and the

coverage (if any) under such COBRA continuation provision; and

''(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

''(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

''(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

''(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information

on coverage of classes and categories of health benefits available under such entity's plan or coverage; and

"(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

"(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

"(f) SPECIAL ENROLLMENT PERIODS.—

"(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

"(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

"(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

"(C) The employee's or dependent's coverage described in subparagraph (A)—

"(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

"(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours

of employment) or employer contributions toward such coverage were terminated.

''(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

''(2) FOR DEPENDENT BENEFICIARIES.—

''(A) IN GENERAL.—If—

''(i) a group health plan makes coverage available with respect to a dependent of an individual;

''(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period); and

''(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in

subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

''(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

''(i) the date dependent coverage is made available; or

''(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

''(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

''(i) in the case of marriage, not later than the first day of the first month begin-

ning after the date the completed request for enrollment is received;

"(ii) in the case of a dependent's birth, as of the date of such birth; or

"(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

"(3) SPECIAL RULES FOR APPLICATION IN CASE OF MEDICAID AND CHIP.—

"(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if either of the following conditions is met:

"(i) TERMINATION OF MEDICAID OR CHIP COVERAGE.—The employee or dependent is covered under a Medicaid plan under title XIX of the Social Security Act

or under a State child health plan under title XXI of such Act and coverage of the employee or dependent under such a plan is terminated as a result of loss of eligibility for such coverage and the employee requests coverage under the group health plan (or health insurance coverage) not later than 60 days after the date of termination of such coverage.

''(ii) ELIGIBILITY FOR EMPLOYMENT ASSISTANCE UNDER MEDICAID OR CHIP.—The employee or dependent becomes eligible for assistance, with respect to coverage under the group health plan or health insurance coverage, under such Medicaid plan or State child health plan (including under any waiver or demonstration project conducted under or in relation to such a plan), if the employee requests coverage under the group health plan or health insurance coverage not later than 60 days after the date the employee or dependent is determined to be eligible for such assistance.

"(B) COORDINATION WITH MEDICAID AND CHIP.—

"(i) OUTREACH TO EMPLOYEES REGARDING AVAILABILITY OF MEDICAID AND CHIP COVERAGE.—

"(I) IN GENERAL.—Each employer that maintains a group health plan in a State that provides medical assistance under a State Medicaid plan under title XIX of the Social Security Act, or child health assistance under a State child health plan under title XXI of such Act, in the form of premium assistance for the purchase of coverage under a group health plan, shall provide to each employee a written notice informing the employee of potential opportunities then currently available in the State in which the employee resides for premium assistance under such plans for health coverage of the employee or the employee's dependents. For purposes of compliance with this subclause, the employer may use any State-specific

model notice developed in accordance with section 701(f)(3)(B)(i)(II) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181(f)(3)(B)(i)(II)).

"(II) OPTION TO PROVIDE CONCURRENT WITH PROVISION OF PLAN MATERIALS TO EMPLOYEE.—An employer may provide the model notice applicable to the State in which an employee resides concurrent with the furnishing of materials notifying the employee of health plan eligibility, concurrent with materials provided to the employee in connection with an open season or election process conducted under the plan, or concurrent with the furnishing of the summary plan description as provided in section 104(b) of the Employee Retirement Income Security Act of 1974.

"(ii) DISCLOSURE ABOUT GROUP HEALTH PLAN BENEFITS TO STATES FOR MEDICAID AND CHIP ELIGIBLE INDIVIDUALS.—In the case of an enrollee in a

group health plan who is covered under a Medicaid plan of a State under title XIX of the Social Security Act or under a State child health plan under title XXI of such Act, the plan administrator of the group health plan shall disclose to the State, upon request, information about the benefits available under the group health plan in sufficient specificity, as determined under regulations of the Secretary of Health and Human Services in consultation with the Secretary that require use of the model coverage coordination disclosure form developed under section 311(b)(1)(C) of the Children's Health Insurance Reauthorization Act of 2009, so as to permit the State to make a determination (under paragraph (2)(B), (3), or (10) of section 2105(c) of the Social Security Act or otherwise) concerning the cost-effectiveness of the State providing medical or child health assistance through premium assistance for the purchase of coverage under such group health plan and in order for the State to provide supplemental benefits required

under paragraph (10)(E) of such section or other authority.

''(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

''(1) IN GENERAL.—A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condition exclusion allowed under subsection (a) with respect to any particular coverage option may impose an affiliation period for such coverage option, but only if—

''(A) such period is applied uniformly without regard to any health status-related factors; and

''(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

''(2) AFFILIATION PERIOD.—

''(A) DEFINED.—For purposes of this title, the term 'affiliation period' means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such pe-

riod and no premium shall be charged to the participant or beneficiary for any coverage during the period.

''(B) BEGINNING.—Such period shall begin on the enrollment date.

''(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

''(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

''SEC. 199A. EXTENSION OF DEPENDENT COVERAGE.

''(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child (who is not married) until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the

preceding sentence to make coverage available for a child of a child receiving dependent coverage.

''(b) REGULATIONS.—The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to modify the definition of 'dependent' as used in the Internal Revenue Code of 1986 with respect to the tax treatment of the cost of coverage.

''SEC. 199B. ANNUAL LIMITATION ON COST-SHARING.

''(a) IN GENERAL.—

''(1) 2014.—The cost-sharing incurred under a group health plan or group or individual health insurance coverage with respect to self-only coverage or coverage other than self-only coverage for a plan year beginning in 2014 shall not exceed the dollar amounts in effect under section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986 for self-only and family coverage, respectively, for taxable years beginning in 2014.

''(2) 2015 AND LATER.—In the case of any plan year beginning in a calendar year after 2014, the limitation under this paragraph shall—

''(A) in the case of self-only coverage, be equal to the dollar amount under paragraph (1)

for self-only coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage under subsection (c) for the calendar year; and

''(B) in the case of other coverage, twice the amount in effect under subparagraph (A).

If the amount of any increase under subparagraph (A) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.

''(b) COST-SHARING.—In this section:

''(1) IN GENERAL.—The term 'cost-sharing' includes—

''(A) deductibles, coinsurance, copayments, or similar charges; and

''(B) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan.

''(2) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.

''(c) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of subsection (a)(2)(A), the premium adjustment percentage for any calendar year is the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2013 (as determined by the Secretary).

''SEC. 199C. ENFORCEMENT OF CERTAIN HEALTH INSURANCE REQUIREMENTS.

''(a) STATE ENFORCEMENT.—

''(1) STATE AUTHORITY.—Each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part with respect to such issuers.

''(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) of sections 196 through 199A with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insur-

ance coverage in connection with group health plans or individual health insurance coverage in such State.

''(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

''(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) described in subsection (a)(2) only—

''(A) as provided under such subsection; and

''(B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

''(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

''(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such plan or issuer is subject to a civil money penalty under this subsection.

''(B) LIABILITY FOR PENALTY.—In the case of a failure by—

''(i) a health insurance issuer, the issuer is liable for such penalty; or

"(ii) a group health plan that is a non-Federal governmental plan which is—

"(I) sponsored by 2 or more employers, the plan is liable for such penalty; or

"(II) not so sponsored, the employer is liable for such penalty.

"(C) AMOUNT OF PENALTY.—

"(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

"(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

"(iii) LIMITATIONS.—

"(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILI-

GENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

"(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

"(D) ADMINISTRATIVE REVIEW.—

"(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an

opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

''(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

''(E) JUDICIAL REVIEW.—

''(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order

imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

''(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

''(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

''(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to

appeal as provided in chapter 83 of title 28 of such Code.

''(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

''(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

''(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

''(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

''(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

''(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 196 or section 197 or 196(b)(1) with respect to genetic information in connection with the plan.

''(B) AMOUNT.—

''(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

''(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term 'noncompliance period' means, with respect to any failure, the period—

''(I) beginning on the date such failure first occurs; and

''(II) ending on the date the failure is corrected.

''(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

''(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

''(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

''(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

''(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de mini-

mis, clause (i) shall be applied by substituting '$15,000' for '$2,500' with respect to such person.

''(D) LIMITATIONS.—

''(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

''(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

''(I) such failure was due to reasonable cause and not to willful neglect; and

''(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exer-

cising reasonable diligence would have known, that such failure existed.

''(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

''(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

''(II) $500,000.

''(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

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

''(1) GOVERNMENTAL PLAN.—The term 'governmental plan' has the meaning given such term

under section 3(32) of the Employee Retirement Income Security Act of 1974 and any Federal governmental plan.

''(2) FEDERAL GOVERNMENTAL PLAN.—The term ''Federal governmental plan'' means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

''(3) NON-FEDERAL GOVERNMENTAL PLAN.—The term 'non-Federal governmental plan' means a governmental plan that is not a Federal governmental plan.''.

(b) CONFORMING AMENDMENT.—The table of contents under section 1(b) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191) is amended by inserting after the item relating to section 195 the following:

''Sec. 196. Guaranteed availability of coverage.
''Sec. 197. Fair health insurance premiums.
''Sec. 198. Prohibiting discrimination against individual participants and beneficiaries based on health status.
''Sec. 199. Prohibition of preexisting condition exclusions or other discrimination based on health status.
''Sec. 199A. Extension of dependent coverage.
''Sec. 199B. Annual limitation on cost-sharing.
''Sec. 199C. Enforcement of certain health insurance requirements.''.

(c) ERISA AND IRC ENFORCEMENT.—

(1) ERISA.—Subpart B of part 7 of title I of the Employee Retirement Income Security Act of

1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following new section:

"SEC. 716. OTHER MARKET REFORMS.

"Sections 196 and 197 of the Health Insurance Portability and Accountability Act of 1996 shall apply to health insurance issuers providing health insurance coverage in connection with group health plans, and sections 198 through 199B of such Act shall apply to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subpart, and to the extent that any provision of this part conflicts with a provision of such section 196 or 197 with respect to health insurance issuers providing health insurance coverage in connection with group health plans or of such section 198, 199, 199A, or 199B with respect to group health plans or health insurance issuers providing health insurance coverage in connection with group health plans, the provisions of such sections 196 through 199B shall apply.".

(2) IRC.—Subchapter B of chapter 100 of subtitle K of title 26 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 9816. OTHER MARKET REFORMS.

''Sections 196 and 197 of the Health Insurance Portability and Accountability Act of 1996 shall apply to health insurance issuers providing health insurance coverage in connection with group health plans, and sections 198 through 199B of such Act shall apply to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subchapter, and to the extent that any provision of this chapter conflicts with a provision of such section 196 or 197 with respect to health insurance issuers providing health insurance coverage in connection with group health plans or of such section 198, 199, 199A, or 199B with respect to group health plans or health insurance issuers providing health insurance coverage in connection with group health plans, the provisions of such sections 196 through 199B shall apply.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date on which the Supreme Court of the United States issues a decision striking down the Patient Protection and Affordable Care Act (Public Law 111–148) in its entirety.

Subtitle B—Expanding Coverage Options

SEC. 211. 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, in-

cluding a corporation or similar organization that operates on a cooperative basis (within the meaning of section 1381 of the Internal Revenue Code of 1986)), for substantial purposes other than that of obtaining or providing medical care;

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

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

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

''SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—The applicable authority shall prescribe by regulation a procedure under which, subject

to subsection (b), the applicable authority shall certify association health plans which apply for certification as meeting the requirements of this part.

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

''(c) REQUIREMENTS APPLICABLE TO CERTIFIED PLANS.—An association health plan with respect to which certification under this part is in effect shall meet the 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; wholesaling/distributing; or any other trade or business or industry which has been indicated as having average or above-average risk or health claims experience by reason of State rate filings, denials of coverage, proposed premium rate levels, or other means demonstrated by such plan in accordance with regulations.

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

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

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

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

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

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

''(A) BOARD MEMBERSHIP.—

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

''(ii) LIMITATION.—

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

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

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

in subclause (I) who is a provider of medical care under the plan.

''(iii) CERTAIN PLANS EXCLUDED.—Clause (i) shall not apply to an association health plan which is in existence on the date of the enactment of this section.

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

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

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

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

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

"SEC. 804. PARTICIPATION AND COVERAGE REQUIREMENTS.

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

''(1) each participating employer must be—

''(A) a member of the sponsor;

''(B) the sponsor; or

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

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

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

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

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

''(b) COVERAGE OF PREVIOUSLY UNINSURED EMPLOYEES.—In the case of an association health plan in existence on the date of the enactment of 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 insur-

ance 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 pro-

hibits an exclusion of a specific disease from such coverage.

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

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

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

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

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

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

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

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

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

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

''(i) The plan shall secure aggregate excess/stop loss insurance for the plan with an attachment point which is not greater than 125 percent of expected gross annual claims. The applicable authority may by regulation provide for upward adjustments in the amount of such percentage in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

''(ii) The plan shall secure specific excess/stop loss insurance for the plan with an attachment point which is at least equal

to an amount recommended by the plan's qualified actuary. The applicable authority may by regulation provide for adjustments in the amount of such insurance in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

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

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

section are met if the plan establishes and maintains surplus in an amount at least equal to—

''(1) $500,000; or

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

''(c) ADDITIONAL REQUIREMENTS.—In the case of any association health plan described in subsection (a)(2), the applicable authority may provide such additional requirements relating to reserves, excess/stop loss insurance, and indemnification insurance as the applicable authority considers appropriate. Such requirements may be provided by regulation with respect to any such plan or any class of such plans.

''(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSURANCE.—The applicable authority may provide for adjustments to the levels of reserves otherwise required under subsections (a) and (b) with respect to any plan or class

of plans to take into account excess/stop loss insurance provided with respect to such plan or plans.

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

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

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

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

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

"(C) CONTINUED DUTY OF THE SECRETARY.—The Secretary shall not cease to

carry out the provisions of paragraph (2) on account of the failure of a plan to pay any payment when due.

''(2) PAYMENTS BY SECRETARY TO CONTINUE EXCESS/STOP LOSS INSURANCE COVERAGE AND INDEMNIFICATION INSURANCE COVERAGE FOR CERTAIN PLANS.—In any case in which the applicable authority determines that there is, or that there is reason to believe that there will be: (A) A failure to take necessary corrective actions under section 809(a) with respect to an association health plan described in subsection (a)(2); or (B) a termination of such a plan under section 809(b) or 810(b)(8) (and, if the applicable authority is not the Secretary, certifies such determination to the Secretary), the Secretary shall determine the amounts necessary to make payments to an insurer (designated by the Secretary) to maintain in force excess/stop loss insurance coverage or indemnification insurance coverage for such plan, if the Secretary determines that there is a reasonable expectation that, without such payments, claims would not be satisfied by reason of termination of such coverage. The Secretary shall, to the extent provided in advance in appropriation

Acts, pay such amounts so determined to the insurer designated by the Secretary.

''(3) ASSOCIATION HEALTH PLAN FUND.—

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

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

ance' 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 prescribe by regulation) provides for payment to the plan with respect to claims under the plan which the plan is unable to satisfy by reason of a termination pursuant to section 809(b) (relating to mandatory termination);

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

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

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

''(j) SOLVENCY STANDARDS WORKING GROUP.—

''(1) IN GENERAL.—Within 90 days after the date of the enactment of 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 accordance with regulations which the applicable authority shall prescribe.

"(B) ADEQUACY OF CONTRIBUTION RATES.—A statement of actuarial opinion, signed by a qualified actuary, which sets forth a description of the extent to which contribution rates are adequate to provide for the payment of all obligations and the maintenance of required reserves under the plan for the 12-month period beginning with such date within such 120-day period, taking into account the expected coverage and experience of the plan. If the contribution rates are not fully adequate, the statement of actuarial opinion shall indicate the extent to which the rates are inadequate and the changes needed to ensure adequacy.

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

tuarial opinion signed by a qualified actuary, which sets forth the current value of the assets and liabilities accumulated under the plan and a projection of the assets, liabilities, income, and expenses of the plan for the 12-month period referred to in subparagraph (B). The income statement shall identify separately the plan's administrative expenses and claims.

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

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

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

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

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

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

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

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

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

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

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

"SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TERMINATION.

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

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

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

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

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

"SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMINATION.

"(a) ACTIONS TO AVOID DEPLETION OF RESERVES.—An association health plan which is certified under this part and which provides benefits other than

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

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

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

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

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

tence of this subsection are remedied or the plan is terminated.

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

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

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

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

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

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

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

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

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

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

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

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

''(1) the sponsor and plan administrator;

''(2) each participant;

''(3) each participating employer; and

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

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

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

''(f) JURISDICTION OF COURT.—

''(1) IN GENERAL.—Upon the filing of an application for the appointment as trustee or the issuance of a decree under this section, the court to which the application is made shall have exclusive jurisdiction of the plan involved and its property wherever located with the powers, to the extent consistent with

the purposes of this section, of a court of the United States having jurisdiction over cases under chapter 11 of title 11, United States Code. Pending an adjudication under this section such court shall stay, and upon appointment by it of the Secretary as trustee, such court shall continue the stay of, any pending mortgage foreclosure, equity receivership, or other proceeding to reorganize, conserve, or liquidate the plan, the sponsor, or property of such plan or sponsor, and any other suit against any receiver, conservator, or trustee of the plan, the sponsor, or property of the plan or sponsor. Pending such adjudication and upon the appointment by it of the Secretary as trustee, the court may stay any proceeding to enforce a lien against property of the plan or the sponsor or any other suit against the plan or the sponsor.

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

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

"SEC. 811. STATE ASSESSMENT AUTHORITY.

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

tenance organizations for health insurance coverage offered in such State in connection with a group health plan;

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

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

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

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

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

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

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

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

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

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

''(7) INDIVIDUAL MARKET.—

''(A) IN GENERAL.—The term 'individual market' means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

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

''(i) IN GENERAL.—Subject to clause (ii), such term includes coverage offered in

connection with a group health plan that has fewer than 2 participants as current employees or participants described in section 732(d)(3) on the first day of the plan year.

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

''(8) PARTICIPATING EMPLOYER.—The term 'participating employer' means, in connection with an association health plan, any employer, if any individual who is an employee of such employer, a partner in such employer, or a self-employed individual who is such employer (or any dependent, as defined under the terms of the plan, of such individual) is or was covered under such plan in connection with the status of such individual as such an employee, partner, or self-employed individual in relation to the plan.

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

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

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

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

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

''(C) in the case of an association health plan in existence on the date of the enactment of 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 Secretary that all requirements for certification under this part would be met with respect to such plan, fund, or program if such plan, fund, or program were a group health plan, such plan, fund, or program shall be treated for purposes of this title as an employee welfare benefit plan on and after the date of such demonstration.".

(b) CONFORMING AMENDMENTS TO PREEMPTION RULES.—

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

"(E) The preceding subparagraphs of this paragraph do not apply with respect to any State law in the case

of an association health plan which is certified under part 8.''.

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

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

ment,'', 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

SEC. 212. 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 par-

ticipating 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. 213. 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 bar-

gaining 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. 214. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

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

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

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

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

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

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

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

''(B) in any other case, the Secretary shall take into account the places of residence of the participants and beneficiaries under the plan

and the State in which the trust is maintained.''.

SEC. 215. 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 Act)) 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 op-

erations 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.

SEC. 216. 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, 2021.

Subtitle C—Improving Commercial Health Insurance

SEC. 221. INVISIBLE GUARANTEED COVERAGE 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 Guaranteed Coverage Pool Reinsurance Program (in this section referred to as the ''IGCPR program'').

(b) STATE GRANTS.—Under the IGCPR 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 Guaranteed Coverage 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 Guaranteed Coverage 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 Guaranteed Coverage Pool described in paragraph (2).

(2) FEDERAL DEFAULT QUALIFYING INVISIBLE GUARANTEED COVERAGE 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 Guaranteed Coverage 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, 2021, 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 GUARANTEED COVERAGE POOL.—For purposes of this section, the term ''qualifying Invisible Guaranteed Coverage 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 2021 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.

(h) REPORT.—The Secretary of Health and Human Services, in collaboration with the Comptroller General of the United States, shall submit to Congress, not later than January 1, 2026, and again 5 years thereafter, a report on the status of reinsurance pool funding, along with any recommendations with respect to future allocations or funding methods for such pool.

SEC. 222. 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, 2021.

(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. 223. REFUNDABLE CREDITS FOR COVERAGE UNDER A QUALIFIED HEALTH PLAN FOR INDIVIDUALS OFFERED EMPLOYER-SPONSORED INSURANCE.

(a) IN GENERAL.—Section 36B(c)(2) of the Internal Revenue Code of 1986 is amended—

(1) in subparagraph (B)(i), by inserting ''or section 5000A(f)(1)(B)'', and

(2) by striking subparagraph (C).

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

SEC. 224. 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 2021' 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 2021 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) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to taxable years beginning after December 31, 2021.

SEC. 225. 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, 2021, as the Secretary may implement through interim final regulation, 5 to 1 for adults (consistent with section 2707(c))''.

SEC. 226. 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 speci-

fied 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	3	4.3	3	4.3	3	4.3	3	4.3
150%–200%	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7
200%–250%	6.7	6.7	6.7	7.6	6.7	8.5	6.7	8.5	6.7	8.5
250%–300%	6.7	6.7	7.6	7.6	8.3	9.8	8.3	9.8	8.3	9.8
300%–400%	6.7	7	7.6	8	9.8	10	9.8	10	9.8	10
400%-600%	7	9	8	10	10	15	10	15	10	15

"(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 2021, 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 2021, over the rate of growth in the consumer price index for calendar year 2021.

"(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 the preceding calendar year exceeds an amount equal to 0.504 percent of the gross domestic product for such calendar year.".

(b) EXPANSION OF ELIGIBILITY.—Section 36B of the Internal Revenue Code of 1986 is amended—

(1) in subsection (c)(1)(A), by striking ''400'' and inserting ''600''; and

(2) in subsection (f)(2)(B)(i), by striking ''400'' each place such reference appears and inserting ''600'' in each such place.

(c) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 2021.

SEC. 227. PREMIUM ASSISTANCE.

Notwithstanding any other provision of law, the Secretary of the Treasury shall calculate the credit allowable under section 36B of the Internal Revenue Code of 1986 based on the taxpayer's prior year tax return and the Secretary of Health and Human Services shall provide for open enrollment periods that end on April 15.

SEC. 228. 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 will have out-of-pocket limits that are 30 percent higher than bronze plans.''; 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, 2021.

SEC. 229. COPPER AND BRONZE PLANS.

Notwithstanding any other provision of law, refundable credits for coverage under a qualified health plan and cost-sharing reductions may be used to purchase bronze and copper plans.

SEC. 230. 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 period 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. 231. 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 periods 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. 232. 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 enroll-

ment period) every 12, 24, or 36 months, as determined by the State.''.

SEC. 233. 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, 2021, 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.

TITLE III—COMPETITION, TRANSPARENCY AND ACCOUNTABILITY

Subtitle A—Provider and Insurer Competition

SEC. 301. 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 ADVANTAGE 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 located in a county whose population density is above the median population density for all counties in the United States with respect to which there is a Herfindahl-Hirschman Index (HHI) of greater than 4,000, to apply the average reimbursement rate with respect to individuals (regardless of whether such an individual is entitled to or eligible for benefits under this title, but excluding individ-

uals 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 enrolled under part C.''; 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—

''(i) the HRR market share of such hospital (as determined under subparagraph (B)) is less than 0.15; or

''(ii) the hospital is located in a rural area (as defined in section 1886(d)(2)(D)).

''(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 program under State law.

(3) ELIGIBILITY.—

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

(iv) The State does not have in effect any Certificate of Public Advantage laws that clearly articulate the State's intent to displace competition in favor of regulation or that violate State or Federal antitrust laws.

(v) The State does not have in effect any network adequacy laws regulating a health plan's ability to deliver benefits by providing reasonable access to a sufficient number of in-network primary care and specialty physicians, as well as all health care services included under the terms of an insuree's contract with a health insurer.

(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.

(d) CRITICAL ACCESS HOSPITAL REIMBURSEMENT RATES.—

(1) PART A.—Section 1814(l)(1) of the Social Security Act (42 U.S.C. 1395f(l)(1)) is amended by

inserting ''(or, for 2021, 102, plus 1 percentage point for each subsequent year through 2029, and 110 for each subsequent year thereafter)'' after ''101''.

(2) PART B.—Section 1834(g)(1) of such Act (42 U.S.C. 1395m(g)(1)) is amended by inserting ''(or, for 2021, 102, plus 1 percentage point for each subsequent year through 2029, and 110 for each subsequent year thereafter)'' after ''101''.

SEC. 302. 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''.

SEC. 303. 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 de-

scribed 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. 304. LEVELING THE PLAYING FIELD BETWEEN PAYERS AND PROVIDERS.

(a) EXEMPTION.—It shall not be a violation of the antitrust laws for one or more private health insurer issuers or their designated agents to jointly negotiate prices of particular hospital services with a hospital provider with regards to the reimbursement policies of the insurers for those services.

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

(1) ANTITRUST LAWS.—The term ''antitrust laws'' has the meaning given it in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition.

(2) HEALTH INSURANCE ISSUER.—The term ''health insurance issuer'' means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in subparagraph (C)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974

(29 U.S.C. 1144(b)(2)). Such term does not include a group health plan.

(3) HEALTH MAINTENANCE ORGANIZATION.—The term ''health maintenance organization'' means—

(A) a Federally qualified health maintenance organization (as defined in section 300e(a) of title 42 of the United States Code),

(B) an organization recognized under State law as a health maintenance organization, or

(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(c) EFFECTIVE DATE.—This section shall take effect on the date of the enactment of this Act but shall not apply with respect to conduct that occurs before such date.

SEC. 305. INCREASING TRANSPARENCY BY REMOVING GAG CLAUSES ON PRICE AND QUALITY INFORMATION.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by the preceding sections, is amended by adding at the end the following:

"SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING GAG CLAUSES ON PRICE AND QUALITY INFORMATION.

"(a) INCREASING PRICE AND QUALITY TRANSPARENCY FOR PLAN SPONSORS AND GROUP AND INDIVIDUAL MARKET AND CONSUMERS.—

"(1) GROUP HEALTH PLANS.—A group health plan or health insurance issuer offering group health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict a group health plan or health insurance issuer from—

"(A) providing provider-specific cost or quality of care information, through a consumer engagement tool or any other means, to referring providers, the plan sponsor, enrollees, or eligible enrollees of the plan or coverage;

"(B) electronically accessing de-identified claims and encounter data for each enrollee in the plan or coverage, upon request and consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Ge-

netic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990, with respect to the applicable health plan or health insurance coverage, including, on a per claim basis—

''(i) financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract;

''(ii) provider information, including name and clinical designation;

''(iii) service codes; or

''(iv) any other data element normally included in claim or encounter transactions when received by a plan or issuer; or

''(C) sharing data described in subparagraph (A) or (B) with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Genetic Information Nondiscrimination Act of

2008, and the Americans with Disabilities Act of 1990.

''(2) INDIVIDUAL HEALTH INSURANCE COVERAGE.—A health insurance issuer offering individual health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, or other service provider offering access to a network of providers that would directly or indirectly restrict the health insurance issuer from—

''(A) providing provider-specific price or quality of care information, through a consumer engagement tool or any other means, to referring providers, enrollees, or eligible enrollees of the plan or coverage; or

''(B) sharing, for plan design, plan administration, and plan, financial, legal, and quality improvement activities, data described in subparagraph (A) with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Ge-

netic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990.

''(3) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in paragraph (1)(A) or (2)(A) prevents a health care provider, network or association of providers, or other service provider from placing reasonable restrictions on the public disclosure of the information described in such paragraphs (1) and (2).

''(4) ATTESTATION.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall annually submit to, as applicable, the applicable authority described in section 2723 or the Secretary of Labor, an attestation that such plan or issuer is in compliance with the requirements of this subsection.

''(5) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to otherwise limit group health plan, plan sponsor, or health insurance issuer access to data currently permitted under the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act, the amendments to this Act made by the Genetic Information Nondiscrimination Act of

2008, and the Americans with Disabilities Act of 1990.''.

SEC. 306. BANNING ANTICOMPETITIVE TERMS IN FACILITY AND INSURANCE CONTRACTS THAT LIMIT ACCESS TO HIGHER QUALITY, LOWER COST CARE.

(a) IN GENERAL.—Section 2729B of the Public Health Service Act, as added by section 301, is amended by adding at the end the following:

''(b) PROTECTING HEALTH PLANS NETWORK DESIGN FLEXIBILITY.—

''(1) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not enter into an agreement with a provider, network or association of providers, or other service provider offering access to a network of service providers if such agreement, directly or indirectly—

''(A) restricts the group health plan or health insurance issuer from—

''(i) directing or steering enrollees to other health care providers; or

''(ii) offering incentives to encourage enrollees to utilize specific health care providers;

''(B) requires the group health plan or health insurance issuer to enter into any additional contract with an affiliate of the provider, such as an affiliate of the provider, as a condition of entering into a contract with such provider;

''(C) requires the group health plan or health insurance issuer to agree to payment rates or other terms for any affiliate not party to the contract of the provider involved; or

''(D) restricts other group health plans or health insurance issuers not party to the contract from paying a lower rate for items or services than the contracting plan or issuer pays for such items or services.

''(2) ADDITIONAL REQUIREMENT FOR SELF-INSURED PLANS.—A self-insured group health plan shall not enter into an agreement with a provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers if such agreement directly or indirectly requires the group health plan to certify, attest, or otherwise confirm in writing that the group health plan is bound by restrictive contracting terms between the service provider and a third-party

administrator that the group health plan is not party to, without a disclosure that such terms exist.

''(3) EXCEPTION FOR CERTAIN GROUP MODEL ISSUERS.—Paragraph (1)(A) shall not apply to a group health plan or health insurance issuer offering group or individual health insurance coverage with respect to—

''(A) a health maintenance organization (as defined in section 2791(b)(3)), if such health maintenance organization operates primarily through exclusive contracts with multi-specialty physician groups, nor to any arrangement between such a health maintenance organization and its affiliates; or

''(B) a value-based network arrangement, such as an exclusive provider network, accountable care organization, center of excellence, a provider sponsored health insurance issuer that operates primarily through aligned multi-specialty physician group practices or integrated health systems, or such other similar network arrangements as determined by the Secretary through rulemaking.

''(4) ATTESTATION.—A group health plan or health insurance issuer offering group or individual

health insurance coverage shall annually submit to, as applicable, the applicable authority described in section 2723 or the Secretary of Labor, an attestation that such plan or issuer is in compliance with the requirements of this subsection.

''(c) MAINTENANCE OF EXISTING HIPAA, GINA, AND ADA PROTECTIONS.—Nothing in this section shall modify, reduce, or eliminate the existing privacy protections and standards provided by reason of State and Federal law, including the requirements of parts 160 and 164 of title 45, Code of Federal Regulations (or any successor regulations).

''(d) REGULATIONS.—The Secretary, not later than 1 year after the date of enactment of the Fair Care Act of 2020, shall promulgate regulations to carry out this section.

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to limit network design or cost or quality initiatives by a group health plan or health insurance issuer, including accountable care organizations, exclusive provider organizations, networks that tier providers by cost or quality or steer enrollees to centers of excellence, or other pay-for-performance programs.

''(f) CLARIFICATION WITH RESPECT TO ANTITRUST LAWS.—Compliance with this section does not constitute

compliance with the antitrust laws, as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)).''.

(b) EFFECTIVE DATE.—Section 2729B of the Public Health Service Act (as added by section 301 and amended by subsection (a)) shall apply with respect to any contract entered into on or after the date that is 18 months after the date of enactment of this Act. With respect to an applicable contract that is in effect on the date of enactment of this Act, such section 2729B shall apply on the earlier of the date of renewal of such contract or 3 years after such date of enactment.

SEC. 307. REPEALING ELIGIBILITY OF CERTAIN ACOS.

(a) IN GENERAL.—Section 1899(b)(1) of the Social Security Act (42 U.S.C. 1395jjj(b)(1)) is amended by striking subparagraphs (C) through (E).

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2021.

SEC. 308. 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 Edu-

cation 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. 309. ALTERNATIVE PAYMENT MODEL FOR CERTAIN SHOPPABLE PROCEDURES.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)) may elect, with respect to a plan year, to provide a set payment amount to an enrollee under such plan or coverage for certain shoppable procedures (as defined in subsection (b)) in accordance with the provisions of this section in lieu of otherwise providing coverage for such a procedure under such plan or coverage, but only if the enrollee so agrees to such set payment amount.

(b) DEFINITION.—For purposes of this section, the term ''shoppable procedure'' means a procedure specified by the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') with respect to which individuals may be expected to compare prices for such procedure of health care providers and facilities, including primary and preventive services, prenatal care and

childbirth, common surgeries that can be scheduled, and other similar services.

(c) SET PAYMENT RULES.—A set payment described in subsection (a) under a group health plan or group or individual health insurance coverage offered by a health insurance issuer shall—

(1) be disclosed prior to beginning of each plan year such payment is in effect and shall not vary during such plan year;

(2) be the same amount with respect to the same shoppable procedure furnished in a geographic area (as defined by the Secretary);

(3) not be less than the median negotiated rate for all group health plans and health insurance coverage offered in such area for such procedure;

(4) be made available to an enrolled under such plan or such coverage regardless of the provider or facility furnishing the shoppable procedure;

(5) represent the entirety of the payment obligation of such plan or such issuer with respect to such procedure; and

(6) may be retained by such enrollee to the extent that the amount of such payment exceeds the amount charged by such provider or facility for such procedure.

(d) PROVISION OF PRICE INFORMATION.—Each health care provider and facility that may furnish a shoppable procedure during a year shall post in a public area a notice containing the prices that will be charged by such provider of facility with respect to each such procedure to individuals making payment for such services pursuant to a set payment amount described in subsection (a).

(e) EHB WAIVER AUTHORITY.—The Secretary may waive such provisions of section 1302(b) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(b)) with respect to a group health plan, health insurance issuer offering group or individual health insurance coverage, and a plan year as the Secretary determines necessary to allow for the provision of set payment amounts described in subsection (a).

Subtitle B—Price Transparency

SEC. 321. PRICE TRANSPARENCY.

Section 1866 of the Social Security Act (42 U.S.C. 1395cc), as amended by section 301, 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 common shoppable 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) COMMON SHOPPABLE 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 common shoppable 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. 322. PRICE TRANSPARENCY REQUIREMENTS.

(a) HOSPITALS.—Section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)) is amended—

(1) by striking ''Each hospital'' and inserting the following:

''(1) IN GENERAL.—Each hospital'';

(2) by inserting '', in a machine-readable format, via open application program interfaces (APIs)'' after ''a list'';

(3) by inserting '', along with such additional information as the Secretary may require with respect to such charges for purposes of promoting

public awareness of hospital pricing in advance of receiving a hospital item or service'' before the period; and

(4) by adding at the end the following:

''(2) DEFINITION OF STANDARD CHARGES.—Notwithstanding any other provision of law, for purposes of paragraph (1), the term 'standard charges' means the rates hospitals, including providers or entities that contract with or practice at a hospital, charge for all items and services at a minimum, chargemaster rates, rates that hospitals negotiate with third party payers across all plans, including those related to a patient's specific plan, discounted cash prices, and other rates determined by the Secretary.

''(3) ENFORCEMENT.—In addition to any other enforcement actions or penalties that may apply under subsection (b)(3) or another provision of law, a hospital that fails to provide the information required by this subsection and has not completed a corrective action plan to comply with the requirements of such subsection shall be subject to a civil monetary penalty of an amount not to exceed $300 per day that the violation is ongoing as determined by the Secretary. Such penalty shall be imposed and

collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.''.

(b) TRANSPARENCY IN COVERAGE.—Section 1311(e)(3) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(e)(3)) is amended—

(1) in subparagraph (A)—

(A) in clause (vii), by inserting before the period the following: '', including, for all items and services covered under the plan, aggregate information on specific payments the plan has made to out-of-network health care providers on behalf of plan enrollees'';

(B) by designating clause (ix) as clause (x); and

(C) by inserting after clause (viii), the following:

''(ix) Information on the specific negotiated payment rates between the plan and health care providers for all items and services covered under the plan.'';

(2) in subparagraph (B)—

(A) in the heading, by striking ''USE'' and inserting ''DELIVERY METHODS AND USE'';

(B) by inserting ", as applicable," after "English proficiency"; and

(C) by inserting after the second sentence, the following: "The Secretary shall establish standards for electronic delivery and access to such information by individuals, free of charge, in machine readable format, through an Internet website and via open APIs.";

(3) in subparagraph (C)—

(A) in the first sentence, by inserting "or out-of-network provider" after "item or service by a participating provider";

(B) in the second sentence, by striking "through an Internet website" and inserting "free of charge, in machine readable format, through an Internet website, and via open APIs, in accordance with standards established by the Secretary,"; and

(C) by adding at the end the following: "Such information shall include specific negotiated rates that allow for comparison between providers and across plans, and related to a patient's specific plan, including after an enrollee has exceeded their deductible responsibility."; and

(4) in subparagraph (D) by striking ''subparagraph (A)'' and inserting ''subparagraphs (A), (B), and (C)''.

SEC. 323. DESIGNATION OF NONGOVERNMENTAL, NONPROFIT TRANSPARENCY ORGANIZATIONS TO LOWER AMERICANS' HEALTH CARE COSTS.

(a) IN GENERAL.—Subpart C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as amended by the preceding sections, is further amended by adding at the end the following:

''SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NONPROFIT TRANSPARENCY ORGANIZATION TO LOWER AMERICANS' HEALTH CARE COSTS.

''(a) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, not later than 1 year after the date of enactment of the Fair Care Act of 2020, shall enter into contracts with at least 2 nonprofit entities to support the establishment and maintenance of a database that receives and utilizes health care claims information and related information and issues reports that are available to the public and authorized users, and are submitted to the Department of Health and Human Services.

''(b) REQUIREMENTS.—

''(1) IN GENERAL.—The database established under subsection (a) shall—

"(A) improve transparency by using de-identified health care data to—

"(i) inform patients about the cost, quality, and value of their care;

"(ii) assist providers and hospitals, as they work with patients, to make informed choices about care;

"(iii) enable providers, hospitals, and communities to improve services and outcomes for patients by benchmarking their performance against that of other providers, hospitals, and communities;

"(iv) enable purchasers, including employers, employee organizations, and health plans, to develop value-based purchasing models, improve quality, and reduce the cost of health care and insurance coverage for enrollees;

"(v) enable employers and employee organizations to evaluate network design and construction, and the cost of care for enrollees;

"(vi) facilitate State-led initiatives to lower health care costs and improve quality; and

"(vii) promote competition based on quality and cost;

"(B) collect medical claims, prescription drug claims, and remittance data consistent with the protections and requirements of subsection (d);

"(C) be established in such a manner that allows the data collected pursuant to subparagraph (B) to be shared with any State all-payer claims database or regional database operated with authorization from States, at cost, using a standardized format, if such State or regional database also submits claims data to the database established under this section; and

"(D) be available to—

"(i) the Director of the Congressional Budget Office, the Comptroller General of the United States, the Executive Director of the Medicare Payment Advisory Commission, and the Executive Director of the Medicaid and CHIP Payment Advisory Commission, upon request, subject to the privacy and security requirements of authorized users under subsection (e)(2); and

"(ii) authorized users, including employers, employee organizations, providers, group health plans, health insurance issuers, researchers, and policymakers, subject to subsection (e).

"(2) PRIVACY AND SECURITY; BREACH NOTIFICATIONS.—

"(A) REGULATIONS.—

"(i) IN GENERAL.—The Secretary shall issue regulations prescribing the extent to which, and the manner in which, the following rules (and any successors of such rules) shall apply to the activities under this section of an entity receiving a contract under subsection (a):

"(I) The Privacy Rule under part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or any successor regulations).

"(II) The Security Rule under part 160 and subparts A and C of part 164 of such title 45 (or any successor regulations).

"(III) The Breach Notification Rule under part 160 and subparts A

and D of part 164 of such title 45 (or any successor regulations).

''(ii) SUPPLEMENTAL REGULATIONS.—In order to ensure data privacy and security and the notification of breaches, the Secretary may issue such supplemental regulations on the subjects of the rules listed under clause (i) as the Secretary determines appropriate to address differences between the activities described by this section and the activities covered by such rules.

''(B) ENFORCEMENT.—Section 1176 of Social Security Act shall apply with respect to a violation of this paragraph in the same manner such section 1176 applies to a violation of part C of title XI of the Social Security Act, and the Secretary may include in the regulations promulgated under this section provisions to apply such section to this paragraph.

''(C) PROCEDURE.—

''(i) TIMING.—The Secretary shall issue the initial set of regulations under this paragraph not later than 1 year after

the date of enactment of the Fair Care Act of 2020.

''(ii) AUTHORITY TO USE INTERIM FINAL PROCEDURES.—The Secretary may make such initial set of regulations effective and final immediately upon issuance, on an interim basis, and provide for a period of public comment on such initial set of regulations after the date of publication.

''(D) REQUIREMENTS OF ENTITY.—An entity receiving the contract under this section shall—

''(i) not disclose to the public any individually identifiable health information or proprietary financial information;

''(ii) strictly limit staff access to the data to staff with appropriate training, clearance, and background checks and require regular privacy and security training;

''(iii) maintain effective security standards for transferring data or making data available to authorized users;

''(iv) develop a process for providing access to data to authorized users, in a se-

cure manner that maintains privacy and confidentiality of data; and

"(v) adhere to current best security practices with respect to the management and use of such data for health services research, in accordance with applicable Federal privacy law.

"(3) CONSULTATION.—

"(A) ADVISORY COMMITTEE.—Not later than 180 days after the date of enactment of the Fair Care Act of 2020, the Secretary shall convene an Advisory Committee (referred to in this section as the 'Committee'), consisting of 13 members, to advise the Secretary, a contracting entity, and Congress on the establishment, operations, and use of the database established under this section.

"(B) MEMBERSHIP.—

"(i) APPOINTMENT.—In accordance with clause (ii), the Secretary, in consultation with the Secretary of Labor and the Comptroller General of the United States shall, not later than 180 days after the date of enactment of the Fair Care Act of 2020, appoint members to the Committee

who have distinguished themselves in the fields of health services research, health economics, health informatics, or the governance of State all-payer claims databases, or who represent organizations likely to submit data to or use the database, including patients, employers, or employee organizations that sponsor group health plans, health care providers, health insurance issuers, or third-party administrators of group health plans. Such members shall serve 3-year terms on a staggered basis. Vacancies on the Committee shall be filled by appointment consistent with this subsection not later than 3 months after the vacancy arises.

''(ii) COMPOSITION.—In accordance with clause (i)—

''(I) the Secretary, in consultation with the Secretary of Labor, shall appoint to the Committee—

''(aa) 1 member selected by the Secretary, in coordination with the Secretary of Labor, to

serve as the chair of the Committee;

''(bb) the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, or a designee of such Assistant Secretary;

''(cc) 1 representative of the Centers for Medicare & Medicaid Services;

''(dd) 1 representative of the Agency for Health Research and Quality;

''(ee) 1 representative of the Office for Civil Rights of the Department of Health and Human Services with expertise in data privacy and security;

''(ff) 1 representative of the National Center for Health Statistics; and

''(gg) 1 representative of the Employee Benefits and Security

Administration of the Department of Labor; and

''(II) the Comptroller General of the United States shall appoint to the Committee—

''(aa) 1 representative of an employer that sponsors a group health plan;

''(bb) 1 representative of an employee organization that sponsors a group health plan;

''(cc) 1 academic researcher with expertise in health economics or health services research;

''(dd) 1 consumer advocate; and

''(ee) 2 additional members.

''(C) DUTIES.—The Committee shall—

''(i) advise the Secretary on the management of the contract under subsection (a);

''(ii) assist and advise the entities receiving the contract under subsection (a) in establishing—

''(I) the scope and format of the data to be submitted under subsection (d);

''(II) best practices with respect to de-identification of data, as appropriate;

''(III) the appropriate uses of data by authorized users, including developing standards for the approval of requests by organizations to access and use the data; and

''(IV) the appropriate formats and methods for making reports and analyses based on the database to the public;

''(iii) conduct an annual review of whether data was used according to the appropriate uses as described in clause (ii)(II), and advise the designated entities on using the data for authorized purposes;

''(iv) report, as appropriate, to the Secretary and Congress on the operation of the database and opportunities to better achieve the objectives of this section;

"(v) establish additional restrictions on researchers who receive compensation from entities described in subsection (e)(2)(B)(ii), in order to protect proprietary financial information; and

"(vi) establish objectives for research and public reporting.

"(4) STATE REQUIREMENTS.—A State may require health insurance issuers and other payers to submit claims data to the database established under this section, provided that such data is submitted to the entities awarded contracts under this section in a form and manner established by the Secretary, and pursuant to subsection (d)(4)(B).

"(5) SANCTIONS.—The Secretary shall take appropriate action to sanction users who attempt to re-identify data accessed pursuant to paragraph (1)(D).

"(c) CONTRACT REQUIREMENTS.—

"(1) COMPETITIVE PROCEDURES.—The Secretary shall enter into the contract under subsection (a) using full and open competition procedures pursuant to chapter 33 of title 41, United States Code.

''(2) ELIGIBLE ENTITIES.—To be eligible to enter into a contract described in subsection (a), an entity shall—

''(A) be a private nonprofit entity governed by a board that includes representatives of the academic research community and individuals with expertise in employer-sponsored insurance, research using health care claims data and actuarial analysis;

''(B) conduct its business in an open and transparent manner that provides the opportunity for public comment on its activities; and

''(C) agree to comply with any requirements imposed under the rulemaking described in subsection (d)(4)(A).

''(3) CONSIDERATIONS.—In awarding a contract under subsection (a), the Secretary shall consider an entity's experience in—

''(A) health care claims data collection, aggregation, quality assurance, analysis, and security;

''(B) supporting academic research on health costs, spending, and utilization for and by privately insured patients;

''(C) working with large health insurance issuers and third-party administrators to assemble a national claims database;

''(D) effectively collaborating with and engaging stakeholders to develop reports;

''(E) meeting budgets and timelines, including in connection with report generation; and

''(F) facilitating the creation of, or supporting, State all-payer claims databases.

''(4) CONTRACT TERM.—A contract awarded under this section shall be for a period of 5 years, and may be renewed after a subsequent competitive bidding process under this section.

''(5) TRANSITION OF CONTRACT.—If the Secretary, following a competitive process at the end of the contract period, selects a new entity to maintain the database, all data shall be transferred to the new entity according to a schedule and process to be determined by the Secretary. Upon termination of a contract, no entity may keep data held by the database or disclose such data to any entity other than the entity so designated by the Secretary. The Secretary shall include enforcement terms in any contract with an organization chosen under this section,

to ensure the timely transfer of all data, and any associated code or algorithms, to a new entity in the event of contract termination.

"(d) RECEIVING HEALTH INFORMATION.—

"(1) REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary of Labor shall ensure that the applicable self-insured group health plan, through its third-party administrator, pharmacy benefit manager, or other entity designated by the group health plan, as applicable, electronically submits all claims data with respect to the plan, pursuant to subparagraph (B).

"(B) SCOPE OF INFORMATION AND FORMAT OF SUBMISSION.—An entity awarded the contract under subsection (a), in consultation with the Committee described in subsection (b)(3), and pursuant to the privacy and security requirements of subsection (b)(2), shall—

"(i) specify the data elements required to be submitted under subparagraph (A), which shall include all data related to transactions described in subparagraphs (A) and (E) of section 1173(a)(2) of the Social Security Act, including all data ele-

ments normally present in such transactions when adjudicated, and enrollment information;

"(ii) specify the form and manner for such submissions, and the historical period to be included in the initial submission; and

"(iii) offer an automated submission option to minimize administrative burdens for entities required to submit data.

"(C) DE-IDENTIFICATION OF DATA.—An entity awarded the contract under subsection (a) shall—

"(i) establish a process under which data is de-identified consistent with the de-identification requirements under section 164.514 of title 45, Code of Federal Regulations (or any successor regulations), while retaining the ability to link data longitudinally for the purposes of research on cost and quality, and the ability to complete risk adjustment and geographic analysis;

"(ii) ensure that any third-party subcontractors who perform the de-identifica-

tion process described in clause (i) retain only the minimum necessary information to perform such a process, and adhere to effective security and encryption practices in data storage and transmission;

''(iii) store claims and other data collected under this subsection only in de-identified form, in accordance with section 164.514 of title 45, Code of Federal Regulations (or any successor regulations); and

''(iv) ensure that individually identifiable data is encrypted, in accordance with guidance issued by the Secretary under section 13402(h)(2) of the HITECH Act.

''(2) APPLICABLE SELF-INSURED GROUP HEALTH PLAN.—For purposes of paragraph (1), a self-insured group health plan is an applicable self-insured group health plan if such plan is self-administered, or is administered by a third-party plan administrator that meets 1 or both of the following criteria:

''(A) Administers health, medical, or pharmacy benefits for more than 50,000 enrollees.

''(B) Is one of the 5 largest administrators or issuers of self-insured group health plans in

a State in which such administrator operates, as measured by the aggregate number of enrollees in plans administered by such administrator in such State, as determined by the Secretary.

''(3) THIRD-PARTY ADMINISTRATORS.—In the case of a third-party administrator that is required under this subsection to submit claims data with respect to an applicable self-insured group health plan, such administrator shall submit claims data with respect to all self-insured group health plans that the administrator administers, including such plans that are not applicable self-insured group health plans, as described in paragraph (2).

''(4) RECEIVING OTHER INFORMATION.—

''(A) MEDICARE DATA.—The Secretary, through rulemaking, shall ensure that the data made available to such entity is available to qualified entities under section 1874(e) of the Social Security Act is made available to each entity awarded a contract under subsection (a).

''(B) STATE DATA.—An entity awarded a contract under subsection (a) shall collect data from State all payer claims databases that seek access to the database established under this section.

''(5) AVAILABILITY OF DATA.—An entity required to submit data under this subsection may not place any restrictions on the use of such data by authorized users.

''(e) USES OF INFORMATION.—

''(1) IN GENERAL.—An entity awarded a contract under subsection (a) shall make the database available to users who are authorized under this subsection, at cost, and reports and analyses based on the data available to the public with no charge.

''(2) AUTHORIZATION OF USERS.—

''(A) IN GENERAL.—An entity may request authorization by an entity awarded a contract under subsection (a) for access to the database in accordance with this paragraph.

''(B) APPLICATION.—An entity desiring authorization under this paragraph shall submit to an entity awarded a contract an application for such access, which shall include—

''(i) in the case of an entity requesting access for research purposes—

''(I) a description of the uses and methodologies for evaluating health system performance using such data; and

''(II) documentation of approval of the research by an institutional review board, if applicable for a particular plan of research; or

''(ii) in the case of an entity such as an employer, health insurance issuer, third-party administrator, or health care provider, requesting access for the purpose of quality improvement or cost-containment, a description of the intended uses for such data.

''(C) REQUIREMENTS.—

''(i) RESEARCH.—Upon approval of an application for research purposes under subparagraph (B)(i), the authorized user shall enter into a data use and confidentiality agreement with an entity awarded a contract under subsection (a), which shall include a prohibition on attempts to re-identify and disclose individually identifiable health information and proprietary financial information.

''(ii) QUALITY IMPROVEMENT AND COST-CONTAINMENT.—In consultation with the Committee described in subsection

(b)(3), the Secretary shall, through rule-making, establish the form and manner in which authorized users described in sub-paragraph (B)(ii) may access data. Data provided to such authorized users shall be provided in a form and manner such that users may not obtain individually identifiable price information with respect to direct competitors. Upon approval, such authorized user shall enter into a data use and confidentiality agreement with the entity.

''(iii) CUSTOMIZED REPORTS.—Employers and employer organizations may request customized reports from an entity awarded a contract under subsection (a), at cost, subject to the requirements of this section with respect to privacy, security, and proprietary financial information.

''(iv) NON-CUSTOMIZED REPORTS.—An entity awarded a contract under subsection (a), in consultation with the Committee, shall make available to all authorized users aggregate data sets, free of charge.

''(f) FUNDING.—

''(1) INITIAL FUNDING.—There are authorized to be appropriated, and there are appropriated, out of monies in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2020, for the implementation of the initial contract and establishment of the database under this section.

''(2) ONGOING FUNDING.—There are authorized to be appropriated $15,000,000 for each of fiscal years 2021 through 2025, for purposes of carrying out this section (other than the grant program under subsection (h)).

''(g) ANNUAL REPORT.—

''(1) SUBMISSION.—On each of the dates described in paragraph (2), an entity receiving a contract under subsection (a) shall submit to Congress, the Secretary of Health and Human Services, and the Secretary of Labor and publish online for access by the general public, a report containing a description of—

''(A) trends in the price, utilization, and total spending on health care services, including a geographic analysis of differences in such trends;

''(B) limitations in the data set;

"(C) progress towards the objectives of this section; and

"(D) the performance by the entity of the duties required under such contract.

"(2) DATES DESCRIBED.—The reports described in paragraph (1) shall be submitted—

"(A) not later than 3 years after the date of enactment of the Fair Care Act of 2020;

"(B) the later of 1 year after the date that is 3 years after such date of enactment or March 1 of the year after the date that is 3 years after such date of enactment; and

"(C) March 1 of each year thereafter.

"(3) PUBLIC REPORTS AND RESEARCH.—An entity receiving a contract under subsection (a) shall, in coordination with authorized users, make analyses and research available to the public on an ongoing basis to promote the objectives of this section.

"(h) GRANTS TO STATES.—

"(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, may award grants to States for the purpose of establishing and maintaining State all-payer claims databases that im-

prove transparency of data in order to meet the goals of subsection (a)(1).

''(2) REQUIREMENT.—To be eligible to receive the funding under paragraph (1), a State shall submit data to the database as described in subsection (b)(1)(C), using the format described in subsection (d)(1).

''(3) FUNDING.—There is authorized to be appropriated $100,000,000 for the period of fiscal years 2020 through 2029 for the purpose of awarding grants to States under this subsection.

''(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

''(1) IN GENERAL.—Claims data provided to the database, and the database itself shall not be considered public records and shall be exempt from public disclosure requirements.

''(2) RESTRICTIONS ON USES FOR CERTAIN PROCEEDINGS.—Data disclosed to authorized users shall not be subject to discovery or admission as public information, or evidence in judicial or administrative proceedings without consent of the affected parties.

''(j) DEFINITIONS.—

''(1) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable

health information' has the meaning given such term in section 1171(6) of the Social Security Act.

''(2) PROPRIETARY FINANCIAL INFORMATION.—The term 'proprietary financial information' means data that would disclose the terms of a specific contract between an individual health care provider or facility and a specific group health plan, Medicaid managed care organization or other managed care entity, or health insurance issuer offering group or individual coverage.

''(k) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect or modify enforcement of the privacy, security, or breach notification rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations).''.

(b) GAO REPORT.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on—

(A) the performance of the entity awarded a contract under section 2795(a) of the Public Health Service Act, as added by subsection (a), under such contract;

(B) the privacy and security of the information reported to the entity; and

(C) the costs incurred by such entity in performing such duties.

(2) REPORTS.—Not later than 2 years after the effective date of the first contract entered into under section 2795(a) of the Public Health Service Act, as added by subsection (a), and again not later than 4 years after such effective date, the Comptroller General of the United States shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 324. PROTECTING PATIENTS AND IMPROVING THE ACCURACY OF PROVIDER DIRECTORY INFORMATION.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by the preceding sections, is further amended by adding at the end the following:

"SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE ACCURACY OF PROVIDER DIRECTORY INFORMATION.

''(a) NETWORK STATUS OF PROVIDERS.—

''(1) IN GENERAL.—Beginning on the date that is one year after the date of enactment of this section, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

''(A) establish business processes to ensure that all enrollees in such plan or coverage receive proof of a health care provider's network status, based on what a plan or issuer knows or could reasonably know—

''(i) through a written electronic communication from the plan or issuer to the enrollee, as soon as practicable and not later than 1 business day after a telephone inquiry is made by such enrollee for such information;

''(ii) through an oral confirmation, documented by such issuer or coverage, and kept in the enrollee's file for a minimum of 2 years; and

''(iii) in real-time through an online health care provider directory search tool maintained by the plan or issuer; and

''(B) include in any print directory a disclosure that the information included in the di-

rectory is accurate as of the date of the last data update and that enrollees or prospective enrollees should consult the group health plan or issuer's electronic provider directory on its website or call a specified customer service telephone number to obtain the most current provider directory information.

''(2) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER BUSINESS PROCESSES.—Beginning on the date that is one year after the date of enactment of the Fair Care Act of 2020, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall establish business processes to—

''(A) verify and update, at least once every 90 days, the provider directory information for all providers included in the online health care provider directory search tool described in paragraph (1)(A)(iii); and

''(B) remove any provider from such online directory search tool if such provider has not verified the directory information within the previous 6 months or the plan or issuer has been unable to verify the provider's network participation.

''(b) COST-SHARING LIMITATIONS.—

''(1) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not apply, and shall ensure that no provider applies cost-sharing to an enrollee for treatment or services provided by a health care provider in excess of the normal cost-sharing applied for in-network care (including any balance bill issued by the health care provider involved), if such enrollee, or health care provider referring such enrollee, demonstrates (based on the electronic, written information described in subsection (a)(1)(A)(i), the oral confirmation described in subsection (a)(1)(A)(ii), or a copy of the online provider directory described in subsection (a)(1)(A)(iii) on the date the enrollee attempted to obtain the provider's network status) that the enrollee relied on the information described in subsection (a)(1), if the provider's network status or directory information on such directory was incorrect at the time the treatment or services involved was provided.

''(2) REFUNDS TO ENROLLEES.—If a health care provider submits a bill to an enrollee in violation of paragraph (1), and the enrollee pays such

bill, the provider shall reimburse the enrollee for the full amount paid by the enrollee in excess of the in-network cost-sharing amount for the treatment or services involved, plus interest, at an interest rate determined by the Secretary.

''(c) PROVIDER BUSINESS PROCESSES.—A health care provider shall have in place business processes to ensure the timely provision of provider directory information to a group health plan or a health insurance issuer offering group or individual health insurance coverage to support compliance by such plans or issuers with subsection (a)(1). Such providers shall submit provider directory information to a plan or issuers, at a minimum—

''(1) when the provider begins a network agreement with a plan or with an issuer with respect to certain coverage;

''(2) when the provider terminates a network agreement with a plan or with an issuer with respect to certain coverage;

''(3) when there are material changes to the content of provider directory information described in subsection (a)(1); and

''(4) every 90 days throughout the duration of the network agreement with a plan or issuer.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—Subject to paragraph (2), a health care provider that violates a requirement under subsection (c) or takes actions that prevent a group health plan or health insurance issuer from complying with subsection (a)(1) or (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(2) SAFE HARBOR.—The Secretary may waive the penalty described under paragraph (1) with respect to a health care provider that unknowingly violates subsection (b)(1) with respect to an enrollee if such provider rescinds the bill involved and, if applicable, reimburses the enrollee within 30 days of the date on which the provider billed the enrollee in violation of such subsection.

''(3) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(e) SAVINGS CLAUSE.—Nothing in this section shall prohibit a provider from requiring in the terms of a con-

tract, or contract termination, with a group health plan or health insurance issuer—

''(1) that the plan or issuer remove, at the time of termination of such contract, the provider from a directory of the plan or issuer described in subsection (a)(1); or

''(2) that the plan or issuer bear financial responsibility, including under subsection (b), for providing inaccurate network status information to an enrollee.

''(f) DEFINITION.—For purposes of this section, the term 'provider directory information' includes the names, addresses, specialty, and telephone numbers of individual health care providers, and the names, addresses, and telephone numbers of each medical group, clinic, or facility contracted to participate in any of the networks of the group health plan or health insurance coverage involved.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to preempt any provision of State law relating to health care provider directories or network adequacy.''.

(b) EFFECTIVE DATE.—Section 2729C of the Public Health Service Act, as added by subsection (a), shall take effect with respect to plan years beginning on or after the

date that is 18 months after the date of enactment of this Act.

SEC. 325. ENSURING ENROLLEE ACCESS TO COST-SHARING INFORMATION.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by the preceding sections, is further amended by adding at the end the following:

"SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.

''(a) PROVIDER DISCLOSURES.—A provider that is in-network with respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage shall provide to an enrollee in the plan or coverage who submits a request for the information described in paragraph (1) or (2), together with accurate and complete information about the enrollee's coverage under the applicable plan or coverage—

''(1) as soon as practicable and not later than 2 business days after the enrollee requests such information, a good faith estimate of the expected enrollee cost-sharing for the provision of a particular health care service (including any service that is reasonably expected to be provided in conjunction with such specific service); and

''(2) as soon as practicable and not later than 2 business days after an enrollee requests such information, the contact information for any ancillary providers for a scheduled health care service.

''(b) INSURER DISCLOSURES.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall provide an enrollee in the plan or coverage with a good faith estimate of the enrollee's cost-sharing (including deductibles, copayments, and coinsurance) for which the enrollee would be responsible for paying with respect to a specific health care service (including any service that is reasonably expected to be provided in conjunction with such specific service), as soon as practicable and not later than 2 business days after a request for such information by an enrollee.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—Subject to paragraph (2), a health care provider that violates a requirement under subsection (a) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

''(2) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil

money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.''.

(b) EFFECTIVE DATE.—Section 2729G of the Public Health Service Act, as added by subsection (a), shall apply with respect to plan years beginning on or after the date that is 18 months after the date of enactment of this Act.

SEC. 326. 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. 327. TIMELY BILLS FOR PATIENTS.

(a) IN GENERAL.—

(1) AMENDMENT.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

''SEC. 399V–7. TIMELY BILLS FOR PATIENTS.

''(a) IN GENERAL.—The Secretary shall require—

''(1) health care facilities, or in the case of practitioners providing services outside of such a facility, practitioners, to provide to patients a list of services rendered during the visit to such facility or

practitioner, and, in the case of a facility, the name of the provider for each such service, upon discharge or end of the visit or by postal or electronic communication as soon as practicable and not later than 5 calendar days after discharge or date of visit; and

''(2) health care facilities and practitioners to furnish all adjudicated bills to the patient as soon as practicable, but not later than 45 calendar days after discharge or date of visit.

''(b) PAYMENT AFTER BILLING.—No patient may be required to pay a bill for health care services any earlier than 35 days after the postmark date of a bill for such services.

''(c) EFFECT OF VIOLATION.—

''(1) NOTIFICATION AND REFUND REQUIREMENTS.—

''(A) PROVIDER LISTS.—If a facility or practitioner fails to provide a patient a list as required under subsection (a)(1), such facility or practitioner shall report such failure to the Secretary.

''(B) BILLING.—If a facility or practitioner bills a patient after the 45-calendar-day period described in subsection (a)(2), such facility or practitioner shall—

''(i) report such bill to the Secretary; and

''(ii) refund the patient for the full amount paid in response to such bill with interest, at a rate determined by the Secretary.

''(2) CIVIL MONETARY PENALTIES.—

''(A) IN GENERAL.—The Secretary may impose civil monetary penalties of up to $10,000 a day on any facility or practitioner that—

''(i) fails to provide a list required under subsection (a)(1) more than 10 times, beginning on the date of such tenth failure;

''(ii) submits more than 10 bills outside of the period described in subsection (a)(2), beginning on the date on which such facility or practitioner sends the tenth such bill;

''(iii) fails to report to the Secretary any failure to provide lists as required under paragraph (1)(A), beginning on the date that is 45 calendar days after discharge or visit; or

''(iv) fails to send any bill as required under subsection (a)(2), beginning on the date that is 45 calendar days after the date of discharge or visit, as applicable.

''(B) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section, shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(3) SAFE HARBOR.—The Secretary may exempt a practitioner or facility from the penalties under paragraph (2)(A) or extend the period of time specified under subsection (a)(2) for compliance with such subsection if a practitioner or facility—

''(A) makes a good-faith attempt to send a bill within 30 days but is unable to do so because of an incorrect address; or

''(B) experiences extenuating circumstances (as defined by the Secretary), such as a hurricane or cyberattack, that may reasonably delay delivery of a timely bill.''.

(2) RULEMAKING.—Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate final regulations to define the term ''extenuating circumstance'' for purposes of section 399V–7(c)(3)(B) of the Public Health Service Act, as added by paragraph (1).

(b) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER REQUIREMENTS.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11), as amended by the preceding sections, is further amended by adding at the end the following:

''SEC. 2729D. TIMELY BILLS FOR PATIENTS.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall have in place business practices with respect to in-network facilities and practitioners to ensure that claims are adjudicated in order to facilitate facility and practitioner compliance with the requirements under section 399V–7(a).

''(b) CLARIFICATION.—Nothing in subsection (a) prohibits a provider and a group health plan or health insurance issuer from establishing in a contract the timeline for submission by either party to the other party of billing information, adjudication, sending of remittance information, or any other coordination required between the pro-

vider and the plan or issuer necessary for meeting the deadline described in section 399V–7(a)(2).''.

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect 6 months after the date of enactment of this Act.

SEC. 328. 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. 329. 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. 330. 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, 2021, 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).

SEC. 331. 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. 332. GROUP HEALTH PLAN REPORTING REQUIREMENTS.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.), as amended by the preceding sections, is further amended by adding at the end the following:

"SEC. 2797. GROUP HEALTH PLAN REPORTING.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall submit to the Secretary, not later than March 1 of each year, the following information with respect to the health plan in the previous plan year:

''(1) The beginning and end dates of the plan year.

''(2) The number of enrollees.

''(3) Each State in which the plan is offered.

''(4) The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by the issuer, and the total number of paid claims for each such drug.

''(5) The 50 most costly prescription drugs with respect to the plan by total annual spending, and the annual amount spent by the plan for each such drug.

''(6) The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan in each such plan year.

''(7) Total spending on health care services by such group health plan, broken down by—

"(A) the type of costs, including—

"(i) hospital costs;

"(ii) health care provider and clinical service costs;

"(iii) costs for prescription drugs; and

"(iv) other medical costs; and

"(B) spending on prescription drugs by—

"(i) the health plan; and

"(ii) the enrollees.

"(8) The average monthly premium—

"(A) paid by employers on behalf of enrollees; and

"(B) paid by enrollees.

"(9) Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan, including—

"(A) the amounts so paid for each therapeutic class of drugs; and

"(B) the amounts so paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan from drug manufacturers during the plan year.

''(10) Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in paragraph (9).

''(b) REPORT.—Not later than 18 months after the date on which the first report is required under subsection (a) and biannually thereafter, the Secretary, acting through the Assistant Secretary of Planning and Evaluation and in coordination with the Inspector General of the Department of Health and Human Services, shall make available on the internet website of the Department of Health and Human Services a report on prescription drug reimbursements under group health plans, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans, aggregated in such a way as no drug or plan specific information will be made public.

''(c) PRIVACY PROTECTIONS.—No confidential or trade secret information submitted to the Secretary under subsection (a) shall be included in the report under subsection (b).''.

SEC. 333. GOVERNMENT ACCOUNTABILITY OFFICE STUDY ON PROFIT- AND REVENUE-SHARING IN HEALTH CARE.

(a) STUDY.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to—

(1) describe what is known about profit- and revenue-sharing relationships in the commercial health care markets, including those relationships that—

(A) involve one or more—

(i) physician groups that practice within a hospital included in the profit- or revenue-sharing relationship, or refer patients to such hospital;

(ii) laboratory, radiology, or pharmacy services that are delivered to privately insured patients of such hospital;

(iii) surgical services;

(iv) hospitals or group purchasing organizations; or

(v) rehabilitation or physical therapy facilities or services; and

(B) include revenue- or profit-sharing whether through a joint venture, management

or professional services agreement, or other form of gain-sharing contract;

(2) describe Federal oversight of such relationships, including authorities of the Department of Health and Human Services and the Federal Trade Commission to review such relationships and their potential to increase costs for patients, and identify limitations in such oversight; and

(3) as appropriate, make recommendations to improve Federal oversight of such relationships.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit a report on the study conducted under subsection (a) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Education and Labor and Committee on Energy and Commerce of the House of Representatives.

Subtitle C—Prescription Drug Competition and Innovation

SEC. 341. 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. 342. PREVENTING BLOCKING OF GENERIC DRUGS.

(a) IN GENERAL.—Section 505(j)(5)(B)(iv)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)(I)) is amended—

(1) by striking ''180 days after the date'' and inserting ''180 days after the earlier of the following:

''(aa) The date''; and

(2) by adding at the end the following:

''(bb) The date on which all of the following conditions are first met, provided no application submitted by any first applicant is approved on or before such date:

''(AA) An application for the drug submitted by an applicant other than a first applicant has received tentative approval and could receive approval, if no first applicant were eligible for 180-day exclusivity under this clause, and such applicant has not entered into an agreement that would prevent commercial marketing upon approval and has submitted a notification to the Secretary documenting that it has not entered into an agreement that would prevent commercial marketing.

''(BB) Thirty-three months have passed since the date of submission of an application for the drug by one first applicant, if there is only one first applicant, or, in the case of more than one first applicant, 33 months have passed since the date of submission of all such applications.

''(CC) Approval of an application for the drug submitted by at least one

first applicant would not be precluded under clause (iii).''.

(b) INFORMATION.—Not later than 60 days of the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall publish, as appropriate and available, information sufficient to allow applicants to assess whether the conditions described in subitems (AA) through (CC) of section 505(j)(5)(B)(iv)(I)(bb) of the Federal Food, Drug, and Cosmetic Act (as amended by subsection (a)) have been or will be satisfied for all applications where the exclusivity period under (iv)(I) of section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (as so amended) has not expired, and shall provide updates to reflect the most recent information available to the Secretary.

SEC. 343. ENSURING TIMELY ACCESS TO GENERICS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)(i), by inserting '', 10.31,'' after ''10.30'';

(B) in subparagraph (E)—

(i) by striking ''application and'' and inserting ''application or'';

(ii) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary''; and

(iii) by striking the second sentence and inserting the following:

''(ii) PRIMARY PURPOSE OF DELAYING.—

''(I) IN GENERAL.—In determining whether a petition was submitted with the primary purpose of delaying an application, the Secretary may consider the following factors:

''(aa) Whether the petition was submitted in accordance with paragraph (2)(B), based on when the petitioner knew or reasonably should have known the relevant information relied upon to form the basis of such petition.

''(bb) Whether the petitioner has submitted multiple or serial petitions or supplements to petitions raising issues that reasonably could have been known to

the petitioner at the time of submission of the earlier petition or petitions.

''(cc) Whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act could be approved.

''(dd) Whether the petition was submitted without relevant data or information in support of the scientific positions forming the basis of such petition.

''(ee) Whether the petition raises the same or substantially similar issues as a prior petition to which the Secretary has responded substantively already, including if the subsequent submission follows such response from the Secretary closely in time.

"(ff) Whether the petition requests changing the applicable standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner's version of the same drug.

"(gg) The petitioner's record of submitting petitions to the Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.

"(hh) Other relevant and appropriate factors, which the Secretary shall describe in guidance.

"(II) GUIDANCE.—The Secretary may issue or update guidance, as ap-

propriate, to describe factors the Secretary considers in accordance with subclause (II).'';

(C) by adding at the end the following:

''(iii) REFERRAL TO THE FEDERAL TRADE COMMISSION.—The Secretary shall establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. Such procedures shall include notification to the petitioner by the Secretary.'';

(D) by striking subparagraph (F);

(E) by redesignating subparagraphs (G) through (I) as subparagraphs (F) through (H), respectively; and

(F) in subparagraph (H), as so redesignated, by striking ''submission of this petition'' and inserting ''submission of this document'';

(2) in paragraph (2)—

(A) by redesignating subparagraphs (A) through (C) as subparagraphs (C) through (E), respectively;

(B) by inserting before subparagraph (C), as so redesignated, the following:

''(A) IN GENERAL.—A person shall submit a petition to the Secretary under paragraph (1) before filing a civil action in which the person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act. Such petition and any supplement to such a petition shall describe all information and arguments that form the basis of the relief requested in any civil action described in the previous sentence.

''(B) TIMELY SUBMISSION OF CITIZEN PETITION.—A petition and any supplement to a petition shall be submitted within 60 days after the person knew, or reasonably should have known, the information that forms the basis of the request made in the petition or supplement.'';

(C) in subparagraph (C), as so redesignated—

(i) in the heading, by striking ''WITHIN 150 DAYS'';

(ii) in clause (i), by striking ''during the 150-day period referred to in paragraph (1)(F),''; and

(iii) by amending clause (ii) to read as follows:

''(ii) on or after the date that is 151 days after the date of submission of the petition, the Secretary approves or has approved the application that is the subject of the petition without having made such a final decision.'';

(D) by amending subparagraph (D), as so redesignated, to read as follows:

''(D) DISMISSAL OF CERTAIN CIVIL ACTIONS.—

''(i) PETITION.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (A), the court shall

dismiss without prejudice the action for failure to exhaust administrative remedies.

''(ii) TIMELINESS.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (B), the court shall dismiss with prejudice the action for failure to timely file a petition.

''(iii) FINAL RESPONSE.—If a civil action is filed against the Secretary with respect to any issue raised in a petition timely filed under paragraph (1) in which the petitioner requests that the Secretary take any form of action that could, if taken, set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act before the Secretary has taken final agency action on

the petition within the meaning of subparagraph (C), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.''; and

(E) in clause (iii) of subparagraph (E), as so redesignated, by striking ''as defined under subparagraph (2)(A)'' and inserting ''within the meaning of subparagraph (C)''; and

(3) in paragraph (4)—

(A) by striking ''EXCEPTIONS'' and all that follows through ''This subsection does'' and inserting ''EXCEPTIONS.—This subsection does'';

(B) by striking subparagraph (B); and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly.

SEC. 344. 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.

SEC. 345. 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. 346. PROVISIONAL APPROVAL OF NEW HUMAN DRUGS.

(a) IN GENERAL.—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 of the following:

''SEC. 524B. PROVISIONAL APPROVAL OF NEW HUMAN DRUGS.

''(a) PRIORITY REVIEW AND EVALUATION OF APPLICATIONS.—

''(1) IN GENERAL.—The Secretary shall establish a priority review system to evaluate applications submitted under this pathway for provisional approval within 90 days of receipt of a completed application.

''(2) REVIEW OF APPLICATIONS DURING EPIDEMICS AND PANDEMICS.—In the case of an epidemic or pandemic, including with respect to

COVID–19, the Secretary shall accept and review various portions of an application submitted under the pathway under this section for provisional approval on a rolling basis, and the review of any part of an application so submitted shall be completed not later than 3 weeks after submission.

''(3) OTHER DESIGNATIONS.—If a drug submitted for review under the pathway under this section is eligible for a special designation by the Secretary under this Act, including as a drug for a rare disease or condition under section 526, all benefits of such other designation shall be available for use under provisional approval, including any tax credits and waiving of fees under chapter VII.

''(b) ELIGIBILITY.—A drug may be eligible for provisional approval under this section if the Secretary determines that the drug is intended for the treatment, prevention, or medical diagnosis of—

''(1) a serious or life-threatening disease or condition for which there is a reasonable likelihood that premature death will occur without early medical intervention for an individual contracting or being diagnosed with such disease or condition;

''(2) a disease or condition that poses a threat of epidemic or pandemic; or

''(3) a disease or condition associated with morbidity that has a substantial impact on day-to-day functioning.

''(c) STANDARD OF REVIEW FOR APPROVAL.—

''(1) REQUIREMENTS.—An application for provisional approval under this section may be approved only if the Secretary determines that—

''(A) there is substantial evidence of safety for the drug, such that there is evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety of the drug involved, on the basis of which it could fairly and responsibly be concluded that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling; and

''(B) there is relevant early evidence based on adequate and well-controlled investigations, including early-stage clinical investigations, to establish that—

''(i) the drug provides a positive therapeutic outcome; and

"(ii) the outcome of the drug is consistent with or greater than currently marketed on-label therapies, with equal or fewer side effects, if there are currently marketed on-label therapies.

"(2) PROTOCOLS.—The Secretary shall promulgate rules that establish the appropriate protocols for a sponsor of an application for provisional approval under this section and the Commissioner to follow to enable rolling, real-time, mid-trial submission while preserving the integrity of the ongoing trial and without penalizing the sponsor for making use of this pathway.

"(3) REAL WORLD EVIDENCE.—The Secretary shall allow the use of real world evidence (as defined in section 505F(b)), including real world data used to generate real world evidence, to support an application for provisional approval under this section, and to fulfill the follow-up requirements and support applications for full approval as described under section 505 or section 351 of the Public Health Service Act, as applicable.

"(4) USE OF SCIENTIFICALLY SUBSTANTIATED SURROGATES.—

''(A) IN GENERAL.—The sponsor of an application for provisional approval under this section may use scientifically substantiated surrogates to support such application.

''(B) DEFINITION.—In subparagraph (A), the term 'scientifically substantiated surrogates' means surrogate endpoints to predict clinical benefit other than such endpoints previously validated by the Secretary, based on—

''(i) epidemiologic, therapeutic, pathophysiologic, or other evidence; or

''(ii) an effect on a clinical endpoint other than survival or irreversible morbidity of interest.

''(d) TRANSPARENCY AND PATIENT MONITORING REQUIREMENTS.—

''(1) REGISTRIES.—

''(A) IN GENERAL.—The sponsor of a drug provisionally approved under this section shall require that all patients who use such drug participate in an observational registry and consent to the sponsor's collection, and submission to the registry, of data related to the patient's use of such drug until such drug receives full approval under section 505 or section 351 of the

Public Health Service Act, or the provisional approval is rescinded.

''(B) REQUIREMENTS FOR REGISTRIES.—An observational registry described in subparagraph (A) may be run by a third party, such as a government, for profit, or non-profit organization, and shall track all patients who use the provisionally approved drug.

''(C) ACCESSIBILITY.—An observational registry described in subparagraph (A) shall be easily accessible for—

''(i) all patients who are participating in any registry related to a provisionally approved drug that allows for easy, unrestricted (or transparent) access for such patients to their patient data and related information regarding their usage of the provisionally approved drug; and

''(ii) approved researchers and medical professionals who may access data maintained in the registry, which access shall be for public health research and only in a de-identified, aggregated manner.

''(2) FUNDING.—An observational registry under this subsection shall be maintained, as applicable—

''(A) by the sponsor of the drug provisionally approved under this section that is the subject of the registry;

''(B) by a third party, such as a government, for profit, or nonprofit organization; or

''(C) the Federal Government, in the case of any drug so approved that is intended to treat a disease or condition associated with an epidemic or pandemic.

''(3) SPONSOR REQUIREMENTS.—

''(A) IN GENERAL.—For any drug application provisionally approved under this section, the Secretary shall notify the sponsor of the exact data such sponsor is required to submit to an observational registry.

''(B) ANNUAL REVIEW OF THE REGISTRY; PENALTIES.—The Secretary shall conduct an annual review of observational registries established under this subsection. If, at such an annual review, less than 90 percent of patients are participating in an observational registry with respect to a drug approved under this section,

the Secretary shall issue to the sponsor of such drug a civil monetary penalty of not more than $100,000. If a violation of this section is not corrected within the 30-day period following notification, the sponsor shall, in addition to any penalty under this subparagraph be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected. If application patient participation in an observational registry is not at or above 90 percent within 6 months of issuance of such penalty, the provisional approval shall be withdrawn.

''(4) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit an annual report to Congress on all drugs granted provisional approval under this section. Such report shall include—

''(A) the number of patients treated with each such drug, and the number of patients tracked in an observational registry with respect to each such drug;

''(B) a discussion of the minimum amount of data required in the registries, including patient treatments and uses, length of use, side effects encountered, relevant biomarkers or sci-

entifically substantiated surrogates, scan results, cause of death and how long the patient lived, and adverse drug effects;

"(C) a list of all such drugs for which an application for full approval under section 505 of this Act or section 351 of the Public Health Service Act, or an application for an extension of provisional approval under this section, has been submitted; and

"(D) a list of all applications denied provisional approval under this section, together with an explanation for the decisions to deny each such application.

"(e) WITHDRAWAL OF PROVISIONAL APPROVAL.—

"(1) IN GENERAL.—The Secretary shall withdraw provisional approval under this section if there are a significant number of patients who experience serious adverse effects, compared to the other currently marketed on-label therapies that are available for the applicable disease or condition.

"(2) EFFECT OF WITHDRAWAL.—If a provisional approval is withdrawn under this subsection, the sponsor may not make the drug available to any new patients, but may be allowed to continue to make such drug available to patients who started

taking the drug prior to the date of withdrawal, for as long a period as dictated by patient need, as determined by the Secretary.

''(f) TRANSPARENCY.—Any scientific, medical, academic, or health care journal publishing an article explaining, releasing, conveying or announcing research findings which were funded by the Department of Health and Human Services shall be prohibited from publishing such research unless—

''(1) such article conveying research findings is made publicly available on the journal's internet website without a paywall or charge not later than 3 months after the date on which such article was first provided to subscribers of such journal (or first made available for purchase); and

''(2) the article's author or researcher or author's institution (or, in the case of multiple authors, researchers, or institutions, all such authors, researchers, or institutions) received less than 30 percent of funding for such research from the Department of Health and Human Services throughout the period of time the research was conducted.

''(g) INFORMED CONSENT.—Prior to receiving a drug provisionally approved under this section, the sponsor of the drug shall receive from each patient, or the patient's

representative, informed consent, through a signed informed consent form, acknowledging that such patient understands that the drug did not undergo the usual process for full approval of a drug by the Food and Drug Administration, and that such patient is willing to accept the risks involved in taking such drug.

''(h) POSTMARKET CONTROLS AND LABELING.—

''(1) FDA ANNUAL REVIEW OF REGISTRY DATA.—The Secretary shall annually review the data made available through the observational registries under subsection (d) and make a determination regarding whether the side effect profile of any drug approved under this pathway does not support the benefit provided, or the data shows the benefit is less than the benefits offered through other, fully approved drugs.

''(2) LABELING.—The sponsor of the provisionally approved drug shall ensure that all labeling and promotional materials for the drug bear the statement 'provisionally approved by the FDA pending a full demonstration of effectiveness under application number _____' (specifying the application number assigned by the Secretary in place of the blank). All promotional, educational and marketing materials for provisionally approved products shall

be reviewed and approved by the Secretary before such materials are distributed.

''(3) RESCISSION OF PROVISIONAL APPROVAL.—If the Secretary determines that the side effect profile of any drug included in such observational registries does not support the benefit provided by such drug, or that the data shows that the benefit is less than the benefits offered through other, fully approved drugs, the Secretary shall rescind such provisional approval.

''(i) DURATION OF PROVISIONAL APPROVAL; REQUIREMENT TO BRING DRUG TO MARKET.—

''(1) DURATION; RENEWALS.—The period of provisional approval for a drug approved under this section is effective for a 2-year period. The sponsor may request renewal for provisional approval status for up to 3 subsequent 2-year periods by the Secretary. Provisional approval status with respect to a drug shall not exceed a total of 6 years from the initial date the sponsor was awarded provisional approval status.

''(2) MARKETING REQUIREMENT.—If any drug that receives provisional approval status under this section is not brought to market within 180 days of the approval, such approval shall be rescinded.

''(j) LIMITATION ON LIABILITY.—With respect to any claim under State law alleging that a drug sold or otherwise made available pursuant to a grant of provisional approval under this section is unsafe or ineffective, no liability in a cause of action shall lie against a sponsor or manufacturer, unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

''(k) APPLYING FOR FULL APPROVAL.—

''(1) IN GENERAL.—Except as provided under paragraph (2), the sponsor of a drug granted provisional approval pursuant to this section may, at any point, submit an application for full approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act, as applicable.

''(2) EFFECT OF RECESSION ON APPROVAL AND AUTOMATIC APPROVAL.—

''(A) IN GENERAL.—The sponsor of a drug granted provisional approval pursuant to this section that has been rescinded under subsection (h)(3), may submit an application for full approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act at any time.

''(B) AUTOMATIC APPROVAL.—Such full approval may be awarded at any time for any drug granted provisional approval pursuant to this section if the sponsor of the drug establishes a 15 percent improvement in an important endpoint, including surrogate endpoints not validated by the Food and Drug Administration, compared to a standard drug.

''(3) REAL-TIME EPIDEMIC AND PANDEMIC VACCINE APPROVAL.—

''(A) IN GENERAL.—In the case of a vaccine developed in response to an epidemic or pandemic, including COVID–19, the Secretary shall share data information regarding the approval of the vaccine with the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention as the review nears completion.

''(B) EVALUATION.—Any vaccine that has been approved by the Secretary for an epidemic or pandemic-related disease, including COVID–19, shall be evaluated by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention not later than 1 week after the date of submission

to the Advisory Committee by the Secretary of the vaccine.

''(l) PATIENT ADVOCATE GENERAL.—Not later than 6 months after the date of enactment of the Promising Pathway Act, the Secretary shall establish within the Office of the Commissioner, the position of Patient Advocate General, who shall provide assistance to patients and their families who use drugs under evaluation in this pathway or drugs reviewed or approved under section 505 or section 351 of the Public Health Service Act. Such assistance shall include providing bi-informational communication about maintaining patient health, delivery of proper informed consent, participating in clinical investigations, completing required documentation in order to participate in the applicable programs, and providing other information.''.

(b) CONFORMING AMENDMENT.—Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)) is amended by inserting '', or there is in effect a provisional approval under section 524B with respect to such drug'' before the period.

(c) REIMBURSEMENT.—

(1) PRIVATE HEALTH INSURERS.—Section 2719A of the Public Health Service Act (42 U.S.C.

300gg–19a) is amended by adding at the end the following:

''(e) TREATMENT OF CERTAIN DRUGS.—A group health plan or health insurance issuer of group or individual health insurance coverage shall not deny coverage of any drug provisionally approved under section 524B of the Federal Food, Drug, and Cosmetic Act on the basis of such drug being experimental. In determining coverage under the applicable plan or coverage, a group health plan or health insurance issuer shall treat a drug provisionally approved under such section in the same manner as such plan or coverage would treat a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of this Act. Nothing in this subsection shall be construed to require a group health plan or health insurance issuer to cover any specific drug provisionally approved under such section 524B.''.

(2) FEDERAL HEALTH CARE PROGRAMS.—The requirement under subsection (e) of section 2719A of the Public Health Service Act (as added by paragraph (1)) shall apply with respect to coverage determinations under a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))) in the same man-

ner such requirement applies under such subsection (e).

(3) CONFORMING AMENDMENT.—Section 1927(k)(2)(A)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)(A)(i)) is amended—

(A) by striking ''or which'' and inserting '', which''; and

(B) by inserting '', or which is provisionally approved under section 524B of such Act'' before the semicolon.

SEC. 347. CONSOLIDATING 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. 348. EXCLUSIVITY PERIOD FOR BRAND NAME BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351(k)(7)(A) of the Public Health Service Act (42 U.S.C. 262(k)(7)(A)) is amended by striking ''12 years'' and inserting ''5 years''.

(b) CONFORMING CHANGES.—Paragraphs (2)(A) and (3)(A) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) is amended by striking ''12 years'' each place it appears and inserting ''5 years''.

(c) APPLICABILITY.—This Act and the amendments made by this Act apply only with respect to a biological product for which the reference product (as such term is used in section 351 of the Public Health Service Act (42 U.S.C. 262)) is licensed under subsection (a) of such section on or after the date of enactment of this Act.

SEC. 349. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

''(D) DEEMED LICENSES.—

''(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

''(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

''(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food,

Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.''.

SEC. 350. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended by adding at the end the following: ''With respect to an application for a biological product submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) with a filing date that is not later than September 23, 2019, and that does not receive final approval on or before March 23, 2020, such application shall be deemed to be withdrawn and the Secretary shall refund the fee paid under section 736(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(1)(B)). Notwithstanding any such withdrawal of the drug application, the Secretary shall consider any previously conducted scientific review and accelerate review of any such subsequent application with respect to such

biological product under section 351 of the Public Health Service Act (42 U.S.C. 262). The Secretary shall provide additional assistance to the sponsor or manufacturer of such application.''.

SEC. 351. REGULATION OF MANUFACTURER-SPONSORED COPAY CONTRIBUTIONS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may establish a mechanism to regulate drug manufacturers' financial contributions to patient out-of-pocket costs, such as drug copays.

SEC. 352. ANTITRUST EXEMPTION FOR PRIVATE HEALTH INSURER ISSUERS TO NEGOTIATE WHOLESALE ACQUISITION PRICES OF PRESCRIPTION DRUGS PURCHASED FROM DRUG MANUFACTURERS.

(a) EXEMPTION.—It shall not be a violation of the antitrust laws for one or more private health insurer issuers or their designated agents to jointly negotiate wholesale acquisition prices of a prescription drug with a manufacturer of a prescription drug with regards to the reimbursement policies of the insurers of the manufacturer's drugs so long as no one single wholesale acquisition price is jointly determined between the insurance issuers or their designated agents.

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

(1) ANTITRUST LAWS.—The term ''antitrust laws'' has the meaning given it in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition.

(2) HEALTH INSURANCE ISSUER.—The term ''health insurance issuer'' means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in subparagraph (C)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(2))). Such term does not include a group health plan.

(3) HEALTH MAINTENANCE ORGANIZATION.—The term ''health maintenance organization'' means—

(A) a Federally qualified health maintenance organization (as defined in section 300e(a) of title 42 of the United States Code),

(B) an organization recognized under State law as a health maintenance organization, or

(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(4) MANUFACTURER.—The term ''manufacturer'' means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(5) PRESCRIPTION DRUG.—The term ''prescription drug'' means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

(c) EFFECTIVE DATE.—This section shall take effect on the date of the enactment of this Act but shall not apply with respect to conduct that occurs before such date.

SEC. 353. BIOLOGICAL PRODUCT INNOVATION.

Section 351(j) of the Public Health Service Act (42 U.S.C. 262(j)) is amended—

(1) by striking ''except that a product'' and inserting ''except that—

''(1) a product'';

(2) by striking ''Act.'' and inserting ''Act; and''; and

(3) by adding at the end the following:

''(2) no requirement under such Act regarding an official compendium (as defined in section 201(j) of such Act), or other reference in such Act to an official compendium (as so defined), shall apply with respect to a biological product subject to regulation under this section.''.

SEC. 354. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears

and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)—

(i) by amending clause (i) to read as follows:

''(i) not later than 30 days after the date of approval of such applications—

''(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and''; and

(ii) in clause (ii), by inserting ''or biological product'' before the period;

(D) by amending subsection (s) to read as follows:

''(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

''(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

''(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

''(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)), by amending subparagraph (C) to read as follows:

''(C) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of

which has been approved in any other application under section 505(b)(1); or

''(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.'';

(4) in section 529(a)(4) (21 U.S.C. 360ff(a)(4)), by striking subparagraphs (A) and (B) and inserting the following:

''(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

''(B)(i) is for such a drug—

''(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

''(II) that is the subject of an application submitted under section 505(b)(1); or

''(ii) or is for such a biological product—

''(I) that contains no active ingredient that has been previously approved in any

other application under section 351(a) or 351(k) of the Public Health Service Act; and

"(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;"; and

(5) in section 565A(a)(4) (21 U.S.C. 360bbb–4a(a)(4)), by amending subparagraph (D) to read as follows:

"(D) is for—

"(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

"(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.".

(b) TECHNICAL CORRECTIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by repealing clause (i); and

(B) in subsection (j)(5)(F), by repealing clause (i); and

(2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C. 355a(c)(1)(A)(i)), by striking ''(c)(3)(D)'' and inserting ''(c)(3)(E)''.

SEC. 355. PROMPT APPROVAL OF DRUGS RELATED TO SAFETY INFORMATION.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

''(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY INFORMATION IS ADDED TO LABELING.—

''(1) GENERAL RULE.—A drug for which an application has been submitted or approved under subsection (b)(2) or (j) shall not be considered ineligible for approval under this section or misbranded under section 502 on the basis that the labeling of the drug omits safety information, including contraindications, warnings, precautions, dosing, administration, or other information pertaining to safety, when the omitted safety information is protected by exclusivity under clause (iii) or (iv) of subsection (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),

or section 527(a), or by an extension of such exclusivity under section 505A or 505E.

''(2) LABELING.—Notwithstanding clauses (iii) and (iv) of subsection (j)(5)(F), clauses (iii) and (iv) of subsection (c)(3)(E), or section 527, the Secretary shall require that the labeling of a drug approved pursuant to an application submitted under subsection (b)(2) or (j) that omits safety information described in paragraph (1) include a statement of any appropriate safety information that the Secretary considers necessary to assure safe use.

''(3) AVAILABILITY AND SCOPE OF EXCLUSIVITY.—This subsection does not affect—

''(A) the availability or scope of exclusivity or an extension of exclusivity described in subparagraph (A) or (B) of section 505A(o)(3);

''(B) the question of the eligibility for approval under this section of any application described in subsection (b)(2) or (j) that omits any other aspect of labeling protected by exclusivity under—

''(i) clause (iii) or (iv) of subsection (j)(5)(F);

''(ii) clause (iii) or (iv) of subsection (c)(3)(E); or

''(iii) section 527(a); or

''(C) except as expressly provided in paragraphs (1) and (2), the operation of this section or section 527.''.

SEC. 356. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

Section 351(k)(2)(A)(iii) of the Public Health Service Act (42 U.S.C. 262(k)(2)(A)(iii)) is amended—

(1) in subclause (I), by striking ''; and'' and inserting a semicolon;

(2) in subclause (II), by striking the period and inserting ''; and''; and

(3) by adding at the end the following:

''(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.''.

SEC. 357. EDUCATION ON BIOLOGICAL PRODUCTS.

Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products,

including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

''(3) FORMAT.—The educational materials provided under paragraph (1) may be—

''(A) in formats such as webinars, continuing medical education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

''(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish the following information:

''(A) The action package of each biological product licensed under subsection (a) or (k).

''(B) The summary review of each biological product licensed under subsection (a) or (k).

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing medical education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

SEC. 358. 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 II (of chapter 5) 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. 359. 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 D—Prescription Drug and Pharmacy Benefit Manager Transparency

SEC. 361. PATENT DISCLOSURE REQUIREMENTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

"(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO PATENTS.—

"(1) APPROVED APPLICATION HOLDER LISTING REQUIREMENTS.—

"(A) IN GENERAL.—Beginning on the date of enactment of this subsection, within 30 days of approval of an application under subsection (a) or (k), the holder of such approved application shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(B) PREVIOUSLY APPROVED OR LICENSED BIOLOGICAL PRODUCTS.—

"(i) PRODUCTS APPROVED UNDER SECTION 351 OF THE PHSA.—Not later than 30 days after the date of enactment of the Fair Care Act of 2020, the holder of a biological product license that was approved under subsection (a) or (k) before the date of enactment of such Act shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(ii) PRODUCTS APPROVED UNDER SECTION 505 OF THE FFDCA.—Not later

than 30 days after March 23, 2021, the holder of an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act that is deemed to be a license for the biological product under this section on March 23, 2021, shall submit a list of each patent required to be disclosed (as described in paragraph (3)).

''(C) UPDATES.—The holder of a biological product license approved under subsection (a) or (k) shall submit to the Secretary a list that includes—

''(i) any patent first required to be disclosed (as described in paragraph (3)) after the submission under subparagraph (A) or (B), as applicable, within 30 days of the earlier of—

''(I) the date of issuance of such patent by the United States Patent and Trademark Office; or

''(II) the date of approval of a supplemental application for the biological product; and

"(ii) any patent, or any claim with respect to a patent, included on the list pursuant to this paragraph with respect to the biological product subsequently determined to be invalid or unenforceable, within 30 days of a determination of patent invalidity.

"(2) PUBLICATION OF INFORMATION.—

"(A) IN GENERAL.—Within 1 year of the date of enactment of the Fair Care Act of 2020, the Secretary shall publish and make available to the public a single, easily searchable, list that includes—

"(i) the official and proprietary name of each biological product licensed under subsection (a) or (k), and of each biological product application approved under section 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for the biological product under this section on March 23, 2021;

"(ii) with respect to each biological product described in clause (i), each patent submitted in accordance with paragraph (1);

''(iii) the date of licensure and application number for each such biological product;

''(iv) the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product;

''(v) the licensure status for each such biological product, including whether the license at the time of listing is approved, withdrawn, or revoked;

''(vi) any period of any exclusivity under subsection (k)(7)(A) or subsection (k)(7)(B) of this section or section 527 of the Federal Food, Drug, and Cosmetic Act, and any extension of such period in accordance with subsection (m) of this section with respect to each such biological product, and the date on which such exclusivity expires;

''(vii) information regarding any determination related to biosimilarity or interchangeability for each such biological product; and

"(viii) information regarding approved indications for each such biological product, in such manner as the Secretary determines appropriate.

"(B) UPDATES.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include—

"(i)(I) each biological product licensed under subsection (a) or (k) during the 30-day period; and

"(II) with respect to each biological product described in subclause (I), the information described in clauses (i) through (viii) of subparagraph (A); and

"(ii) any updates to information previously published in accordance with subparagraph (A).

"(3) PATENTS REQUIRED TO BE DISCLOSED.—In this section, a 'patent required to be disclosed' is any patent for which the holder of a biological product license approved under subsection (a) or (k), or a biological product application approved under section 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for a biological prod-

uct under this section on March 23, 2021, believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder with respect to the biological product that is the subject of such license, if a person not licensed by the holder engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of such license.''.

(b) DISCLOSURE OF PATENTS.—Section 351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)(i)) is amended by inserting ''included in the list provided by the reference product sponsor under subsection (o)(1)'' after ''a list of patents''.

(c) RESTRICTION ON CLAIMS OF PATENT INFRINGEMENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

''(7) The owner of a patent that should have been included in the list described in section 351(o)(1) of the Public Health Service Act (42 U.S.C. 262(o)(1)), including any updates required under subparagraph (C) of that section, but was not timely included in such list, may not bring an action under this section for infringement of the patent.''.

(d) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to carry out subsection (o) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a).

(e) RULE OF CONSTRUCTION.—Nothing in this Act, including an amendment made by this Act, shall be construed to require or allow the Secretary of Health and Human Services to delay the licensing of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 362. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO PATENTS.—

''(1) APPROVED APPLICATION HOLDER LISTING REQUIREMENTS.—

''(A) IN GENERAL.—Beginning on the date of enactment of the Fair Care Act of 2020, within 60 days of approval of an application under subsection (a) or (k), the holder of such approved application shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(B) PREVIOUSLY APPROVED OR LICENSED BIOLOGICAL PRODUCTS.—

"(i) PRODUCTS LICENSED UNDER SECTION 351 OF THE PHSA.—Not later than 30 days after the date of enactment of the Fair Care Act of 2020, the holder of a biological product license that was approved under subsection (a) or (k) before the date of enactment of such Act shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(ii) PRODUCTS APPROVED UNDER SECTION 505 OF THE FFDCA.—Not later than 30 days after March 23, 2020, the holder of an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act that is deemed to be a license for the biological product under this section on March 23, 2020, shall submit to the Secretary a list of each patent required to be disclosed (as described in paragraph (3)).

"(C) UPDATES.—The holder of a biological product license that is the subject of an applica-

tion under subsection (a) or (k) shall submit to the Secretary a list that includes—

"(i) any patent not previously required to be disclosed (as described in paragraph (3)) under subparagraph (A) or (B), as applicable, within 30 days of the earlier of—

"(I) the date of issuance of such patent by the United States Patent and Trademark Office; or

"(II) the date of approval of a supplemental application for the biological product; and

"(ii) any patent, or any claim with respect to a patent, included on the list pursuant to this paragraph, that the Patent Trial and Appeal Board of the United States Patent and Trademark Office determines in a written decision to cancel as unpatentable, within 30 days of such decision.

"(2) PUBLICATION OF INFORMATION.—

"(A) IN GENERAL.—Within 1 year of the date of enactment of the Fair Care Act of 2020, the Secretary shall publish and make

available to the public a single, easily searchable list that includes—

"(i) the official and proprietary name of each biological product licensed, or deemed to be licensed, under subsection (a) or (k);

"(ii) with respect to each biological product described in clause (i), each patent submitted in accordance with paragraph (1);

"(iii) the date of licensure and application number for each such biological product;

"(iv) the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product;

"(v) the licensure status for each such biological product, including whether the license at the time of listing is approved, withdrawn, or revoked;

"(vi) with respect to each such biological product, any period of exclusivity under paragraph (6), (7)(A), or (7)(B) of subsection (k) of this section or section

527 of the Federal Food, Drug, and Cosmetic Act, and any extension of such period in accordance with subsection (m) of this section, for which the Secretary has determined such biological product to be eligible, and the date on which such exclusivity expires;

''(vii) any determination of biosimilarity or interchangeability for each such biological product; and

''(viii) information regarding approved indications for each such biological product, in such manner as the Secretary determines appropriate.

''(B) UPDATES.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include—

''(i)(I) each biological product licensed under subsection (a) or (k) during the 30-day period; and

''(II) with respect to each biological product described in subclause (I), the information described in clauses (i) through (viii) of subparagraph (A); and

"(ii) any updates to information previously published in accordance with subparagraph (A).

"(C) NONCOMPLIANCE.—Beginning 18 months after the date of enactment of the Fair Care Act of 2020, the Secretary, in consultation with the Director of the United States Patent and Trademark Office, shall publish and make available to the public a list of any holders of biological product licenses, and the corresponding biological product or products, that failed to submit information as required under paragraph (1), including any updates required under paragraph (1)(C), in such manner and format as the Secretary determines appropriate. If information required under paragraph (1) is submitted following publication of such list, the Secretary shall remove such holders of such biological product licenses from the public list in a reasonable period of time.

"(3) PATENTS REQUIRED TO BE DISCLOSED.—In this section, a 'patent required to be disclosed' is any patent for which the holder of a biological product license approved under subsection (a) or (k), or a biological product application approved under sec-

tion 505 of the Federal Food, Drug, and Cosmetic Act and deemed to be a license for a biological product under this section on March 23, 2020, believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner that has granted an exclusive license to the holder with respect to the biological product that is the subject of such license, if a person not licensed by the owner engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of such license.''.

(b) DISCLOSURE OF PATENTS.—Section 351(l)(3)(A)(i) of the Public Health Service Act (42 U.S.C. 262(l)(3)(A)(i)) is amended by inserting ''included in the list provided by the reference product sponsor under subsection (o)(1)'' after ''a list of patents''.

(c) REVIEW AND REPORT ON NONCOMPLIANCE.—Not later than 30 months after the date of enactment of this Act, the Secretary shall—

(1) solicit public comments regarding appropriate remedies, in addition to the publication of the list under subsection (o)(2)(C) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a), with respect to holders of biological product licenses who fail to timely submit infor-

mation as required under subsection (o)(1) of such section 351, including any updates required under subparagraph (C) of such subsection (o)(1); and

(2) submit to Congress an evaluation of comments received under paragraph (1) and the recommendations of the Secretary concerning appropriate remedies.

(d) REGULATIONS.—The Secretary of Health and Human Services may promulgate regulations to carry out subsection (o) of section 351 of the Public Health Service Act (42 U.S.C. 262), as added by subsection (a).

(e) RULE OF CONSTRUCTION.—Nothing in this Act, including an amendment made by this Act, shall be construed to require or allow the Secretary of Health and Human Services to delay the licensing of a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 363. ORANGE BOOK MODERNIZATION.

(a) SUBMISSION OF PATENT INFORMATION FOR BRAND NAME DRUGS.—

(1) IN GENERAL.—Paragraph (1) of section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended to read as follows:

''(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the pro-

visions of subsection (a). Such persons shall submit to the Secretary as part of the application—

"(i) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

"(ii) a full list of the articles used as components of such drug;

"(iii) a full statement of the composition of such drug;

"(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

"(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

"(vi) specimens of the labeling proposed to be used for such drug;

"(vii) any assessments required under section 505B; and

"(viii) the patent number and expiration date, of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug, and that—

''(I) claims the drug for which the applicant submitted the application and is a drug substance patent or a drug product patent; or

''(II) claims the method of using the drug for which approval is sought or has been granted in the application.

''(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) that claims such drug or a method of using such drug is issued after the filing date, the applicant shall amend the application to include such patent information.''.

(2) GUIDANCE.—The Secretary of Health and Human Services shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required under subsection (b)(1)(A)(i) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by paragraph (1).

(b) CONFORMING CHANGES TO REQUIREMENTS FOR SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—Section 505(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(2)) is amended—

(1) by inserting before the first sentence the following: ''Not later than 30 days after the date of approval of an application under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subclause (I) or (II) of subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. The holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subclause (I) or (II) of subsection (b)(1)(A)(viii) that is issued after the date of approval of the application, not later than 30 days after the date of issuance of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application.'';

(2) by inserting after ''the patent number and the expiration date of any patent which'' the following: ''fulfills the criteria in subsection (b) and'';

(3) by inserting after the third sentence (as amended by paragraph (1)) the following: ''Patent information that is not the type of patent informa-

tion required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.''; and

(4) by inserting after ''could not file patent information under subsection (b) because no patent'' the following: ''of the type required to be submitted in subsection (b)(1)(A)(viii)''.

(c) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

''(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired under—

''(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E) of this section;

''(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

''(III) clause (ii), (iii), or (iv) of paragraph (5)(F) of this subsection;

''(IV) section 505A;

''(V) section 505E;

''(VI) section 527(a); or

''(VII) subsection (u)''.

(d) ORANGE BOOK UPDATES WITH RESPECT TO INVALIDATED PATENTS.—

(1) IN GENERAL.—

(A) AMENDMENTS.—Section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)(A)), as amended by subsection (c), is further amended by adding at the end the following:

''(v) In the case of a listed drug for which the list under clause (i) includes a patent for such drug, and where the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office have cancelled any claim of the patent pursuant to a decision by the Patent Trial and Appeal Board in an inter partes review conducted under chapter 31 of title 35, United States Code, or a post-grant review conducted under chapter 32 of that title, and from which no appeal has been taken, or can be taken, the holder of the applicable approved application shall notify the Secretary, in writing, within 14 days of such cancellation, and, if the patent has been deemed wholly inoperative or invalid, or if a patent claim has been cancelled, the revisions required under clause (iii) shall include striking the patent or

information regarding such patent claim from the list with respect to such drug, as applicable, except that the Secretary shall not remove a patent from the list before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV) with respect to such patent.''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall not apply with respect to any determination with respect to a patent or patent claim that is made prior to the date of enactment of this Act.

(2) NO EFFECT ON FIRST APPLICANT EXCLUSIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I), as amended by the preceding sections, is amended by adding at the end the following: ''This subclause shall apply even if a patent is stricken from the list under paragraph (7)(A), pursuant to paragraph (7)(A)(v), provided that, at the time that the first applicant submitted an application under this subsection containing a certification described in paragraph (2)(A)(vii)(IV), the patent that was the subject of such certification was included in such list with respect to the listed drug.''.

SEC. 364. MODERNIZING THE LABELING OF CERTAIN GENERIC DRUGS.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503C the following:

"SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN DRUGS.

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

''(1) The term 'covered drug' means a drug approved under section 505(c)—

''(A) for which there are no unexpired patents included in the list under section 505(j)(7) and no unexpired period of exclusivity;

''(B) for which the approval of the application has been withdrawn for reasons other than safety or effectiveness; and

''(C) for which, with respect to the labeling—

''(i) new scientific evidence is available regarding the conditions of use of the drug;

''(ii) there is a relevant accepted use in clinical practice that is not reflected in the approved labeling; or

"(iii) the labeling of such drug does not reflect current legal and regulatory requirements.

"(2) The term 'period of exclusivity', with respect to a drug approved under section 505(c), means any period of exclusivity under clause (ii), (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii), or (iv) of section 505(j)(5)(F), or section 505A, 505E, or 527.

"(3) The term 'generic version' means a drug approved under section 505(j) whose reference drug is a covered drug.

"(4) The term 'relevant accepted use' means a use for a drug in clinical practice that is supported by scientific evidence that appears to the Secretary to meet the standards for approval under section 505.

"(5) The term 'selected drug' means a covered drug for which the Secretary has determined through the process under subsection (c) that the labeling should be changed.

"(b) IDENTIFICATION OF COVERED DRUGS.—The Secretary may identify covered drugs for which labeling updates would provide a public health benefit. To assist

in identifying covered drugs, the Secretary may do one or both of the following:

''(1) Enter into cooperative agreements or contracts with public or private entities to review the available scientific evidence concerning such drugs.

''(2) Seek public input concerning such drugs, including input on whether there is a relevant accepted use in clinical practice that is not reflected in the approved labeling of such drugs or whether new scientific evidence is available regarding the conditions of use for such drug, by—

''(A) holding one or more public meetings;

''(B) opening a public docket for the submission of public comments; or

''(C) other means, as the Secretary determines appropriate.

''(c) SELECTION OF DRUGS FOR UPDATING.—If the Secretary determines, with respect to a covered drug, that the available scientific evidence meets the standards under section 505 for adding or modifying information to the labeling or providing supplemental information to the labeling regarding the use of the covered drug, the Secretary may initiate the process under subsection (d).

''(d) INITIATION OF THE PROCESS OF UPDATING.—If the Secretary determines that labeling changes are ap-

propriate for a selected drug pursuant to subsection (c), the Secretary shall provide notice to the holders of approved applications for a generic version of such drug that—

''(1) summarizes the findings supporting the determination of the Secretary that the available scientific evidence meets the standards under section 505 for adding or modifying information or providing supplemental information to the labeling of the covered drug pursuant to subsection (c);

''(2) provides a clear statement regarding the additional, modified, or supplemental information for such labeling, according to the determination by the Secretary (including, as applicable, modifications to add the relevant accepted use to the labeling of the drug as an additional indication for the drug); and

''(3) states whether the statement under paragraph (2) applies to the selected drug as a class of covered drugs or only to a specific drug product.

''(e) RESPONSE TO NOTIFICATION.—Within 30 days of receipt of notification provided by the Secretary pursuant to subsection (d), the holder of an approved application for a generic version of the selected drug shall—

''(1) agree to change the approved labeling to reflect the additional, modified, or supplemental in-

formation the Secretary has determined to be appropriate; or

''(2) notify the Secretary that the holder of the approved application does not believe that the requested labeling changes are warranted and submit a statement detailing the reasons why such changes are not warranted.

''(f) REVIEW OF APPLICATION HOLDER'S RESPONSE.—

''(1) IN GENERAL.—Upon receipt of the application holder's response, the Secretary shall promptly review each statement received under subsection (e)(2) and determine which labeling changes pursuant to the Secretary's notice under subsection (d) are appropriate, if any. If the Secretary disagrees with the reasons why such labeling changes are not warranted, the Secretary shall provide opportunity for discussions with the application holders to reach agreement on whether the labeling for the covered drug should be updated to reflect current scientific evidence, and if so, the content of such labeling changes.

''(2) CHANGES TO LABELING.—After considering all responses from the holder of an approved application under paragraph (1) or (2) of subsection

(e), and any discussion under paragraph (1), the Secretary may order such holder to make the labeling changes the Secretary determines are appropriate. Such holder of an approved application shall—

"(A) update its paper labeling for the drug at the next printing of that labeling;

"(B) update any electronic labeling for the drug within 30 days; and

"(C) submit the revised labeling through the form, 'Supplement—Changes Being Effected'.

"(g) VIOLATION.—If the holder of an approved application for the generic version of the selected drug does not comply with the requirements of subsection (f)(2), such generic version of the selected drug shall be deemed to be misbranded under section 502.

"(h) LIMITATIONS; GENERIC DRUGS.—

"(1) IN GENERAL.—With respect to any labeling change required under this section, the generic version shall be deemed to have the same conditions of use and the same labeling as a reference drug for purposes of clauses (i) and (v) of section 505(j)(2)(A). Any labeling change so required shall not have any legal effect for the applicant that is

different than the legal effect that would have resulted if a supplemental application had been submitted and approved to conform the labeling of the generic version to a change in the labeling of the reference drug.

''(2) SUPPLEMENTAL APPLICATIONS.—Changes to labeling made in accordance with this paragraph shall not be eligible for an exclusivity period under this Act.

''(i) DRUG PRODUCT CLASSES.—In the case of a selected drug for which the labeling changes ordered by the Secretary under subsection (d)(2) are required for a class of covered drugs, such labeling changes shall be made for generic versions of such drug in that class.

''(j) RULES OF CONSTRUCTION.—

''(1) APPROVAL STANDARDS.—This section shall not be construed as altering the applicability of the standards for approval of an application under section 505. No order shall be issued under this subsection unless the evidence supporting the changed labeling meets the standards for approval applicable to any change to labeling under section 505.

''(2) REMOVAL OF INFORMATION.—Nothing in this section shall be construed to give the Secretary additional authority to remove approved indications

for drugs, other than the authority described in this section.

''(k) REPORTS.—Not later than 4 years after the date of the enactment of the Fair Care Act of 2020 and every 4 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that—

''(1) describes the actions of the Secretary under this section, including—

''(A) the number of covered drugs and description of the types of drugs the Secretary has selected for labeling changes and the rationale for such recommended changes; and

''(B) the number of times the Secretary entered into discussions concerning a disagreement with an application holder or holders and a summary of the decision regarding a labeling change, if any; and

''(2) includes any recommendations of the Secretary for modifying the program under this section.''.

SEC. 365. REQUIREMENTS WITH RESPECT TO PRESCRIPTION DRUG BENEFITS.

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

"SEC. 2729A. REQUIREMENTS WITH RESPECT TO PRESCRIPTION DRUG BENEFITS.

''A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not, and shall ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, receive from a drug manufacturer a reduction in price or other remuneration with respect to any prescription drug received by an enrollee in the plan or coverage and covered by the plan or coverage, unless—

''(1) any such reduction in price is reflected at the point of sale to the enrollee; and

''(2) any such other remuneration is a flat fee-based service fee that a manufacturer of prescription drugs pays to a pharmacy benefit manager for services rendered to the manufacturer that relate to arrangements by the pharmacy benefit manager to provide pharmacy benefit management services to a health plan or health insurance issuer, if certain

conditions established by the Secretary are met, including requirements that the fees are transparent to the health plan or health insurance issuer.''.

(b) EFFECTIVE DATE.—Section 2729A of the Public Health Service Act, as added by subsection (a), shall take effect on January 1, 2021.

SEC. 366. 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 respect 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 comparable 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, 2021.

(2) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD UNDER TRICARE RETAIL PHAR-

MACY 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 subsection (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 manufacturer 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. 367. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.), as amended by the preceding sections, is further amended by adding at the end the following:

''SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group health insurance coverage or an entity or subsidiary providing pharmacy benefits management services shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party

that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or coverage from making the reports described in subsection (b).

''(b) REPORTS TO GROUP PLAN SPONSORS.—

''(1) IN GENERAL.—Beginning with the first plan year that begins after the date of enactment of the Fair Care Act of 2020, not less frequently than once every 6 months, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan or health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by

the drug manufacturer with respect to the enrollees in such plan or coverage;

''(B) a list of each covered drug dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of enrollees for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by enrollees on such drug, including enrollee spending through copayments, coinsurance, and deductibles; and

"(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

"(I) a list of all other available drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class; and

"(II) the rationale for preferred formulary placement of a particular drug or drugs in that therapeutic category or class;

"(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

"(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of enrollees who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by enrollees, including enrollee spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) to be paid by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or 30-day supply incurred by the health plan or health insurance coverage and its enrollees, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates,

fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

''(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's or health insurance issuer's business to the pharmacy benefit manager.

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of

such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to governmental agencies pursuant to an investigation or enforcement action.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manu-

facturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(c) LIMITATIONS ON SPREAD PRICING.—

''(1) PRESCRIPTION DRUG TRANSACTIONS WITH PHARMACIES INDEPENDENT OF THE ISSUER OR PHARMACY BENEFITS MANAGER.—If the pharmacy that dispenses a prescription drug to an enrollee in a group health plan or group or individual health insurance coverage is not wholly or partially owned by such plan, such issuer, or an entity providing pharmacy benefit management services under such plan or coverage, such plan, issuer, or entity shall not charge the plan, issuer, or enrollee a price for such prescription drug that exceeds the price paid to the pharmacy.

''(2) INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—If the mail order, specialty, or retail pharmacy that dispenses a prescription drug to an enrollee in a group health plan or health insurance coverage is wholly or partially owned by, and submits claims to, such health insurance issuer or an entity providing pharmacy benefit management services under a group health plan or group or individual health insurance coverage, the price charged

for such drug by such pharmacy to such group health plan or health insurance issuer offering group or individual health insurance coverage may not exceed the lesser of—

"(A) the amount paid to the pharmacy for acquisition of the drug; or

"(B) the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other similarly situated pharmacies not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefits management services, as described in paragraph (1).

"(3) SUPPLEMENTARY REPORTING FOR INTRACOMPANY PRESCRIPTION DRUG TRANSACTIONS.—A health insurance issuer of group health insurance coverage or an entity providing pharmacy benefits management services under a group health plan or group health insurance coverage that conducts transactions with a wholly or partially owned pharmacy, as described in paragraph (2), shall submit, together with the report under subsection (b), a supplementary report every 6 months to the plan sponsor that includes—

"(A) an explanation of any benefit design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially owned by that issuer or entity;

"(B) the percentage of total prescriptions charged to the plan, coverage, or enrollees in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially owned by the issuer or entity providing pharmacy benefits management services; and

"(C) a list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan or coverage, or enrollees of the plan or coverage, during the applicable quarter, and, with respect to each drug—

"(i) the amount charged per course of treatment or 30-day supply with respect to enrollees in the plan or coverage, including amounts charged to the plan or coverage and amounts charged to the enrollee;

"(ii) the median amount charged to the plan or coverage, per course of treatment or 30-day supply, including amounts

paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

''(iii) the interquartile range of the costs, per course of treatment or 30-day supply, including amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage; and

''(iv) the lowest cost per course of treatment or 30-day supply, for such drug, including amounts charged to the plan or issuer and enrollee, that is available from any pharmacy included in the network of the plan or coverage.

''(d) FULL REBATE PASS-THROUGH TO PLAN.—

''(1) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy

benefits management services under such health plan or health insurance coverage shall remit 100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of drugs under such health plan or health insurance coverage, to the group health plan.

''(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

''(A) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

''(B) fully disclosed and enumerated to the group health plan sponsor, as described in (b)(1);

''(C) available for audit by the plan sponsor, or a third party designated by a plan sponsor no less than once per plan year; and

''(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by

such issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.

''(3) AUDIT OF REBATE CONTRACTS.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall make rebate contracts with drug manufacturers available for audit by such plan sponsor or designated third party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

''(e) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a), fails to provide information required under subsection (b), engages in spread pricing as defined in subsection (c), or fails to comply with the requirements of subsection (d), or a drug manufacturer that fails to provide information

under subsection (b)(1)(A), in a timely manner shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) SAFE HARBOR.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that

has made a good-faith effort to comply with this section.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit payments to entities offering pharmacy benefits management services for bona fide services using a fee structure not contemplated by this section, provided that such fees are transparent to group health plans and health insurance issuers.

''(g) DEFINITIONS.—In this section—

''(1) the term 'similarly situated pharmacy' means, with respect to a particular pharmacy, another pharmacy that is approximately the same size (as measured by the number of prescription drugs dispensed), and that serves patients in the same geographical area, whether through physical locations or mail order; and

''(2) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''.

SEC. 368. STUDY BY COMPTROLLER GENERAL OF UNITED STATES.

(a) IN GENERAL.—The Comptroller General of the United States (referred to in this section as the ''Comptroller General'') shall, in consultation with appropriate

stakeholders, conduct a study on the role of pharmacy benefit managers.

(b) PERMISSIBLE EXAMINATION.—In conducting the study required under subsection (a), the Comptroller General may examine various qualitative and quantitative aspects of the role of pharmacy benefit managers, such as the following:

(1) The role that pharmacy benefit managers play in the pharmaceutical supply chain.

(2) The state of competition among pharmacy benefit managers, including the market share for the Nation's largest pharmacy benefit managers.

(3) The use of rebates and fees by pharmacy benefit managers, including—

(A) the extent to which rebates are passed on to health plans and whether such rebates are passed on to individuals enrolled in such plans;

(B) the extent to which rebates are kept by such pharmacy benefit managers; and

(C) the role of any fees charged by such pharmacy benefit managers.

(4) Whether pharmacy benefit managers structure their formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives.

(5) The average prior authorization approval time for pharmacy benefit managers.

(6) Factors affecting the use of step therapy by pharmacy benefit managers.

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General shall submit to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report containing the results of the study conducted under subsection (a), including policy recommendations.

Subtitle E—Medicare and Medicaid Prescription Drug Reforms

SEC. 371. MEDICARE PART B REBATE BY MANUFACTURERS FOR DRUGS OR BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.

(a) IN GENERAL.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended by adding at the end the following new subsection:

''(h) REBATE BY MANUFACTURERS FOR DRUGS OR BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.—

''(1) REQUIREMENTS.—

''(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each rebate period (as defined in paragraph (2)(A)) beginning on or after January 1, 2021, the Secretary shall, for each rebatable drug (as defined in paragraph (2)(B)), report to each manufacturer of such rebatable drug the following for such rebate period:

''(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such rebatable drug and rebate period.

''(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such rebatable drug and rebate period.

''(iii) The rebate amount specified under such paragraph for such rebatable drug and rebate period.

''(B) MANUFACTURER REBATE.—

''(i) IN GENERAL.—Subject to clause (ii), for each rebate period beginning on or after January 1, 2021, the manufacturer

of a rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information and rebate amount pursuant to subparagraph (A) for such rebate period, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such rebate period.

''(ii) EXEMPTION FOR SHORTAGES.—The Secretary may reduce or waive the rebate under this subparagraph with respect to a rebatable drug that is listed on the drug shortage list maintained by the Food and Drug Administration pursuant to section 506E of the Federal Food, Drug, and Cosmetic Act.

''(C) REQUEST FOR RECONSIDERATION.—The Secretary shall establish procedures under which a manufacturer of a rebatable drug may request a reconsideration by the Secretary of the rebate amount specified under paragraph (3) for such rebatable drug and rebate period, as reported to the manufacturer pursuant to subparagraph (A)(iii).

"(2) REBATE PERIOD AND REBATABLE DRUG DEFINED.—In this subsection:

"(A) REBATE PERIOD.—The term 'rebate period' means a calendar quarter beginning on or after January 1, 2021.

"(B) REBATABLE DRUG.—The term 'rebatable drug' means a single source drug or biological (other than a biosimilar biological product)—

"(i) described in section 1842(o)(1)(C) for which the payment amount is provided under this section; or

"(ii) for which payment is made separately under section 1833(i) or section 1833(t) and for which the payment amount is calculated based on the payment amount under this section.

"(3) REBATE AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the amount specified in this paragraph for a rebatable drug assigned to a billing and payment code for a rebate period is, subject to paragraph (4), the amount equal to the product of—

"(i) subject to subparagraph (B), the total number of units of the billing and payment code for such rebatable drug furnished during the rebate period; and

"(ii) the amount (if any) by which—

"(I) the amount determined under subsection (b)(4) for such rebatable drug during the rebate period; exceeds

"(II) the inflation-adjusted base payment amount determined under subparagraph (C) of this paragraph for such rebatable drug during the rebate period.

"(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), the total number of units of the billing and payment code for rebatable drugs furnished during a rebate period shall not include units with respect to which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act or a rebate under section 1927.

"(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this

subparagraph for a rebatable drug for a rebate period is—

"(i) the amount determined under subsection (b)(4) for such rebatable drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

"(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the rebate period exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

"(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning July 1, 2019.

"(E) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for July 2019.

"(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a rebate period, the consumer price index for all urban consumers (United States city average) for the last month of the calendar quarter that

is two calendar quarters prior to the rebate period.

''(4) APPLICATION TO NEW DRUGS.—In the case of a rebatable drug first approved or licensed by the Food and Drug Administration after July 1, 2019, the following shall apply:

''(A) DURING INITIAL PERIOD.—For quarters during the initial period in which the payment amount for such drug is determined using the methodology described in subsection (c)(4)—

''(i) clause (ii)(I) of paragraph (3)(A) shall be applied as if the reference to 'the amount determined under subsection (b)(4),' were a reference to 'the wholesale acquisition cost applicable under subsection (c)(4)';

''(ii) clause (i) of paragraph (3)(C) shall be applied—

''(I) as if the reference to 'the amount determined under subsection (b)(4),' were a reference to 'the wholesale acquisition cost applicable under subsection (c)(4)'; and

"(II) as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the first full calendar quarter after the day on which the drug was first marketed; and

"(iii) clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (4)(E) as if the reference to 'July 2019' under such paragraph were a reference to 'the first month of the first full calendar quarter after the day on which the drug was first marketed'.

"(B) AFTER INITIAL PERIOD.—For quarters beginning after such initial period—

"(i) clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the first full calendar quarter for which the Secretary is able to compute an average sales price for the rebatable drug; and

"(ii) clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark

period CPI–U' were defined under paragraph (4)(E) as if the reference to 'July 2019' under such paragraph were a reference to 'the first month of the first full calendar quarter for which the Secretary is able to compute an average sales price for the rebatable drug'.

''(5) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(6) ENFORCEMENT.—

''(A) CIVIL MONEY PENALTY.—

''(i) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to comply with the requirements under paragraph (1)(B) with respect to providing a rebate for a rebatable drug for a rebate period for each such failure in an amount equal to the sum of—

''(I) the rebate amount specified pursuant to paragraph (3) for such drug for such rebate period; and

''(II) 25 percent of such amount.

''(ii) APPLICATION.—The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(B) NO PAYMENT FOR MANUFACTURERS WHO FAIL TO PAY PENALTY.—If the manufacturer of a rebatable drug fails to pay a civil money penalty under subparagraph (A) with respect to the failure to provide a rebate for a rebatable drug for a rebate period by a date specified by the Secretary after the imposition of such penalty, no payment shall be available under this part for such rebatable drug for calendar quarters beginning on or after such date until the Secretary determines the manufacturer has paid the penalty due under such subparagraph.''.

(b) IMPLEMENTATION.—Section 1847A(g) of the Social Security Act (42 U.S.C. 1395w–3(g)) is amended—

(1) in paragraph (4), by striking ''and'' at the end;

(2) in paragraph (5), by striking the period at the end and inserting ''; and''; and

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

''(6) determination of the rebate amount for a rebatable drug under paragraph (3) of subsection (h), including with respect to a new drug pursuant to paragraph (4) of such subsection, including—

''(A) a decision by the Secretary with respect to a request for reconsideration under paragraph (1)(C); and

''(B) the determination of—

''(i) the total number of units of the billing and payment code under paragraph (3)(A)(i); and

''(ii) the inflation-adjusted payment amount under paragraph (3)(C).''.

(c) CONFORMING AMENDMENT TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting ''or subsection (h)'' after ''section 1927''.

SEC. 372. MARKET BASED PART B PRICING INDEX.

Notwithstanding any provision of part B of title XVIII of the Social Security Act, the Secretary of Health and Human Services may make payments for drugs pay-

able under such part based on an international pricing index. In using such an index, the Secretary shall take into account whether the market of each country included in such index is a price-controlled or free market and give more weight under such index to countries with market-based drug policies.

SEC. 373. INNOVATION MODEL TESTING OF MEDICARE DRUG PAYMENTS.

Notwithstanding any provision of section 1115A, the Secretary of Health and Human Services may, under such section, test a model to integrate benefits provided for drugs under parts A, B, and D of title XVIII of the Social Security Act.

SEC. 374. MODIFICATION OF MAXIMUM REBATE AMOUNT UNDER MEDICAID DRUG REBATE PROGRAM.

(a) IN GENERAL.—Subparagraph (D) of section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended to read as follows:

''(D) MAXIMUM REBATE AMOUNT.—

''(i) IN GENERAL.—Except as provided in clause (ii), in no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator

multiple source drug for a rebate period exceed—

"(I) for rebate periods beginning after December 31, 2009, and before September 30, 2022, 100 percent of the average manufacturer price of the drug; and

"(II) for rebate periods beginning on or after October 1, 2022, 125 percent of the average manufacturer price of the drug.

"(ii) NO MAXIMUM AMOUNT FOR DRUGS IF AMP INCREASES OUTPACE INFLATION.—

"(I) IN GENERAL.—If the average manufacturer price with respect to each dosage form and strength of a single source drug or an innovator multiple source drug increases on or after October 1, 2021, and such increased average manufacturer price exceeds the inflation-adjusted average manufacturer price determined with respect to such drug under subclause (II) for the rebate period, clause (i)

shall not apply and there shall be no limitation on the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph for the rebate period with respect to each dosage form and strength of the single source drug or innovator multiple source drug.

''(II) INFLATION-ADJUSTED AVERAGE MANUFACTURER PRICE DEFINED.—In this clause, the term 'inflation-adjusted average manufacturer price' means, with respect to a single source drug or an innovator multiple source drug and a rebate period, the average manufacturer price for each dosage form and strength of the drug for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the 1st day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States

city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.''.

(b) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—Section 1927(c)(2)(B) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting ''and clause (ii)(II) of subparagraph (D)'' after ''clause (ii)(II) of subparagraph (A)''.

(c) TECHNICAL AMENDMENTS.—Section 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

(1) by striking ''subparagraph (A)'' and inserting ''paragraph (3)(A)''; and

(2) by striking ''this subparagraph'' and inserting ''paragraph (3)(C)''.

Subtitle F—Medical Malpractice Reform

SEC. 381. 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 man-

ner 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 ac-

tion 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, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(10) HEALTH CARE 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 phys-

ical 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. 382. 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. 383. 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 sepa-

rate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

(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. 384. 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. 385. 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. 386. PRODUCT LIABILITY FOR HEALTH CARE PROVIDERS.

A health care provider who prescribes, or who dispenses pursuant to a prescription, a medical product approved, 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. 387. 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. 388. 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. 389. 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 testi-

mony 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 section 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. 390. 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. 391. 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 professional 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. 392. 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.

SEC. 393. 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 physician, 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.

SEC. 394. 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. 395. 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.

TITLE IV—MEDICARE AND MEDICAID REFORMS

Subtitle A—Medicaid Reforms

SEC. 401. MEDICAID PAYMENT REFORM.

(a) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1903 the following section:

"SEC. 1903A. REFORMED PAYMENT TO STATES.

''(a) REFORMED PAYMENT SYSTEM.—

''(1) IN GENERAL.—For quarters beginning on or after the implementation date (as defined in subsection (k)(1)), in the case of a State that elects (in a time and manner specified by the Secretary) to apply this section, in lieu of amounts otherwise payable to such State under this title (including any payments attributable to section 1923), except as otherwise provided in this section, the amount payable to such State shall be equal to the sum of the following:

''(A) ADJUSTED AGGREGATE BENEFICIARY-BASED AMOUNT.—The aggregate beneficiary-based amount specified in subsection (b) for the quarter and the State, adjusted under subsection (e).

"(B) CHRONIC CARE QUALITY BONUS.—The amount (if any) of the chronic care quality bonus payment specified in subsection (f) for the quarter for the State.

"(2) REQUIREMENT OF STATE SHARE.—

"(A) IN GENERAL.—A State shall make, from non-Federal funds, expenditures in an amount equal to its State share (as determined under subparagraph (B)) for a quarter for items, services, and other costs for which, but for paragraph (1), Federal funds would have been payable under this title.

"(B) STATE SHARE.—The State share for a State for a quarter in a fiscal year is equal to the product of—

"(i) the aggregate beneficiary-based amount specified in subsection (b) for the quarter and the State; and

"(ii) the ratio of—

"(I) the State percentage described in subparagraph (D)(ii) for such State and fiscal year; to

"(II) the Federal percentage described in subparagraph (D)(i) for such State and fiscal year.

"(C) NONPAYMENT FOR FAILURE TO PAY STATE SHARE.—

"(i) IN GENERAL.—If a State fails to expend the amount required under subparagraph (A) for a quarter in a fiscal year, the amount payable to the State under paragraph (1) shall be reduced by the product of the amount by which the State payment is less than the State share and the ratio of—

"(I) the Federal percentage described in subparagraph (D)(i) for such State and fiscal year; to

"(II) the State percentage described in subparagraph (D)(ii) for such State and fiscal year.

"(ii) GRACE PERIOD.—A State shall not be considered to have failed to provide payment of its required State share for a quarter under subparagraph (A) if the aggregate State payment towards the State's required State share for the 4-quarter period beginning with such quarter exceeds the required State share amount for such 4-quarter period.

"(D) FEDERAL AND STATE PERCENTAGES.—In this paragraph, with respect to a State and a fiscal year:

"(i) FEDERAL PERCENTAGE.—The Federal percentage described in this clause is 75 percent or, if higher, the Federal medical assistance percentage for such State for such fiscal year.

"(ii) STATE PERCENTAGE.—The State percentage described in this clause is 100 percent minus the Federal percentage described in clause (i).

"(E) RULES FOR CREDITING TOWARD STATE SHARE.—

"(i) GENERAL LIMITATION TO MATCHABLE EXPENDITURES.—A payment for expenditures shall not be counted toward the State share under subparagraph (A) unless Federal payments may be used for such expenditures consistent with paragraph (3)(B).

"(ii) FURTHER LIMITATIONS ON ALLOWABLE EXPENDITURES.—A payment for expenditures shall not be counted towards

the State share under subparagraph (A) if the expenditure is for any of the following:

"(I) ABORTION.—Expenditures for an abortion.

"(II) INTERGOVERNMENTAL TRANSFERS.—An expenditure that is attributable to an intergovernmental transfer.

"(III) CERTIFIED PUBLIC EXPENDITURES.—An expenditure that is attributable to certified public expenditures.

"(iii) CREDITING FRAUD AND ABUSE RECOVERIES.—Amounts recovered by a State through the operation of its Medicaid fraud and abuse control unit described in section 1903(q) shall be fully counted toward the State share under subparagraph (A).

"(F) CONSTRUCTION.—Nothing in the paragraph shall be construed as preventing a State from expending, from non-Federal funds, an amount under this title in excess of the amount of the State share.

"(G) DETERMINATION BASED UPON SUBMITTED CLAIMS.—In applying this paragraph with respect to expenditures of a State for a quarter, the determination of the expenditures for such State for such quarter shall be made after the end of the period (which, as of the date of the enactment of this section, is 2 years) for which the Secretary accepts claims for payment under this title with respect to such quarter.

"(3) USE OF FEDERAL PAYMENTS.—

"(A) APPLICATION OF MEDICAID LIMITATIONS.—A State may only use Federal payments received under subsection (a) for expenditures for which Federal funds would have been payable under this title but for this section.

"(B) LIMITATION FOR CERTAIN ELIGIBLES.—

"(i) APPLICATION OF 100 PERCENT FEDERAL POVERTY LINE LIMIT ON ELIGIBILITY.—Subject to clause (iii), a State may not use such Federal payments to provide medical assistance for an individual who has an income (as determined under clause (ii)) that exceeds 100 percent

of the poverty line (as defined in section 2110(c)(5)) applicable to a family of the size involved.

''(ii) DETERMINATION OF INCOME USING MODIFIED ADJUSTED GROSS INCOME WITHOUT ANY 5 PERCENT INCREASE.—In determining income for purposes of clause (i) under section 1902(e)(14) (relating to modified adjusted gross income), the following rules shall apply:

''(I) APPLICATION OF SPEND DOWN.—The State shall take into account the costs incurred for medical care or for any other type of remedial care recognized under State law in the same manner and to the same extent that such State takes such costs into account for purposes of section 1902(a)(17).

''(II) DISREGARD OF 5 PERCENT INCREASE.—Subparagraph (I) of section 1902(e)(14) (relating to a 5 percent reduction) shall not apply.

"(iii) EXCEPTION.—Clause (i) shall not apply to an individual who is—

"(I) a woman described in clause (i) of section 1903(v)(4)(A);

"(II) a child who is an individual described in clause (i) of section 1905(a);

"(III) enrolled in a State plan under this title as of the date of the enactment of this section for the period of continuous enrollment; or

"(IV) described in section 1902(e)(14)(D) (relating to modified adjusted gross income).

"(iv) CLARIFICATION RELATED TO COMMUNITY SPOUSE.—Nothing in this subparagraph shall supersede the application of section 1924 (related to community spouse income and assets).

"(4) EXCEPTIONS FOR PASS-THROUGH PAYMENTS.—

"(A) IN GENERAL.—Paragraph (1) shall not apply, and amounts shall continue to be payable under this title (and not under subsection (a)), in the case of the following pay-

ments (and related administrative costs and expenditures):

"(i) PAYMENTS TO TERRITORIES.—Payments to a State other than the 50 States and the District of Columbia.

"(ii) MEDICARE COST-SHARING.—Payments attributable to Medicare cost-sharing under section 1905(p).

"(iii) PEDIATRIC VACCINES.—Payments attributable to section 1928.

"(iv) EMERGENCY SERVICES FOR CERTAIN INDIVIDUALS.—Payments for treatment of emergency medical conditions attributable to the application of section 1903(v)(2).

"(v) INDIAN HEALTH CARE FACILITIES.—Payments for medical assistance described in the third sentence of section 1905(b).

"(vi) EMPLOYER-SPONSORED INSURANCE (ESI).—Payments for medical assistance attributable to payments to employers for employer-sponsored health benefits coverage.

"(vii) OTHER POPULATIONS WITH LIMITED BENEFIT COVERAGE.—Other payments that are determined by the Secretary to be related to a specified population for which the medical assistance under this title is limited and does not include any inpatient, nursing facility, or long-term care services.

"(B) CERTAIN EXPENSES.—Paragraph (1) shall not apply, and amounts shall continue to be payable under this title (and not under subsection (a)), in the case of the following:

"(i) ADMINISTRATION OF MEDICARE PRESCRIPTION DRUG BENEFIT.—Expenditures described in section 1935(b) (relating to administration of the Medicare prescription drug benefit).

"(ii) PAYMENTS FOR HIT BONUSES.—Payments under section 1903(a)(3)(F) (relating to payments to encourage the adoption and use of certified EHR technology).

"(iii) PAYMENTS FOR DESIGN, DEVELOPMENT, AND INSTALLATION OF MMIS AND ELIGIBILITY SYSTEMS.—Payments under subparagraphs (A)(i) and (H)(i) of section

1903(a)(3) for expenditures for design, development, and installation of the Medicaid management information systems and mechanized verification and information retrieval systems (related to eligibility).

''(5) PAYMENT OF AMOUNTS.—

''(A) IN GENERAL.—Except as the Secretary may otherwise provide, amounts shall be payable to a State under subsection (a) in the same manner as amounts are payable under subsection (d) of section 1903 to a State under subsection (a) of such section.

''(B) INFORMATION AND FORMS.—

''(i) SUBMISSION.—As a condition of receiving payment under subsection (a), a State shall submit such information, in such form, and manner, as the Secretary shall specify, including information necessary to make the computations under subsections (c)(2)(C) and (e).

''(ii) UNIFORM REPORTING.—The Secretary shall develop such forms as may be needed to assure a system of uniform reporting of such information across States.

"(C) REQUIRED REPORTING OF INFORMATION ON MEDICAL LOSS RATIOS FOR MANAGED CARE.—The information required to be reported under subparagraph (B)(i) shall include information on the medical loss ratio with respect to coverage provided under each Medicaid managed care plan with a contract with the State under section 1903(m) or 1932.

"(b) AGGREGATE BENEFICIARY-BASED AMOUNT.—

"(1) IN GENERAL.—The aggregate beneficiary-based amount specified in this subsection for a State for a quarter is equal to the sum of the products, for each of the categories of Medicaid beneficiaries specified in paragraph (2), of the following:

"(A) BENEFICIARY-BASED QUARTERLY AMOUNT.—The beneficiary-based quarterly amount for such category computed under subsection (c) for such State for such quarter.

"(B) NUMBER OF INDIVIDUALS IN CATEGORY.—Subject to subsection (d), the average number of Medicaid beneficiaries enrolled in such category in the State in such quarter.

"(2) CATEGORIES.—The categories specified in this paragraph are the following:

''(A) ELDERLY.—A category of Medicaid beneficiaries who are 65 years of age or older.

''(B) BLIND OR DISABLED.—A category of Medicaid beneficiaries not described in subparagraph (A) who are described in section 1937(a)(2)(B)(ii).

''(C) CHILDREN.—A category of Medicaid beneficiaries not described in subparagraph (B) who are under 21 years of age.

''(D) OTHER ADULTS.—A category of any Medicaid beneficiaries who are not described in a previous subparagraph of this paragraph.

''(c) COMPUTATION OF PER BENEFICIARY, PER CATEGORY QUARTERLY AMOUNT.—

''(1) IN GENERAL.—For a State, for each category of beneficiary for a quarter—

''(A) FIRST REFORM YEAR.—For quarters in the first reform year (as defined in subsection (k)(2)), the beneficiary-based quarterly amount is equal to ¼ of the base average per beneficiary Federal payments for such State for such category determined under paragraph (2), increased by a factor that reflects the sum of the following:

"(i) HISTORICAL MEDICAL CARE COMPONENT OF CPI THROUGH PREVIOUS REFORM YEAR.—The percentage increase in the historical medical care component of the Consumer Price Index for all urban consumers (U.S. city average) from the midpoint of the base fiscal year (as defined in paragraph (6)) to the midpoint of the fiscal year preceding the first reform year.

"(ii) PROJECTED MEDICAL CARE COMPONENT OF CPI FOR THE FIRST REFORM YEAR.—The percentage increase in the projected medical care component of the Consumer Price Index for all urban consumers (U.S. city average) from the midpoint of the previous fiscal year referred to in clause (i) to the midpoint of the first reform year.

"(B) SECOND AND THIRD REFORM YEARS.—The beneficiary-based quarterly amount for a State for a category for quarters in the second reform year or the third reform year is equal to the beneficiary-based quarterly amount under this paragraph for such State and category for the previous reform year in-

creased by the per beneficiary percentage increase (as defined in subparagraph (E)) for such category and reform year.

''(C) FOURTH THROUGH TENTH REFORM YEARS.—The beneficiary-based quarterly amount for a State for a category for quarters in a reform year beginning with the fourth reform year and ending with the tenth reform year is—

''(i) in the case of a State that is a high per beneficiary State or a low per beneficiary State (as defined in paragraph (4)(B)(iii)) for the category, the amount determined under clause (i) or (ii) of paragraph (4)(B) for such State, category, and reform year; or

''(ii) in the case of any other State, the beneficiary-based quarterly amount under this paragraph for such State and category for the previous reform year increased by the per beneficiary percentage increase for such category and reform year.

''(D) ELEVENTH REFORM YEAR AND SUBSEQUENT REFORM YEARS.—The beneficiary-

based quarterly amount for a State for a category for quarters in a reform year beginning with the eleventh reform year is equal to the beneficiary-based quarterly amount under this paragraph for such State and category for the previous reform year increased by the per beneficiary percentage increase for such category and reform year.

''(E) ANNUAL PERCENTAGE INCREASE BEGINNING WITH SECOND REFORM YEAR.—For purposes of this subsection, the term 'per beneficiary percentage increase' means, for a reform year, the sum of—

''(i) the projected percentage change in nominal gross domestic product from the midpoint of the previous reform year to the midpoint of the reform year for which the percentage increase is being applied; and

''(ii) one percentage point.

''(2) BASE PER BENEFICIARY, PER CATEGORY AMOUNT FOR EACH STATE.—

''(A) AVERAGE PER CATEGORY.—

''(i) IN GENERAL.—The Secretary shall determine, consistent with this para-

graph and paragraph (3), a base per beneficiary, per category amount for each of the 50 States and the District of Columbia equal to the average amount, per Medicaid beneficiary, of Federal payments under this title, including payments attributable to disproportionate share hospital payments under section 1923, for each of the categories of beneficiaries under subsection (b)(2) for the base fiscal year for each of the 50 States and the District of Columbia.

''(ii) BEST AVAILABLE DATA.—The determination under clause (i) shall initially be estimated by the Secretary, based upon the best available data at the time the determination is made.

''(iii) UPDATES.—The determination under clause (i) shall be updated by the Secretary on an annual basis based upon improved data. The Secretary shall adjust the amounts under subsection (a)(1)(A) to reflect changes in the amounts so determined based on such updates.

"(B) EXCLUSION OF PASS-THROUGH PAYMENTS.—In computing base per beneficiary, per category amounts under subparagraph (A)(i) the Secretary shall exclude payments described in subsection (a)(4).

"(C) STANDARDIZATION.—

"(i) IN GENERAL.—In computing each such amount, the Secretary shall standardize the amount in order to remove the variation attributable to the following:

"(I) RISK FACTORS.—Such risk factors as age, health and disability status (including high cost medical conditions), gender, institutional status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence.

"(II) GEOGRAPHIC.—Variations in costs on a county-by-county basis.

"(ii) METHOD OF STANDARDIZATION.—

"(I) CONSULTATION IN DEVELOPMENT OF RISK STANDARDIZATION.—In developing the methodology

for risk standardization for purposes of clause (i)(I), the Secretary shall consult with the Medicaid and CHIP Payment and Access Commission, the Medicare Payment Advisory Commission, and the National Association of Medicaid Directors.

''(II) METHOD FOR RISK STANDARDIZATION.—In carrying out clause (i)(I), the Secretary may apply the hierarchal condition category methodology under section 1853(a)(1)(C). If the Secretary uses such methodology, the Secretary shall adjust the application of such methodology to take into account the differences in services provided under this title compared to title XVIII, such as the coverage of long term care, pregnancy, and pediatric services.

''(III) METHOD FOR GEOGRAPHIC STANDARDIZATION.—The Secretary shall apply the standardization under clause (i)(II) in a manner similar to

that applied under section 1853(c)(4)(A)(iii).

''(iii) APPLICATION ON A NATIONAL, BUDGET NEUTRAL BASIS.—The standardization under clause (i) shall be designed and implemented on a uniform national basis and shall be budget neutral so as to not result in any aggregate change in payments under subsection (a).

''(iv) RESPONSE TO NEW RISK.—Subject to clause (iii), the Secretary may adjust the standardization under clause (i) to respond promptly to new instances of communicable diseases and other public health hazards.

''(v) REFERENCE TO APPLICATION OF RISK ADJUSTMENT.—For rules related to the application of risk adjustment to amounts under subsection (a)(1)(A), see subsection (e).

''(D) ADJUSTMENT FOR TEMPORARY FMAP INCREASES.—In computing each base per beneficiary, per category amounts under subparagraph (A)(i) the Secretary shall disregard portions of payments that are attributable to a

temporary increase in the Federal matching rates, including those attributable to the following:

"(i) PPACA DISASTER FMAP.—Section 1905(aa).

"(ii) ARRA.—Section 5001 of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 1396d note).

"(iii) EXTRAORDINARY EMPLOYER PENSION CONTRIBUTION.—Section 614 of the Children's Health Insurance Program Reauthorization Act of 2009 (42 U.S.C. 1396d note).

"(3) ALLOCATION OF NONMEDICAL ASSISTANCE PAYMENTS.—The Secretary shall establish rules for the allocation of payments under this title (other than those payments described in paragraph (1) or (5) of section 1903(a) and including such payments attributable to section 1923)—

"(A) among different categories of beneficiaries; and

"(B) between payments included under subsection (a)(1) and payments described in subsection (a)(4).

''(4) TRANSITION TO A CORRIDOR AROUND THE NATIONAL AVERAGE.—

''(A) DETERMINATION OF NATIONAL AVERAGE BASE PER BENEFICIARY, PER CATEGORY AMOUNT.—Subject to subparagraph (C), the Secretary shall determine a national average base per beneficiary, per category amount equal to the average of the base per beneficiary, per category amounts for each of the 50 States and the District of Columbia determined under paragraph (2), weighted by the average number of beneficiaries in each such category and State as determined by the Secretary consistent with subsection (d) for the base fiscal year.

''(B) TRANSITION ADJUSTMENT.—

''(i) HIGH PER BENEFICIARY STATES.—In the case of a high per beneficiary State (as defined in clause (iii)(I)) for a category, the beneficiary-based quarterly amount for such State and category for a quarter in a reform year (beginning with the fourth reform year and ending with the tenth reform year) is equal to the sum of—

"(I) the product of the State-specific factor for such reform year (as defined in clause (iv)) and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for such State and category if the State were a State described in clause (ii) of paragraph (1)(C), instead of a State described in clause (i) of such paragraph; and

"(II) the product of 1 minus the State-specific factor for such reform year and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for a State and category if the base per beneficiary, per category amount determined under paragraph (2) for the State and category were equal to 110 percent of the national average base per beneficiary, per category amount determined under subparagraph (A) for such category.

"(ii) LOW PER BENEFICIARY STATES.—In the case of a low per bene-

ficiary State (as defined in clause (iii)(II)) for a category, the beneficiary-based quarterly amount for such State and category for a quarter in a reform year (beginning with the fourth reform year and ending with the tenth reform year) is equal to the sum of—

''(I) the product of the State-specific factor for such reform year and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for such State and category if the State were a State described in clause (ii) of paragraph (1)(C), instead of a State described in clause (i) of such paragraph; and

''(II) the product of 1 minus the State-specific factor for such reform year and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for a State and category if the base per beneficiary, per category amount determined under paragraph (2) for the

State and category were equal to 90 percent of the national average base per beneficiary, per category amount determined under subparagraph (A) for such category.

''(iii) HIGH AND LOW PER BENEFICIARY STATES DEFINED.—In this subparagraph:

''(I) HIGH PER BENEFICIARY STATE.—The term 'high per beneficiary State' means, with respect to a category, a State for which the base per beneficiary, per category amount determined under paragraph (2) for such category is greater than 110 percent of the national average base per beneficiary, per category amount determined under subparagraph (A) for such category.

''(II) LOW PER BENEFICIARY STATE.—The term 'low per beneficiary State' means, with respect to a category, a State for which the base per beneficiary, per category amount determined under paragraph (2) for

such category is less than 90 percent of the national average base per beneficiary, per category amount determined under subparagraph (A) for such category.

''(iv) STATE-SPECIFIC FACTOR.—In this subparagraph, the term 'State-specific factor' means—

''(I) for the fourth reform year, 7/8; and

''(II) for a subsequent reform year, the State-specific factor under this clause for the previous reform year minus 1/8.

''(C) NO ADDITIONAL EXPENDITURES.—

''(i) DETERMINATION OF INCREASE IN FEDERAL EXPENDITURES.—For each category for each reform year (beginning with the fourth reform year and ending with the tenth reform year), the Secretary shall determine whether the application of this paragraph—

''(I) to the category for the reform year will result in an aggregate

increase in the aggregate Federal expenditures under subsection (a); and

"(II) to all the categories for the reform year will result in a net aggregate increase in the aggregate Federal expenditures under subsection (a).

"(ii) ADJUSTMENT.—If the Secretary determines under clause (i)(II) that the application of this paragraph to all the categories for a reform year will result in a net aggregate increase in the aggregate Federal expenditures under subsection (a), the Secretary shall reduce the national average base per beneficiary, per category amount computed under subparagraph (A) for each of the categories determined under clause (i)(I) for which there will be an aggregate increase in the aggregate Federal expenditures under subsection (a) by such uniform percentage as will ensure that there is no net aggregate Federal expenditure increase described in clause (i)(II) for the reform year.

"(5) REPORTS ON PER BENEFICIARY RATES; APPEALS.—

"(A) REPORT TO STATES.—Not later than 8 months after the date of the enactment of this section, the Secretary shall submit to each State the Secretary's initial determination of—

"(i) the base per beneficiary, per category amounts under paragraph (2) for such State; and

"(ii) the national average base per beneficiary, per category amounts under paragraph (4)(A).

"(B) OPPORTUNITY TO APPEAL.—Not later than 3 months after the date a State receives notice of the Secretary's initial determination of such base per beneficiary, per category amounts for such State under subparagraph (A)(i), the State may file with the Secretary, in a form and manner specified by the Secretary, an appeal of such determination.

"(C) DETERMINATION ON APPEAL.—Not later than 3 months after receiving such an appeal, the Secretary shall make a final determination on such amounts for such State. If no such appeal is received for a State, the Secretary's initial determination under subparagraph (A)(i) shall become final.

''(6) BASE FISCAL YEAR DEFINED.—In this section, the term 'base fiscal year' means the latest fiscal year, ending before the date of the enactment of this section, for which the Secretary determines that adequate data are available to make the computations required under this subsection.

''(d) NOT COUNTING INDIVIDUALS TO ACCOUNT FOR EXCLUDED PAYMENTS.—Under rules specified by the Secretary, individuals shall not be counted as Medicaid beneficiaries for purposes of subsection (b)(1)(B) and subsection (c)(2)(A) to the extent that such individuals—

''(1) are receiving medical assistance for which payments described under subsection (a)(4)(A) are made; or

''(2) would not have been eligible to enroll under the State plan (or waiver of such plan) in the State in which such individual is so enrolled if the rules for eligibility for enrollment under such plan (or waiver) were the same as such rules for eligibility in effect as of January 1, 2009.

''(e) RISK ADJUSTMENT.—

''(1) IN GENERAL.—The amount under subsection (a)(1)(A) shall be adjusted under this subsection in an appropriate manner, specified by the

Secretary and consistent with paragraph (2), to take into account—

"(A) the factors described in subsection (c)(2)(C)(i)(I) within a category of beneficiaries; and

"(B) variations in costs on a county-by-county basis for medical assistance and administrative expenses.

"(2) METHOD OF ADJUSTMENT.—

"(A) IN GENERAL.—The adjustments under paragraph (1) shall be made in a manner similar to the manner in which similar adjustments are made under subsection (c)(2)(C) and consistent with the requirements of clause (iii) of such subsection and subparagraph (B).

"(B) BIANNUAL UPDATE OF RISK ADJUSTMENT METHODOLOGY.—In applying clause (i)(I) of subsection (c)(2)(C) for purposes of subparagraph (A), the Secretary shall, in consultation with the entities described in clause (ii)(I) of such subsection, update the risk adjustment methodology applied as appropriate not less often than every 2 years.

"(f) CHRONIC CARE QUALITY BONUS PAYMENTS.—

''(1) DETERMINATION OF BONUS PAYMENTS.—If the Secretary determines that, based on the reports under paragraph (5), with respect to categories of chronic disease for which chronic care performance targets had been established under paragraph (3) for each category of Medicaid beneficiaries specified under subsection (b)(2) such targets have been met by a State for a reform year, the Secretary shall make an additional payment to such State in the amount specified in paragraph (6) for each quarter in the succeeding reform year. Such payments shall be made in a manner specified by the Secretary and may only be used consistent with subsection (a)(3).

''(2) IDENTIFICATION OF CATEGORIES OF CHRONIC DISEASE.—The Secretary shall determine the categories of chronic disease for which bonus payments may be available under this subsection for each category of Medicaid beneficiaries.

''(3) ADOPTION OF QUALITY MEASUREMENT SYSTEM AND IDENTIFICATION OF PERFORMANCE TARGETS.—

''(A) SYSTEM AND DATA.—With respect to the categories of chronic disease under paragraph (2), the Secretary shall adopt a quality

measurement system that uses data described in paragraph (4) and is similar to the Five-Star Quality Rating System used to indicate the performance of Medicare Advantage plans under part C of title XVIII.

''(B) TARGETS.—Using such system and data, the Secretary shall establish for each reform year the chronic care performance targets for purposes of the payments under paragraph (1). Such performance targets shall be established in consultation with States, associations representing individuals with chronic illnesses, entities providing treatment to such individuals for such chronic illnesses, and other stakeholders, including the National Association of Medicaid Directors and the National Governors Association.

''(4) DATA TO BE USED.—The data to be used under paragraph (3) shall include—

''(A) data collected through methods such as—

''(i) the 'Healthcare Effectiveness Data and Information Set' (also known as 'HEDIS') (or an appropriate successor performance measurement tool);

"(ii) the 'Consumer Assessment of Healthcare Providers and Systems' (also known as 'CAHPS') (or an appropriate successor performance measurement tool); and

"(iii) the 'Health Outcomes Survey' (also known as 'HOS') (or an appropriate successor performance measurement tool); and

"(B) other data collected by the State.

"(5) REPORTS.—

"(A) IN GENERAL.—Each State shall collect, analyze, and report to the Secretary, at a frequency and in a manner to be established by the Secretary, data described in paragraph (4) that permit the Secretary to monitor the State's performance relative to the chronic care performance targets established under paragraph (3).

"(B) REVIEW AND VERIFICATION.—The Secretary may review the data collected by the State under subparagraph (A) to verify the State's analysis of such data with respect to the performance targets under paragraph (3).

"(6) AMOUNT OF BONUS PAYMENTS.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (C), with respect to each category of Medicaid beneficiaries, in the case of a State that the Secretary determines, based on the chronic care performance targets set under paragraph (3) for a reform year for such category, performs—

"(i) in the top five States in such category, subject to subparagraph (C)(ii), the amount of the bonus for each quarter in the succeeding reform year shall be 10 percent of the payment amount otherwise paid to the State under subsection (a) for individuals enrolled under the plan within such category;

"(ii) in the next five States in such category, subject to subparagraph (C)(ii), the amount of the bonus for each such quarter shall be 5 percent of the payment amount otherwise paid to the State under subsection (a) for individuals enrolled under the plan within such category;

"(iii) in the next five States in such category, subject to clauses (i) and (iii) of subparagraph (C), the amount of the

bonus for each such quarter shall be 3 percent of the payment amount otherwise paid to the State under subsection (a) for individuals enrolled under the plan within such category;

''(iv) in the next five States in such category, subject to clauses (i) and (iii) of subparagraph (C), the amount of the bonus for each such quarter shall be 2 percent of the payment amount otherwise paid to the State under subsection (a) for individuals enrolled under the plan within such category; and

''(v) in the next five States in such category, subject to clauses (i) and (iii) of subparagraph (C), the amount of the bonus for each such quarter shall be 1 percent of the payment amount otherwise paid to the State under subsection (a) for individuals enrolled under the plan within such category.

''(B) AGGREGATE ANNUAL LIMIT FOR EACH CATEGORY OF MEDICAID BENEFICIARIES.—

''(i) IN GENERAL.—In no case may the aggregate amount of bonuses under this subsection for quarters in a reform year for a category of Medicaid beneficiaries exceed the limit specified in clause (ii) for the reform year.

''(ii) LIMIT.—The limit specified in this clause—

''(I) for the second reform year is equal to $250,000,000; or

''(II) for a subsequent reform year is equal to the limit specified in this clause for the previous reform year increased by the per beneficiary percentage increase determined under paragraph (1)(E) of subsection (c).

''(C) LIMITATION AND PRORATION OF BONUSES BASED ON APPLICATION OF AGGREGATE LIMIT.—

''(i) NO BONUS FOR THIRD OR SUBSEQUENT TIERS UNLESS AGGREGATE LIMIT NOT REACHED ON FIRST TWO TIERS.—No bonus shall be payable under clause (iii), (iv), or (v) of subparagraph (A) for a category of Medicaid beneficiaries for a quar-

ter in a reform year unless the aggregate amount of bonuses under clauses (i) and (ii) of such subparagraph for such category and reform year is less than the limit specified in subparagraph (B)(ii) for the reform year.

''(ii) PRORATION FOR FIRST TWO TIERS.—If the aggregate amount of bonuses under clauses (i) and (ii) of subparagraph (A) for a category of Medicaid beneficiaries for quarters in a reform year exceeds the limit specified in subparagraph (B)(ii) for the reform year, the amount of each such bonus shall be prorated in a manner so the aggregate amount of such bonuses is equal to such limit.

''(iii) PRORATION FOR NEXT THREE TIERS.—If the aggregate amount of bonuses under clauses (i) and (ii) of subparagraph (A) for a category of Medicaid beneficiaries for quarters in a reform year is less than the limit specified in subparagraph (B)(ii) for the reform year, but the aggregate amount of bonuses under clauses (i) through (v) of subparagraph (A) for the

category and such quarters in the reform year exceeds the limit specified in subparagraph (B)(ii) for the reform year, the amount of each bonus in clauses (iii), (iv), and (v) of subparagraph (A) shall be prorated in a manner so the aggregate amount of all the bonuses under subparagraph (A) is equal to such limit.

''(g) STATE OPTION FOR RECEIVING MEDICARE PAYMENTS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

''(1) IN GENERAL.—Under this subsection a State may elect for quarters beginning on or after the implementation date in a reform year to receive payment from the Secretary under paragraph (3). As a condition of receiving such payment, the State shall agree to provide to full-benefit dual eligible individuals eligible for medical assistance under the State plan—

''(A) the medical assistance to which such eligible individuals would otherwise be entitled under this title; and

''(B) any items and services which such eligible individuals would otherwise receive under title XVIII.

"(2) PROVIDER PAYMENT REQUIREMENT.—

"(A) IN GENERAL.—A State electing the option under this subsection shall provide payment to health care providers for the items and services described under paragraph (1)(B) at a rate that is not less than the rate at which payments would be made to such providers for such items and services under title XVIII.

"(B) FLEXIBILITY IN PAYMENT METHODS.—Nothing in subparagraph (A) shall be construed as preventing a State from using alternative payment methodologies (such as bundled payments or the use of accountable care organizations (as such term is used in section 1899)) for purposes of making payments to health care providers for items and services provided to dual eligible individuals in the State under the option under this subsection.

"(3) PAYMENTS TO STATES IN LIEU OF MEDICARE PAYMENTS.—With respect to a full-benefit dual eligible individual, in the case of a State that elects the option under paragraph (1) for quarters in a reform year—

"(A) the Secretary shall not make any payment under title XVIII for items and services

furnished to such individual for such quarters; and

"(B) the Secretary shall pay to the State, in addition to the amounts paid to such State under subsection (a), the amount that the Secretary would, but for this subsection, otherwise pay under title XVIII for items and services furnished to such an individual in such State for such quarters.

"(4) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DEFINED.—In this subsection, the term 'full-benefit dual eligible individual' means an individual who meets the requirements of section 1935(c)(6)(A)(ii).

"(h) AUDITS.—The Secretary shall conduct such audits on the number and classification of Medicaid beneficiaries under such subsections and expenditures under this section as may be necessary to ensure appropriate payments under this section.

"(i) TREATMENT OF WAIVERS.—

"(1) NO IMPACT ON CURRENT WAIVERS.—In the case of a waiver of requirements of this title pursuant to section 1115 or other law that is in effect as of the date of the enactment of this section, nothing in this section shall be construed to affect such

waiver for the period of the waiver as approved as of such date.

''(2) APPLICATION OF BUDGET NEUTRALITY TO SUBSEQUENT WAIVERS AND RENEWALS TAKING SECTION INTO ACCOUNT.—In the case of a waiver of requirements of this title pursuant to section 1115 or other law that is approved or renewed after the date of the enactment of this section, to the extent that such approval or renewal is conditioned upon a demonstration of budget neutrality, budget neutrality shall be determined taking into account the application of this section.

''(j) REPORT TO CONGRESS.—Not later than January 1 of the second reform year, the Secretary shall submit to Congress a report on the implementation of this section.

''(k) DEFINITIONS.—In this section:

''(1) IMPLEMENTATION DATE.—The term 'implementation date' means—

''(A) July 1, 2021, if this section is enacted on or before July 1, 2020; or

''(B) July 1, 2022, if this section is enacted after July 1, 2020.

''(2) REFORM YEARS.—

''(A) The term 'reform year' means a fiscal year beginning with the first reform year.

''(B) The term 'first reform year' means the fiscal year in which the implementation date occurs.

''(C) The terms 'second', 'third', and successive similar terms mean, with respect to a reform year, the second, third, or successive reform year, respectively, succeeding the first reform year.''.

(b) CONFORMING AMENDMENTS.—

(1) CONTINUED APPLICATION OF CLAWBACK PROVISIONS.—

(A) CONTINUED APPLICATION.—Subsections (a) and (c)(1)(C) of section 1935 of such Act (42 U.S.C. 1396u–5) are each amended by inserting ''or 1903A(a)'' after ''1903(a)''.

(B) TECHNICAL AMENDMENT.—Section 1935(d)(1) of the Social Security Act (42 U.S.C. 1396u–5(d)(1)) is amended by inserting ''except as provided in section 1903A(g)'' after ''any other provision of this title''.

(2) PAYMENT RULES UNDER SECTION 1903.—

(A) Section 1903(a) of the Social Security Act (42 U.S.C. 1396b(a)) is amended, in the matter before paragraph (1), by inserting ''and

section 1903A'' after ''except as otherwise provided in this section''.

(B) Section 1903(d) of such Act (42 U.S.C. 1396b(d)) is amended—

(i) in paragraph (1), by inserting ''and under section 1903A'' after ''subsections (a) and (b)'';

(ii) in paragraph (2)—

(I) in subparagraph (A), by inserting ''or section 1903A'' after ''was made under this section''; and

(II) in subparagraph (B), by inserting ''or section 1903A'' after ''under subsection (a)'';

(iii) in paragraph (4)—

(I) by striking ''under this subsection'' and inserting '', with respect to this section or section 1903A, under this subsection''; and

(II) by striking ''under this section'' and inserting ''under the respective section''; and

(iv) in paragraph (5), by inserting ''or section 1903A'' after ''overpayment under this section''.

(3) CONFORMING WAIVER AUTHORITY.—Section 1115(a)(2)(A) of the Social Security Act (42 U.S.C. 1315(a)(2)(A)) is amended by striking ''or 1903'' and inserting ''1903, or 1903A''.

(4) REPORT ON ADDITIONAL CONFORMING AMENDMENTS NEEDED.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that includes a description of any additional technical and conforming amendments to law that are required to properly carry out this Act.

SEC. 402. 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: ''(or, in the case of a taxpayer enrolled through an Exchange utilized by such State that makes the election described in section 1903A of the Social Security Act, the percentage established by such State under part A of title IV of such Act for purposes of eligibility under title XIX of such Act as of January 1, 2009)''.

(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.

SEC. 403. 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 deter-

mined 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. 404. 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, 2021, 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. 405. PROVIDING FOR STATE APPROVAL AND IMPLEMENTATION OF SPECIFIED WAIVERS UNDER THE MEDICAID PROGRAM.

Section 1115 of the Social Security Act (42 U.S.C. 1315) is amended—

(1) in subsection (d)—

(A) in paragraph (1), by striking "An application" and inserting "Subject to paragraph (4), an application"; and

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

''(4)(A) An experimental, pilot, or demonstration project undertaken under subsection (a) may be approved or renewed by a State if such project is described in subparagraph (B).

''(B) An experimental, pilot, or demonstration project is described in this subparagraph if such project provides for a waiver of requirements with respect to a State plan (or a waiver of such plan) under title XIX such that—

''(i) individuals enrolled under such plan (or such waiver) may elect to participate in such project with respect to a year; and

''(ii) such individuals who elect to so participate are furnished with primary care services (as described in section 223(c)(1)(D)(ii)(I) of the Internal Revenue Code of 1986) through a direct primary care service arrangement (as defined in such section).

''(C) For purposes of a State's approval or renewal of an experimental, pilot, or demonstration project under subparagraph (A), each reference to 'the Secretary' in subsection (a) shall be deemed to be a reference to 'the State'.''; and

(2) in subsection (e), by inserting ''(other than such a project that is described in paragraph (4)(B))'' before the period at the end.

SEC. 406. 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.''.

Subtitle B—Medicare Reforms

SEC. 411. 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 MEDICARE 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. 412. 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.''.

SEC. 413. 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. 414. 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. 415. 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. 416. 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 2021''; 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 2021''; 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 2021'';

(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 2021''; 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—Medicare Choice and Competition

SEC. 421. COMPETITIVE BIDDING AND PREMIUMS UNDER UNIFIED MEDICARE.

(a) IN GENERAL.—Part E of title XVIII of the Social Security Act, as added by section 101 and amended by section 103, is further amended by adding at the end the following:

''Subpart 3—Competitive Bidding and Premiums

''SEC. 1860E–31. APPLICATION OF COMPETITIVE BIDDING IN ENROLLMENT.

''(a) IN GENERAL.—Notwithstanding any other provision of this title, the Secretary shall, beginning with plan year 2021, establish a method whereby individuals enrolling under this title so enroll through an online process designed to highlight enrollment options for such individuals and allow such individuals to compare costs of enrollment in such options.

''(b) ENROLLMENT OPTIONS.—For purposes of subsection (a), the Secretary shall make the following options available to individuals for enrollment under this title:

''(1) Traditional fee-for-service coverage.

''(2) provider-led risk-bearing plans (also known as ACOs).

''(3) Medicare Advantage plans.

''(c) MEDICARE ADVANTAGE PLAN ACTUARIAL VALUE REQUIREMENT.—Each Medicare Advantage plan offered through the process described in subsection (a) shall have an actuarial value equal to traditional fee-for-service coverage under parts A and B.

''(d) MA DIRECT DEPOSIT OF CERTAIN REBATES.—In the case of an Medicare Advantage plan with a bid for a year that involves a premium differential between such bid and the benchmark for such year and plan, such plan shall provide for a direct deposit of such differential if the applicable enrollee in such plan does not elect any supplemental coverage under such plan.

''(e) ENROLLMENT IN PRESCRIPTION DRUG COVERAGE.—As part of the method described in subsection (a), the Secretary shall establish a process to allow an individual to enroll in prescription drug coverage. In the case of an individual who enrolls in a Medicare Advantage plan, such coverage shall be provided under such plan. In a case of an individual who enrolls in an ACO, such coverage shall be provided under such network. In the case of an individual who enrolls under traditional fee-for-serv-

ice coverage, such drug coverage shall be provided through a prescription drug plan.

''(f) SUPPLEMENTAL BENEFITS.—

''(1) MA PLANS.—An MA plan is allowed to offer two different packages of supplemental benefits (these packages are available only to individuals who select such plans).

''(2) ACOS.—ACOs may limit supplemental options for their enrollees to Medigap plans with contractual ties.

''(3) FEE-FOR-SERVICE.—Fee-for-service individuals may select supplemental coverage from Medigap policies.

''SEC. 1860E–32. COMPETITION.

''(a) BID AREAS.—Market areas used for bid submissions for Medicare Advantage plans, ACOs, and for calculation per person fee-for-services costs shall be metropolitan statistical regions plus associated regions.

''(b) PREMIUMS.—Medicare payment benchmark by market area shall be calculated based on weighted average (by enrollment in previous year) of the premium bids from MA plans, ACOs, and the per person costs of fee-for-service, less the statutory part B premium.

''(c) BENEFICIARY RESPONSIBILITY.—Beneficiaries shall pay the difference between Medicare payment and

required premium of the plan they choose, and get 100 percent of the savings by choosing a plan with a premium below the benchmark.

''(d) TRANSITION.—For beneficiaries who are in fee-for-service at the time of the enactment of this section, there shall be a limit on the amount of a premium increase allowable by year of no more than $20 per month compared to what such premium would have otherwise been if this subpart had not been enacted for each year through the fifth year.

''(e) MULTIYEAR CONTRACTS.—A Medicare Advantage plan may offer to beneficiaries multiyear contracts with guaranteed premiums over such years, bearing the risk of any change in payments from the Secretary in subsequent years. A beneficiary enrolling under such a contract shall be exempt from the method described in subsection (a).''.

(b) CONFORMING AMENDMENTS.—

(1) Section 1853(a)(1)(A) of the Social Security Act is amended by striking ''and section 1859(e)(4)'' and inserting '', section 1859(e)(4), and subpart 3 of part E''.

(2) Section 1853(j) of such Act is amended by inserting ''and subpart 3 of part E'' after ''subsection (o)''.

(3) Section 1854 of such Act is amended—

(A) in subsection (a), after the heading, by inserting ''Subject to subpart 3 of part E:'';

(B) in subsection (b), after the heading, by inserting ''Subject to subpart 3 of part E:'';

(C) in subsection (d), after the heading, by inserting ''Subject to subpart 3 of part E:''; and

(D) in subsection (e), after the heading, by inserting ''Subject to subpart 3 of part E:''.

SEC. 422. NEW UNIFIED ELIGIBILITY AND ENROLLMENT RULES.

(a) IN GENERAL.—Title XVIII of the Social Security Act is amended—

(1) by redesignating part E as part F; and

(2) by inserting after part D the following new part:

''PART E—MEDICARE WITH CHOICE AND COMPETITION

''Subpart 1—Opt-Out and Auto-Enrollment

''SEC. 1860E–11. PART A OPT-OUT AND MA AUTO-ENROLLMENT.

''(a) PERMITTING INDIVIDUALS TO OPT OUT OF PART A COVERAGE WITHOUT LOSING SOCIAL SECURITY BENEFITS.—

''(1) IN GENERAL.—The Secretary shall establish—

''(A) a process by which an individual otherwise entitled to benefits under part A may elect (at a time and in a manner specified under the process) to waive such entitlement; and

''(B) a process by which an individual who elects to waive such entitlement may revoke (at a time and in a manner specified under the process) such waiver.

The process under subparagraph (B) shall be coordinated with the enrollment process under section 1837 for part B.

''(2) APPLICATION OF LATE ENROLLMENT PENALTY.—An individual who revokes a waiver under paragraph (1)(B) shall be subject to a late enrollment penalty as applied under section 1860E–32(c)(2)(C).

''(3) NO IMPACT ON TITLE II BENEFITS.—Notwithstanding any other provision of law, an election of an individual to waive entitlement to benefits under part A under paragraph (1)(A) shall not result in any loss of benefits under title II.

''(4) DEEMED OPT-OUT.—

"(A) An election of an individual to waive entitlement to benefits under part A under paragraph (1)(A) is also deemed the filing of a notice of termination of benefits under part B pursuant to section 1838(b)(1).

"(B) The termination of benefits under part B pursuant to section 1838(b) is also deemed to be a waiver of any entitlement to benefits under part A.

"(b) SPECIAL OPEN ENROLLMENT PERIOD WITHOUT LATE ENROLLMENT PENALTY FOR CURRENT PART A ONLY OR PART B ONLY ENROLLEES.—Notwithstanding any other provision of law, in the case of an individual who as of the general effective date, is entitled to benefits under part A but not enrolled under part B, or who is enrolled under part B but not entitled to benefits (or enrolled) under part A, beginning as of such date, such individual shall be deemed to be enrolled under part B or part A, respectively, unless such individual elects to be enrolled (or entitled to benefits) under neither of such parts during a special open enrollment period specified by the Secretary. No increase in the monthly premium of an individual pursuant to section 1839(b) or section 1818(c) shall be effected in the case of any such individual who is deemed enrolled under part B or part A pursuant to

the previous sentence with respect to any period prior to the date of such enrollment.

''(c) AUTO ENROLLMENT OF DUAL ELIGIBLE INDIVIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

''(1) IN GENERAL.—Except in the case of a State that has elected the maintenance of effort option described in section 1944(b)(2), in the case of an individual described in subparagraph (A)(ii) of section 1935(c)(6) (taking into account the application of subparagraph (B) of such section), the Secretary shall establish a process for the enrollment in an MA–PD plan that is a managed care plan under part C that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860E–41(b)(1)(A). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region.

''(2) RIGHT TO DISENROLL.—Nothing in paragraph (1) shall prevent such an individual from declining enrollment in any such plan (and thereby obtaining coverage under Medicare fee-for-service) or from changing enrollment in such a plan to another MA–PD plan.

"SEC. 1860E–12. COORDINATION WITH PART D.

"(a) DEEMED ENROLLMENT UNDER PART D.—

"(1) IN GENERAL.—The Secretary shall establish a process that, beginning as of the general effective date, provides for the enrollment in a prescription drug plan that has a monthly base beneficiary premium that does not exceed the weighted average of premiums for such plans that provide standard prescription drug coverage (as defined in section 1860D–2(b)) with respect to the area involved (on a random basis among all such plans in the applicable PDP region) of each Medicare enrollee (as defined in section 1860E–51) who—

"(A) failed to enroll in such a prescription drug plan during the applicable enrollment or coverage election period under section 1860D–1(b); and

"(B) failed to elect not to enroll in such a prescription drug plan during an applicable opt-out period described in paragraph (2).

Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment. Such process shall be carried out in the same manner as the process described in section 1860D–1(b)(1)(C).

''(2) OPT-OUT PERIODS.—The process under paragraph (1) shall provide for the opportunity to make an election described in subparagraph (B) of such paragraph during an opt-out period that is coordinated with the relevant enrollment or coverage election period under section 1860D–1.

''(3) LATE ENROLLMENT PENALTIES.—In the case of an individual who makes an election described in paragraph (1)(B) and then enrolls in a prescription drug plan, the late enrollment penalty under section 1860D–13(b) shall apply to the monthly beneficiary premium of such individual, except that in applying such section, any reference to the initial enrollment period of such individual shall be deemed to be a reference to the opt-out period under paragraph (2) during which the individual elected not to enroll in a prescription drug plan.

''(4) NO LATE ENROLLMENT PENALTY FOR CURRENT FEE-FOR-SERVICE BENEFICIARIES WITHOUT DRUG COVERAGE.—In the case of an individual who is a Medicare enrollee before the date of enactment of this section and who was not enrolled under a prescription drug plan before being enrolled under such a plan pursuant to paragraph (1), there shall be no increase in the base beneficiary premium of an

individual under section 1860D–13 by a late enrollment penalty under subsection (b) of such section with respect to any period prior to the date of such enrollment.

''(b) REFERENCE TO REQUIRED PRESCRIPTION DRUG COVERAGE UNDER PART C.—For provision requiring coverage under MA plans to include prescription drug coverage, see section 1860E–26.''.

(b) LIMITATION ON MEDICAID BENEFITS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following new subsection:

''(ll) LIMITATION ON BENEFITS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Effective as of the general effective date (as specified in section 1860E–62), except in the case of a State which has elected the option described in section 1944(b)(2), in the case of an individual described in subparagraph (A)(ii) of section 1935(c)(6) (taking into account the application of subparagraph (B) of such section), notwithstanding any other provision of law, medical assistance shall not be available under this title for any items and services for which payment may be made under title XVIII.''.

(c) MEDICAID MAINTENANCE OF EFFORT AND ALTERNATIVES.—Title XIX of the Social Security Act is

amended by inserting after section 1943 the following new section:

''MAINTENANCE OF EFFORT OPTIONS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS

''SEC. 1944. (a) IN GENERAL.—Effective as of the general effective date (as specified in section 1860E–62), a State shall elect, in a form and manner specified by the Secretary, a maintenance of effort option described in subsection (b). In the case of a State that fails to make such an election, the State shall be deemed to have elected the option described in subsection (b)(3).

''(b) MAINTENANCE OF EFFORT OPTIONS DESCRIBED.—The following are maintenance of effort options described in this subsection for a State, which shall apply to all individuals described in subparagraph (A)(ii) of section 1935(c)(6) (taking into account the application of subparagraph (B) of such section) for such State:

''(1) ENROLLMENT OF DUAL ELIGIBLES IN COMPREHENSIVE MEDICAID MANAGED CARE PLAN.—

''(A) IN GENERAL.—The State enrolls all such individuals in a comprehensive Medicaid managed care plan offered by a managed care entity under section 1932.

''(B) PAYMENT OF SUBSIDY AMOUNT TO STATE.—In the case of a State that elects the option under this paragraph with respect to an

individual, the Secretary established under section 1860E–51 shall pay to the State the same amount that the individual would be entitled to have paid as an income-related premium subsidy under section 1860E–41(b)(1)(A) plus the amount that the Secretary estimates would have been paid with respect to the individual under part D (including the actuarial value of subsidy payments under sections 1860D–13 and 1860D–14). Such payment shall be made in appropriate part from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841.

''(C) RELATION TO PART D RULES.—In the case of a State that has elected the option under this paragraph, notwithstanding any other provision of law—

''(i) the coverage provided under this option shall be in lieu of any coverage that may otherwise be provided under part D; and

''(ii) the payment to the State under subparagraph (B) shall be in lieu of any

payments otherwise made with respect to such individual under such part.

''(2) OTHER INNOVATIVE ALTERNATIVES.—

''(A) IN GENERAL.—The State submits to the Secretary, and has approved by the Secretary, an innovative alternative proposal relating to coordinating coverage of such individuals under Medicare and the State plan under title XIX.

''(B) PROCESS FOR REVIEW.—With respect to proposals submitted to the Secretary under subparagraph (A), the Secretary shall approve such a proposal if the State demonstrates with respect to the proposal that—

''(i) there would be no increased cost to the Federal Government if it were approved; and

''(ii) there would be no reduction in the quality of care provided to such individuals if the proposal were approved.''.

(d) CONFORMING AMENDMENTS.—

(1) SECTION 226.—Section 226 of the Social Security Act (42 U.S.C. 426) is amended—

(A) in subsection (a), in the matter preceding paragraph (1), by inserting ", subject to section 1860E–11(a)" after "individual who";

(B) in subsection (b), in the matter preceding paragraph (1), by inserting ", subject to section 1860E–11(a)" after "individual who"; and

(C) in subsection (c), in the matter preceding paragraph (1), by inserting ", subject to section 1860E–11(a)" after "subsection (a)".

(2) SECTION 226A.—Section 226A(a) of such Act (42 U.S.C. 426–1(a)) is amended, in the matter preceding paragraph (1), by inserting "and subject to section 1860E–11(a)" after "or title XVIII".

(3) SECTION 1932.—Section 1932(a)(2)(B) of the Social Security Act (42 U.S.C. 1396u–2(a)(2)(B)) is amended by striking "A State" and inserting "Except in the case of a State that has elected the maintenance of effort option described in section 1944(b)(2), a State".

SEC. 423. NEW BENEFIT STRUCTURE UNDER UNIFIED MEDICARE.

(a) IN GENERAL.—Part E of title XVIII of the Social Security Act, as added by section 251, is amended by adding at the end the following:

"Subpart 2—Out-of-Pocket Limit

"SEC. 1860E–21. OUT-OF-POCKET LIMIT.

''(a) IN GENERAL.—Beginning with 2021, in the case of a Medicare enrollee, if the amount of the out-of-pocket cost-sharing of such enrollee for a calendar year equals or exceeds the catastrophic limit under subsection (b) for that year—

''(1) the enrollee shall not be responsible for additional out-of-pocket cost-sharing incurred during that year; and

''(2) the Secretary shall establish procedures under which the Secretary shall, in appropriate part from the Part A Medicare FFS Account under section 1817 and the Part B Medicare FFS Account under section 1841—

''(A) pay on behalf of the enrollee the amount of the additional out-of-pocket cost-sharing described in paragraph (1) attributable to deductibles and coinsurance described in subsection (c)(1); and

''(B) reimburse the enrollee the amount of the additional out-of-pocket cost-sharing described in paragraph (1) attributable to deductibles and coinsurance described in subsection (c)(2).

''(b) CATASTROPHIC LIMIT.—The amount of the catastrophic limit under this subsection for a year shall be the dollar amount in effect under section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986 for self-only coverage for taxable years beginning in such year.

''(c) OUT-OF-POCKET COST-SHARING DEFINED.—In this section, the term 'out-of-pocket cost-sharing' means, with respect to an individual, the amount of costs incurred by the individual that are attributable to—

''(1) deductibles and coinsurance imposed under part A or part B; and

''(2) deductibles and coinsurance imposed under standard prescription drug coverage pursuant to section 1860D–2(b) or alternative prescription drug coverage pursuant to section 1860D–2(c) offered by a prescription drug plan.''.

(b) APPLICATION OF OUT-OF-POCKET LIMIT TO MA–PD PLANS.—

(1) IN GENERAL.—Section 1852(a)(1)(B) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(B)) is amended—

(A) in clause (i), by striking ''clause (iii)'' and inserting ''clauses (iii) and (vi)''; and

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

"(vi) OUT-OF-POCKET LIMIT.—The provisions of section 1860E–21—

"(I) shall apply to individuals enrolled under an MA–PD plan in the same manner as such provisions apply to Medicare enrollees under such section, except that in lieu of the application of subsection (a)(2) of such section the MA–PD plan shall establish procedures to provide for payment of any additional out-of-pocket cost-sharing described in subsection (a)(1) of such section incurred by individuals enrolled under the MA–PD plan; and

"(II) as applied under subclause (I), may not be waived by application of this subparagraph.

In applying subsection (b) of section 1860E–21 pursuant to the previous sentence, an MA–PD plan may substitute a dollar amount that is less than the dollar amount specified under such subsection.".

(2) EXEMPTING MA–PD PLANS OFFERING ALTERNATIVE PRESCRIPTION DRUG COVERAGE FROM PART D DEDUCTIBLE AND OUT-OF-POCKET LIMIT

REQUIREMENTS.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended—

(A) in paragraph (2), by striking ''The deductible'' and inserting ''In the case of a prescription drug plan, the deductible''; and

(B) in paragraph (3), by striking ''The coverage provides'' and inserting ''In the case of a prescription drug plan, the coverage provides''.

(c) PRESCRIPTION DRUG PLANS REQUIRED TO REPORT ENROLLEES' OUT-OF-POCKET COST-SHARING.—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) OUT-OF-POCKET COST-SHARING REPORTS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require that, with respect to each claim submitted for items or services furnished to an individual enrolled under the plan pursuant to the contract, the sponsor submits to the Secretary information on the amount of out-of-pocket cost-sharing (as defined in section

1860E–23(c)) applicable to such enrollee for such items or services.''.

(d) CONFORMING AMENDMENTS.—

(1) Section 1813 of the Social Security Act (42 U.S.C. 1395e) is amended—

(A) in subsection (a), by inserting ''Subject to subpart 2 of part E:'' before paragraph (1); and

(B) in subsection (b), by inserting ''Subject to subpart 2 of part E:'' before paragraph (1).

(2) Section 1833 of such Act (42 U.S.C. 1395l) is amended—

(A) in subsection (a), in the matter preceding paragraph (1), by inserting ''and subpart 2 of part E'' after ''succeeding provisions of this section'';

(B) in subsection (b), in the first sentence, by striking ''Before applying'' and inserting ''Subject to subpart 2 of part E, before applying'';

(C) in subsection (c)(1), in the matter preceding subparagraph (A), by inserting ''subject to subpart 2 of part E,'' after ''this part,'';

(D) in subsection (f), by striking ''In establishing'' and inserting ''Subject to subpart 2 of part E, in establishing''; and

(E) in subsection (g)(1), by inserting ''and subpart 2 of part E'' and ''paragraphs (4) and (5)''.

(3) Section 1882(a)(2) of such Act is amended by striking ''No medicare'' and inserting ''Subject to section 1860E–24(c), no medicare''.

SEC. 424. LATE ENROLLMENT PENALTY NOT TO APPLY FOR MONTHS OF ANY HEALTH COVERAGE.

(a) IN GENERAL.—Section 1839(b) of the Social Security Act (42 U.S.C. 1395r) is amended in the second sentence, by inserting before the period at the end the following: ''or months during which the individual has any other health coverage''.

(b) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply for months of coverage beginning after the date of the enactment of this Act.

SEC. 425. MEDIGAP REFORM.

Notwithstanding any provision of section 1882 of the Social Security Act (42 U.S.C. 1395ss), as of the date of the enactment of this Act, no policy may be offered under such section that does not provide guaranteed coverage (without regard to an individual's preexisting condi-

tions, if any) to all individuals eligible to enroll under such policy.

SEC. 426. ACO REVISION.

(a) ENROLLMENT.—Enrollment in such an ACO under such title shall be based on the method established under part E of such title. Such a network shall bear full risk in the event payments under such title do not equal or exceed liabilities under such network.

(b) DIRECTION OF PAYMENT.—An ACO may direct that any payments under such title be made to a centralized entity rather than to an individual provider or supplier.

(c) BIDS.—The Secretary of Health and Human Services shall establish a process whereby such networks compete using a bidding process similar to that described in part E of such title for Medicare Advantage plans.

SEC. 427. PRIMARY CARE OPTIONS.

(a) SELECTION OF PRIMARY CARE PHYSICIAN.—The Secretary shall establish a mechanism under which an individual enrolled under part B of title XVIII of the Social Security Act may select such individual's primary care physician. Such an individual shall not be liable for more than $5 for each visit to such selected physician.

(b) PAYMENT TO PHYSICIAN.—A physician selected under subsection (a) shall receive a monthly fee in lieu

of any other payment under such part B for evaluation and monitoring of such individual. The Secretary shall provide a list of standardized benefits that are included in such payment, including telephone and email communications, office visits, preventive care, and vaccinations.

SEC. 428. GENERAL PROVISIONS; EFFECTIVE DATE.

Part E of title XVIII of the Social Security Act, as inserted by section 101(a)(2) and as previously amended, is further amended by adding at the end the following new subpart:

"Subpart 5.—General Provisions

"SEC. 1860E–51. APPLICABILITY; DEFINITIONS.

''(a) IN GENERAL.—The provisions of this Act are superseded to the extent inconsistent with the provisions of this part.

''(b) TERMINOLOGY.—For purposes of this part:

''(1) MEDICARE ENROLLEE.—

''(A) IN GENERAL.—The term 'Medicare enrollee' means—

''(i) an individual entitled to (or enrolled for benefits) under part A and enrolled under part B; and

''(ii) except as otherwise specified, an individual described in section 1860E–11(a)(3).

''(B) TREATMENT.—Any reference in this Act (or any other Act) in effect before the date of the enactment of this part, to an individual entitled to benefits under part A or enrolled under part B shall be deemed a reference to a Medicare enrollee.

''(2) MEDICARE FEE-FOR-SERVICE.—The term 'Medicare fee-for-service' means the original Medicare fee-for-service program under parts A and B, as modified by this part, and does not include part C or part D.

''(3) MEDICARE FEE-FOR-SERVICE ENROLLEE.—The term 'Medicare fee-for-service enrollee' means a Medicare enrollee who is not enrolled under a Medicare Advantage plan under part C.

''SEC. 1860E–61. GENERAL EFFECTIVE DATE.

''Except as otherwise specified, the provisions of this part shall apply to items and services furnished on or after January 1, 2021, and to plan years beginning on or after such date (referred to in this title as the 'general effective date').''.

Subtitle D—Telehealth Improvements and Expansion

SEC. 431. 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, occupational 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 renewed 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 services (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 patient 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. 432. EXPANDING THE USE OF TELEHEALTH THROUGH THE WAIVER OF CERTAIN REQUIREMENTS.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (4)(C)(i), by striking ''and (7)'' and inserting ''(7), and (8)''; and

(2) by adding at the end the following:

''(8) AUTHORITY TO WAIVE REQUIREMENTS AND LIMITATIONS IF CERTAIN CONDITIONS MET.—

''(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, in the case of telehealth services furnished on or after January 1, 2021, the Secretary may waive any restriction applicable to payment for telehealth services under this subsection that is described in subparagraph (B), but only if the Secretary determines that such waiver would not deny or limit the coverage or provision of benefits under this title, and—

''(i) the Secretary determines that the waiver is expected to reduce spending under this title without reducing the qual-

ity of care or improve the quality of patient care without increasing spending; or

"(ii) the waiver would apply to telehealth services furnished in originating sites located in a high-need health professional shortage area (as designated pursuant to section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A))).

"(B) RESTRICTIONS DESCRIBED.—For purposes of this paragraph, restrictions applicable to payment for telehealth services under paragraph (1) are—

"(i) requirements relating to qualifications for an originating site under paragraph (4)(C)(ii);

"(ii) any geographic limitations under paragraph (4)(C)(i) (other than applicable State law requirements, including State licensure requirements);

"(iii) any limitation on the type of technology used to furnish telehealth services;

"(iv) any limitation on the type of provider of services or supplier who may

furnish telehealth services (other than the requirement that the provider of services or supplier is enrolled under this title);

"(v) any limitation on specific services designated as telehealth services pursuant to this subsection (provided the Secretary determines that such services are clinically appropriate to furnish remotely); or

"(vi) any other limitation relating to the furnishing of telehealth services under this title identified by the Secretary.

"(C) PUBLIC COMMENT.—The Secretary shall establish a process by which stakeholders may (on at least an annual basis) provide public comment for waivers under this paragraph.

"(D) PERIODIC REVIEW OF WAIVERS.—The Secretary shall periodically, but not more often than every 3 years, reassess each waiver under this paragraph to determine whether the waiver continues to meet the conditions applicable under subparagraph (A).".

(b) POSTING OF INFORMATION.—Not later than 2 years after the date on which a waiver under section 1834(m)(8) of the Social Security Act, as added by subsection (a), first becomes effective, and at least biennially

thereafter, the Secretary of Health and Human Services shall post on the internet website of the Centers for Medicare & Medicaid Services—

(1) the number of Medicare beneficiaries receiving telehealth services by reason of each waiver under such section;

(2) the impact of such waivers on expenditures and utilization under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.); and

(3) other outcomes, as determined appropriate by the Secretary.

SEC. 433. EXPANDING THE USE OF TELEHEALTH FOR MENTAL HEALTH SERVICES.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), as amended by the preceding sections, is amended—

(1) in paragraph (4)(C)(i), by striking ''and (8)'' and inserting ''(8), and (9)''; and

(2) by adding at the end the following:

''(9) TREATMENT OF MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH.—The geographic requirements described in paragraph (4)(C)(i) (other than applicable State law requirements, including State licensure requirements) shall not apply with respect to telehealth services that are

mental health services (as determined by the Secretary) furnished on or after January 1, 2021, to an eligible telehealth individual at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph).''.

(b) INCLUSION OF THE HOME AS AN ORIGINATING SITE.—Section 1834(m)(4)(C)(ii)(X) of such Act (42 U.S.C. 1395m(m)(4)(C)(ii)(X)) is amended by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (9)''.

(c) ADDITIONAL SERVICES.—As part of the implementation of the amendments made by this section, the Secretary of Health and Human Services shall consider whether additional services should be added to the services specified in paragraph (4)(F)(i) of section 1834(m) of such Act (42 U.S.C. 1395m) for authorized payment under paragraph (1) of such section.

SEC. 434. USE OF TELEHEALTH IN EMERGENCY MEDICAL CARE.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), as amended by the preceding sections, is amended—

(1) in paragraph (4)(C)(i), by striking ''and (9)'' and inserting ''(9), and (10)''; and

(2) by adding at the end the following:

"(10) TREATMENT OF EMERGENCY MEDICAL CARE FURNISHED THROUGH TELEHEALTH.—The geographic requirements described in paragraph (4)(C)(i) (other than applicable State law requirements, including State licensure requirements) shall not apply with respect to telehealth services that are services for emergency medical care (as determined by the Secretary) furnished on or after January 1, 2021, to an eligible telehealth individual at an originating site described in subclause (II), (V), or (VII) of paragraph (4)(C)(ii).".

(b) ADDITIONAL SERVICES.—As part of the implementation of the amendments made by this section, the Secretary of Health and Human Services shall consider whether additional services should be added to the services specified in paragraph (4)(F)(i) of section 1834(m) of such Act (42 U.S.C. 1395m) for authorized payment under paragraph (1) of such section.

SEC. 435. IMPROVEMENTS TO THE PROCESS FOR ADDING TELEHEALTH SERVICES.

The Secretary shall undertake a review of the process established pursuant to section 1834(m)(4)(F)(ii) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)(ii)), and based on the results of such review—

(1) implement revisions to the process so that the criteria to add services prioritizes, as appropriate, improved access to care through telehealth services; and

(2) provide clarification on what requests to add telehealth services under such process should include.

SEC. 436. RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.

(a) EXPANSION OF ORIGINATING SITES.—Section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)), as amended by the preceding sections, is amended—

(1) in clause (i), by striking ''and (10)'' and inserting ''and (10), and subject to clause (iii),''; and

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

''(iii) RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—The term 'originating site' shall also include any Federally qualified health center and any rural health clinic (as such terms are defined in section 1861(aa)) at which the eligible telehealth individual is located at the time the service is furnished

via a telecommunications system, whether or not the individual is located in an area described in clause (i), insofar as such sites are not otherwise included in the definition of originating site under such clause, subject to applicable State law requirements, including State licensure requirements.''.

(b) EXPANSION OF DISTANT SITES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in the first sentence of paragraph (1)—

(A) by striking ''or a practitioner (described in section 1842(b)(18)(C))'' and inserting '', a practitioner (described in section 1842(b)(18)(C)), a Federally qualified health center, or a rural health clinic''; and

(B) by striking ''or practitioner'' and inserting '', practitioner, Federally qualified health center, or rural health clinic'';

(2) in paragraph (2)(A)—

(A) by inserting ''or to a Federally qualified health center or rural health clinic that serves as a distant site'' after ''a distant site''; and

(B) by striking ''such physician or practitioner'' and inserting ''such physician, practitioner, Federally qualified health center, or rural health clinic''; and

(3) in paragraph (4)—

(A) in subparagraph (A), by inserting ''and includes a Federally qualified health center or rural health clinic that furnishes a telehealth service to an eligible individual'' before the period at the end; and

(B) in subparagraph (F), by adding at the end the following new clause:

''(iii) INCLUSION OF RURAL HEALTH CLINIC SERVICES AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FURNISHED USING TELEHEALTH.—For purposes of this subparagraph, the term 'telehealth services' includes a rural health clinic service or Federally qualified health center service that is furnished using telehealth to the extent that payment codes corresponding to services identified by the Secretary under clause (i) or (ii) are listed on the corresponding claim for such rural

health clinic service or Federally qualified health center service.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2021.

SEC. 437. NATIVE AMERICAN HEALTH FACILITIES.

(a) IN GENERAL.—Section 1834(m)(4)(C) of the Social Security Act (42 U.S.C. 1395m(m)(4)(C)), as amended by the preceding sections, is amended—

(1) in clause (i), by striking ''clause (iii)'' and inserting ''clauses (iii) and (iv)''; and

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

''(iv) NATIVE AMERICAN HEALTH FACILITIES.—The originating site requirements described in clauses (i) and (ii) shall not apply with respect to a facility of the Indian Health Service, whether operated by such Service, or by an Indian tribe (as that term is defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)) or a tribal organization (as that term is defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304)), or a fa-

cility of the Native Hawaiian health care systems authorized under the Native Hawaiian Health Care Improvement Act (42 U.S.C. 11701 et seq.).''.

(b) NO ORIGINATING SITE FACILITY FEE FOR NEW SITES.—Section 1834(m)(2)(B)(i) of the Social Security Act (42 U.S.C. 1395m(m)(2)(B)(i)) is amended, in the matter preceding subclause (I), by inserting ''(other than an originating site that is only described in clause (iv) of paragraph (4)(C), and does not meet the requirement for an originating site under clause (i) of such paragraph)'' after ''the originating site''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2021.

SEC. 438. WAIVER OF TELEHEALTH RESTRICTIONS DURING NATIONAL EMERGENCIES.

Section 1135(b) of the Social Security Act (42 U.S.C. 1320b–5(b)) is amended—

(1) in paragraph (6), by striking ''and'' after the semicolon;

(2) in paragraph (7), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(8) requirements for payment for telehealth services under section 1834(m).''.

SEC. 439. USE OF TELEHEALTH IN RECERTIFICATION FOR HOSPICE CARE.

(a) IN GENERAL.—Section 1814(a)(7)(D)(i) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)) is amended by inserting ''(including through use of telehealth, notwithstanding the requirements in section 1834(m)(4)(C))'' after ''face-to-face encounter''.

(b) GAO REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a report to Congress evaluating the impact of the amendment made by subsection (a) on—

(1) the number and percentage of beneficiaries recertified for the Medicare hospice benefit at 180 days and for subsequent benefit periods;

(2) the appropriateness for hospice care of the patients recertified through the use of telehealth; and

(3) any other factors determined appropriate by the Comptroller General.

SEC. 440. CLARIFICATION FOR FRAUD AND ABUSE LAWS REGARDING TECHNOLOGIES PROVIDED TO BENEFICIARIES.

Section 1128A(i)(6) of the Social Security Act (42 U.S.C. 1320a–7a(i)(6)) is amended—

(1) in subparagraph (I), by striking ''; or'' and inserting a semicolon;

(2) in subparagraph (J), by striking the period at the end and inserting ''; or''; and

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

''(K) the provision of technologies (as defined by the Secretary) on or after the date of the enactment of this subparagraph, by a provider of services or supplier (as such terms are defined for purposes of title XVIII) directly to an individual who is entitled to benefits under part A of title XVIII, enrolled under part B of such title, or both, for the purpose of furnishing telehealth services, remote patient monitoring services, or other services furnished through the use of technology (as defined by the Secretary), if—

''(i) the technologies are not offered as part of any advertisement or solicitation; and

''(ii) the provision of the technologies meets any other requirements set forth in regulations promulgated by the Secretary.''.

SEC. 441. STUDY AND REPORT ON INCREASING ACCESS TO TELEHEALTH SERVICES IN THE HOME.

(a) MEDPAC STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ''Commission'') shall conduct a study on increasing access under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to telehealth services in the home. Such study shall include an analysis of the following:

(1) How different payers allow the home to be an originating site for telehealth services.

(2) Particular types of telehealth services or subgroups of beneficiaries with respect to which allowing the home to be an originating site under the Medicare program would be suitable.

(b) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Commission shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Commission determines appropriate.

SEC. 442. ANALYSIS OF TELEHEALTH WAIVERS IN ALTERNATIVE PAYMENT MODELS.

The second sentence of section 1115A(g) of the Social Security Act (42 U.S.C. 1315a(g)) is amended by inserting ''an analysis of waivers under section (d)(1) related to telehealth and the impact on quality and spending under the applicable titles of such waivers,'' after ''subsection (c),''.

SEC. 443. MODEL TO ALLOW ADDITIONAL HEALTH PROFESSIONALS TO FURNISH TELEHEALTH SERVICES.

Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the end the following new clause:

''(xxviii) Allowing health professionals who are not otherwise eligible under section 1834(m) to furnish telehealth services to furnish such services.''.

SEC. 444. TESTING OF MODELS TO EXAMINE THE USE OF TELEHEALTH UNDER THE MEDICARE PROGRAM.

Section 1115A(b)(2) of the Social Security Act (42 U.S.C. 1315a(b)(2)) is amended by adding at the end the following new subparagraph:

''(D) TESTING MODELS TO EXAMINE USE OF TELEHEALTH UNDER MEDICARE.—The Sec-

retary shall consider testing under this subsection models to examine the use of telehealth under title XVIII.''.

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