

116TH CONGRESS
1ST SESSION

H. R. 1332

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

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2019

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Fair Care Act of 2019”.

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

Sec. 1. Short title; table of contents.

TITLE I—PRIVATE-SECTOR HEALTH INSURANCE REFORMS

Subtitle A—Commercial Health Insurance Provisions

- Sec. 101. Invisible high risk pool reinsurance program; tax on exchange plans.
 Sec. 102. Change in permissible age variation in health insurance premium rates.
 Sec. 103. Employer health insurance mandate repeal.
 Sec. 104. Employer benefits reports.
 Sec. 105. Waivers for State innovation.
 Sec. 106. State-operated Exchanges flexibility for open enrollment periods.
 Sec. 107. Enrollment periods.
 Sec. 108. Short-term limited duration insurance.
 Sec. 109. Promoting health plans that cover individuals in more than one State.
 Sec. 110. Restoring the application of antitrust laws to the business of health insurance.
 Sec. 111. Health plans created under PPACA or offered through Exchanges to be only health plans Federal Government may make available to President, Vice President, Members of Congress, and Federal employees.
 Sec. 112. Cost-sharing reductions.
 Sec. 113. Health savings accounts.
 Sec. 114. Adding copper plans to Exchanges.
 Sec. 115. Eliminating FEHBP eligibility for annuitants.

Subtitle B—Association Health Plans

- Sec. 121. Rules governing association health plans.
 Sec. 122. Clarification of treatment of single employer arrangements.
 Sec. 123. Enforcement provisions relating to association health plans.
 Sec. 124. Cooperation between Federal and State authorities.
 Sec. 125. Effective date and transitional and other rules.

Subtitle C—Tax-Related Provisions

- Sec. 131. Premium assistance adjustment to reflect age.
 Sec. 132. Repeal of annual fee on health insurance providers.
 Sec. 133. Repeal of medical device excise tax.
 Sec. 134. Inclusion in income of certain costs of employer-provided coverage under health plans.
 Sec. 135. Inclusion of certain over-the-counter medical products as qualified medical expenses.
 Sec. 136. Repeal of limitation on health flexible spending arrangements.
 Sec. 137. Medicare part D tax deduction.
 Sec. 138. Repeal of net investment income tax.
 Sec. 139. Basis for purposes of determining gain or loss.
 Sec. 140. Deduction for qualified charity care.
 Sec. 141. Limitation on liability for volunteer health care professionals.

TITLE II—MEDICARE AND MEDICAID REFORMS

Subtitle A—Medicare and Medicaid Reforms

- Sec. 201. Flexible block grant option for States.
 Sec. 202. Medicaid eligibility determinations.

- Sec. 203. Lowering safe harbor threshold with respect to State taxes on health care providers.
- Sec. 204. Income limitations for refundable credits for coverage under a qualified health plan.

Subtitle B—Medicare

- Sec. 221. Off-campus provider-based department medicare site neutral payment.
- Sec. 222. Elimination of Medicare eligibility for certain individuals.
- Sec. 223. Medicare coverage of bad debt.

Subtitle C—Medical Malpractice Reform

- Sec. 231. Encouraging speedy resolution of claims.
- Sec. 232. Compensating patient injury.
- Sec. 233. Maximizing patient recovery.
- Sec. 234. Authorization of payment of future damages to claimants in health care lawsuits.
- Sec. 235. Product liability for health care providers.
- Sec. 236. Definitions.
- Sec. 237. Effect on other laws.
- Sec. 238. Rules of construction.
- Sec. 239. Effective date.
- Sec. 240. Limitation on expert witness testimony.
- Sec. 241. Communications following unanticipated outcome.
- Sec. 242. Expert witness qualifications.
- Sec. 243. Affidavit of merit.
- Sec. 244. Notice of intent to commence lawsuit.

TITLE III—PRESCRIPTION DRUG COMPETITION

Subtitle A—Eliminating Delays of Generic Drugs and Biosimilar Products

- Sec. 301. Actions for delays of generic drugs and biosimilar biological products.
- Sec. 302. REMS approval process for subsequent filers.

Subtitle B—Increasing Access to Drugs and Biosimilar Products

- Sec. 311. Expedited development and priority review for generic complex drug products.
- Sec. 312. Increasing pharmaceutical options to treat an unmet medical need.
- Sec. 313. Preemption of State barriers to the substitution of biosimilar products.

Subtitle C—Limiting Exclusivity Periods Delaying Competition

- Sec. 321. Limiting exclusivity periods for drugs treating rare diseases and conditions.
- Sec. 322. Limiting exclusivity for biosimilar products.

Subtitle D—Congressional Review of Agency Rulemaking

- Sec. 331. Congressional review of the Food and Drug Administration rulemaking.
- Sec. 332. Government Accountability Office study of rules.

Subtitle E—Medicare Prescription Drug Competition

- Sec. 341. Medicare drug coverage.
 Sec. 342. PBM transparency and elimination of DIR fees.
 Sec. 343. Sunset of limit on maximum rebate amount for single source drugs and innovator multiple source drugs.
 Sec. 344. Regulation of manufacturer-sponsored copay contributions.
 Sec. 345. Data reporting to improve the transparency regarding how 340B hospital covered entities provide care for patients.
 Sec. 346. Requiring 340B drug discount program reports by DSH hospital covered entities on low-income utilization rate of outpatient hospital services.

TITLE IV—PROVIDER COMPETITION

- Sec. 401. Hospital consolidation.
 Sec. 402. Price transparency.
 Sec. 403. Repealing shared savings incentives from Medicare shared savings program.
 Sec. 404. Repeal of health care reform provisions limiting Medicare exception to the prohibition on certain physician referrals for hospitals.
 Sec. 405. Advisory group on reducing burden of hospital administrative requirements.
 Sec. 406. Authority of Federal Trade Commission over certain tax-exempt organizations.

TITLE V—DIGITAL HEALTH CARE

- Sec. 501. Access of individuals to protected health information.
 Sec. 502. Expansion of coverage of telehealth services.
 Sec. 503. STARK and AKS exemptions.
 Sec. 504. STARK technical penalty.

1 **TITLE I—PRIVATE-SECTOR**
 2 **HEALTH INSURANCE REFORMS**
 3 **Subtitle A—Commercial Health**
 4 **Insurance Provisions**

5 **SEC. 101. INVISIBLE HIGH RISK POOL REINSURANCE PRO-**
 6 **GRAM; TAX ON EXCHANGE PLANS.**

7 (a) ESTABLISHMENT.—Not later than January 1,
 8 2021, the Secretary of Health and Human Services shall
 9 establish the Invisible High Risk Pool Reinsurance Pro-
 10 gram (in this section referred to as the “IHRPR pro-
 11 gram”).

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

9 (c) FEDERAL DEFAULT.—

10 (1) IN GENERAL.—In the case of a State that
11 does not, by a date and in a manner specified by the
12 Secretary, choose to be awarded a grant under sub-
13 section (b) for a fiscal year to operate a qualifying
14 invisible high risk pool for the State, the Secretary
15 shall, from amounts appropriated under subsection
16 (f) for such fiscal year, use the allocation determined
17 for the State under subsection (d) for participation
18 of such State in the Federal default qualifying invis-
19 ible high risk pool described in paragraph (2).

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

1 risk pool under which health insurance issuers par-
2 ticipating in the Exchange of such a State, with re-
3 spect to designated individuals who are enrolled in
4 health insurance coverage and are expected to expe-
5 rience higher than average health costs as deter-
6 mined by the insurer, cede risk to the pool, without
7 affecting the premium paid by the designated indi-
8 viduals or their terms of coverage. With respect to
9 such pool—

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

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

17 (C) the ceding issuer shall retain the same
18 risk under the ceded policies as under any other
19 policy of the issuer with respect to the first
20 \$10,000 of benefits for each ceded policy in-
21 volved and will not retain any risk under ceded
22 policies after such first \$10,000 of benefits; and

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

1 negotiated rate under such policy for items and
2 services shall be payable at the reimbursement
3 rate under the Medicare program under title
4 XVIII of the Social Security Act for such items
5 and services, or in the case of items and serv-
6 ices for which payment is available under the
7 policy but not the Medicare program, at a rate
8 determined by the Secretary.

9 (d) ALLOCATION METHODOLOGY.—Not later than
10 June 30, 2020, the Secretary shall specify an allocation
11 methodology for determining the amount of funds appro-
12 priated under subsection (f) for a fiscal year to be allo-
13 cated for each State for purposes of subsections (b) and
14 (c). Such methodology shall be based on the number of
15 residents of each State and the general health status of
16 such residents.

17 (e) QUALIFYING INVISIBLE HIGH RISK POOL.—For
18 purposes of this section, the term “qualifying invisible
19 high risk pool” means, with respect to a State, a method
20 of designation under which health insurance issuers iden-
21 tify individuals who experience higher than average health
22 costs as determined by the State and are enrolled in health
23 insurance coverage offered in the individual market, and
24 cede the risk of spending more than \$10,000 on health
25 care services for a single individual to the pool without

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

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

7 (2) the applicable attachment points or coinsur-
8 ance percentages if the ceding issuer retains any
9 portion of the risk under ceded policies, except that
10 the provisions of subparagraphs (C) and (D) of sub-
11 section (c)(2) shall apply to such high risk pool in
12 the same manner as such clauses apply to the Fed-
13 eral default high risk pool; and

14 (3) the mechanism by which high-risk individ-
15 uals are designated for cession to the pool, which
16 may include a list of designated high-cost health
17 conditions.

18 (f) APPROPRIATIONS.—There is appropriated to the
19 Secretary of Health and Human Services
20 \$200,000,000,000 to carry out this section for the period
21 of fiscal year 2020 through fiscal year 2029.

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

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

4 **“Subchapter C—Additional Tax on Health In-**
5 **surance Plans Sold by Insurers Offering**
6 **Plans on Exchanges**

 “Sec. 4401. Additional tax on health insurance plans sold by insurers offering
 plans on exchanges.

7 **“SEC. 4401. ADDITIONAL TAX ON HEALTH INSURANCE**
8 **PLANS SOLD BY INSURERS OFFERING PLANS**
9 **ON EXCHANGES.**

10 “(a) IMPOSITION OF TAX.—There is imposed a tax
11 of \$4 for each policy month of each health insurance policy
12 sold by insurers offering plans through an Exchange es-
13 tablished under the Patient Protection and Affordable
14 Care Act.

15 “(b) LIABILITY.—The tax imposed by subsection (a)
16 shall be paid by the plan sponsor.”.

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

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

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

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

3 Section 2701(a)(1)(A)(iii) of the Public Health Serv-
4 ice Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by in-
5 serting after “(consistent with section 2707(c))” the fol-
6 lowing: “or, for plan years beginning on or after January
7 1, 2020, as the Secretary may implement through interim
8 final regulation, 5 to 1 for adults (consistent with section
9 2707(c))”.

10 **SEC. 103. EMPLOYER HEALTH INSURANCE MANDATE RE-**
11 **PEAL.**

12 (a) IN GENERAL.—Chapter 43 of the Internal Rev-
13 enue Code of 1986 is amended by striking section 4980H.

14 (b) REPEAL OF RELATED REPORTING REQUIRE-
15 MENTS.—Subpart D of part III of subchapter A of chap-
16 ter 61 of such Code is amended by striking section 6056.

17 (c) CONFORMING AMENDMENTS.—

18 (1) Section 6724(d)(1)(B) of such Code is
19 amended by inserting “or” at the end of clause
20 (xxiii), by striking “or” at the end of clause (xxiv),
21 and by striking clause (xxv).

22 (2) Section 6724(d)(2) of such Code is amend-
23 ed by inserting “or” at the end of subparagraph
24 (GG) and by striking subparagraph (HH).

1 (3) The table of sections for chapter 43 of such
2 Code is amended by striking the item relating to sec-
3 tion 4980H.

4 (4) The table of sections for subpart D of part
5 III of subchapter A of chapter 61 of such Code is
6 amended by striking the item relating to section
7 6056.

8 (5) Section 1513 of the Patient Protection and
9 Affordable Care Act is amended by striking sub-
10 section (c).

11 (d) EFFECTIVE DATE.—

12 (1) IN GENERAL.—Except as otherwise pro-
13 vided in this subsection, the amendments made by
14 this section shall apply to months and other periods
15 beginning after December 31, 2020.

16 (2) REPEAL OF STUDY AND REPORT.—The
17 amendment made by subsection (c)(5) shall take ef-
18 fect on the date of the enactment of this Act.

19 **SEC. 104. EMPLOYER BENEFITS REPORTS.**

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

1 (1) The amount the sponsor of such group
2 health plan expended with respect to such individual
3 under such plan for such plan year (or, in the case
4 of a health insurance issuer offering group health in-
5 surance coverage, the amount the employer of such
6 individual contributed for such coverage for such in-
7 dividual for such plan year).

8 (2) The amount the sponsor of such group
9 health plan expended with respect to such individual
10 under such plan for each previous plan year (or, in
11 the case of a health insurance issuer offering group
12 health insurance coverage, the amount the employer
13 of such individual contributed for such coverage for
14 such individual for each previous plan year), if appli-
15 cable.

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

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

1 monetary penalty on the sponsor of such plan or such
2 issuer, as applicable, in an amount not to exceed \$100
3 per individual enrolled in such plan or such coverage per
4 day that such sponsor or issuer failed to provide such noti-
5 fication to such individual.

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

11 **SEC. 105. WAIVERS FOR STATE INNOVATION.**

12 (a) STREAMLINING THE STATE APPLICATION PROC-
13 ESS.—Section 1332 of the Patient Protection and Afford-
14 able Care Act (42 U.S.C. 18052) is amended—

15 (1) in subsection (a)(1)(C), by striking “the
16 law” and inserting “a law or has in effect a certifi-
17 cation”; and

18 (2) in subsection (b)(2)—

19 (A) in the paragraph heading, by inserting
20 “OR CERTIFY” after “LAW”;

21 (B) in subparagraph (A)—

22 (i) by striking “A law” and inserting
23 the following:

24 “(i) LAWS.—A law”; and

1 (ii) by adding at the end the fol-
2 lowing:

3 “(ii) CERTIFICATIONS.—A certifi-
4 cation described in this paragraph is a doc-
5 ument, signed by the Governor of the
6 State, that certifies that such Governor
7 has the authority under existing Federal
8 and State law to take action under this
9 section, including implementation of the
10 State plan under subsection (a)(1)(B).”;
11 and

12 (C) in subparagraph (B)—

13 (i) in the subparagraph heading, by
14 striking “OF OPT OUT”; and

15 (ii) by striking “may repeal a law”
16 and all that follows through the period at
17 the end and inserting the following: “may
18 terminate the authority provided under the
19 waiver with respect to the State by—

20 “(i) repealing a law described in sub-
21 paragraph (A)(i); or

22 “(ii) terminating a certification de-
23 scribed in subparagraph (A)(ii), through a
24 certification for such termination signed by
25 the Governor of the State.”.

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

4 (1) in paragraph (1) by striking “180” and in-
5 serting “90”; and

6 (2) by adding at the end the following:

7 “(3) EXPEDITED DETERMINATION.—

8 “(A) IN GENERAL.—With respect to any
9 application under subsection (a)(1) submitted
10 on or after the date of this paragraph or any
11 such application submitted prior to such date of
12 enactment and under review by the Secretary
13 on such date of enactment, the Secretary shall
14 make a determination on such application,
15 using the criteria for approval otherwise appli-
16 cable under this section, not later than 45 days
17 after the receipt of such application, and shall
18 allow the public notice and comment at the
19 State and Federal levels described under sub-
20 section (a)(4) to occur concurrently if such
21 State application—

22 “(i) is submitted in response to an ur-
23 gent situation, with respect to areas in the
24 State that the Secretary determines are at
25 risk for excessive premium increases or

1 having no health plans offered in the appli-
2 cable health insurance market for the cur-
3 rent or following plan year; or

4 “(ii) is for a waiver that is the same
5 or substantially similar to a waiver that
6 the Secretary already has approved for an-
7 other State.

8 “(B) APPROVAL.—

9 “(i) URGENT SITUATIONS.—

10 “(I) PROVISIONAL APPROVAL.—A
11 waiver approved under the expedited
12 determination process under subpara-
13 graph (A)(i) shall be in effect for a
14 period of 3 years, unless the State re-
15 quests a shorter duration.

16 “(II) FULL APPROVAL.—Subject
17 to the requirements for approval oth-
18 erwise applicable under this section,
19 not later than 1 year before the expi-
20 ration of a provisional waiver period
21 described in subclause (I) with respect
22 to an application described in sub-
23 paragraph (A)(i), the Secretary shall
24 make a determination on whether to
25 extend the approval of such waiver for

1 the full term of the waiver requested
2 by the State, for a total approval pe-
3 riod not to exceed 6 years. The Sec-
4 retary may request additional infor-
5 mation as the Secretary determines
6 appropriate to make such determina-
7 tion.

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

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

21 (c) PROVIDING CERTAINTY FOR STATE-BASED RE-
22 FORMS.—Section 1332(e) of the Patient Protection and
23 Affordable Care Act (42 U.S.C. 18052(e)) is amended by
24 striking “No waiver” and all that follows through the pe-

1 riod at the end and inserting the following: “A waiver
2 under this section—

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

5 “(2) may be renewed, subject to the State meet-
6 ing the criteria for approval otherwise applicable
7 under this section, for unlimited additional 6-year
8 periods upon application by the State; and

9 “(3) may not be suspended or terminated, in
10 whole or in part, by the Secretary at any time before
11 the date of expiration of the waiver period (including
12 any renewal period under paragraph (2)), unless the
13 Secretary determines that the State materially failed
14 to comply with the terms and conditions of the wai-
15 ver.”.

16 (d) ENSURING PATIENT ACCESS TO MORE FLEXIBLE
17 HEALTH PLANS.—Section 1332(b)(1)(B) of the Patient
18 Protection and Affordable Care Act (42 U.S.C.
19 18052(b)(1)(B)) is amended by striking “at least as af-
20 fordable” and inserting “of comparable affordability, in-
21 cluding for low-income individuals, individuals with serious
22 health needs, and other vulnerable populations,”.

23 (e) APPLICABILITY.—The amendments made by this
24 Act to section 1332 of the Patient Protection and Afford-
25 able Care Act (42 U.S.C. 18052)—

1 (1) with respect to applications for waivers
2 under such section 1332 submitted after the date of
3 enactment of this Act and applications for such
4 waivers submitted prior to such date of enactment
5 and under review by the Secretary on the date of en-
6 actment, shall take effect on the date of enactment
7 of this Act; and

8 (2) with respect to applications for waivers ap-
9 proved under such section 1332 before the date of
10 enactment of this Act, shall not require reconsider-
11 ation of whether such applications meet the require-
12 ments of such section 1332, except that, at the re-
13 quest of a State, the Secretary shall recalculate the
14 amount of funding provided under subsection (a)(3)
15 of such section.

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

18 Section 1311(c) of the Patient Protection and Afford-
19 able Care Act (42 U.S.C. 18031(c)) is amended—

20 (1) in paragraph (6), by striking “The Sec-
21 retary” and inserting “Subject to paragraph (7), the
22 Secretary”; and

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

1 “(7) FLEXIBILITY FOR ENROLLMENT PERI-
2 ODS.—

3 “(A) STATE-OPERATED EXCHANGES OPEN
4 ENROLLMENT PERIODS.—In the case of an Ex-
5 change operated by a State, beginning with
6 plan year 2021, the Exchange may provide for
7 open enrollment periods (after the initial enroll-
8 ment period) every 12, 24, or 36 months, as de-
9 termined by the State.”.

10 **SEC. 107. ENROLLMENT PERIODS.**

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

15 “(B) ENROLLMENTS OTHER THAN DURING
16 INITIAL, OPEN, AND SPECIAL ENROLLMENT PE-
17 RIODS.—Beginning with plan year 2021, an Ex-
18 change may provide for enrollments during pe-
19 riod in addition to open enrollment periods de-
20 scribed in subparagraph (A) or paragraph (6)
21 and special enrollment periods described in
22 paragraph (6).”.

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

1 **“SEC. 2710. ENROLLMENT OUTSIDE OF INITIAL, OPEN, AND**
2 **SPECIAL ENROLLMENT PERIOD.**

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

11 **SEC. 108. SHORT-TERM LIMITED DURATION INSURANCE.**

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

15 “(6) SHORT-TERM LIMITED DURATION INSUR-
16 ANCE.—The term ‘short-term limited duration insur-
17 ance’ means health insurance coverage provided pur-
18 suant to a contract with a health insurance issuer
19 that has an expiration date specified in the contract
20 (not taking into account any extensions that may be
21 elected by the policyholder with or without the
22 issuer’s consent) that is less than 12 months after
23 the original effective date of the contract.”.

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

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

4 (2) by adding at the end the following:

5 “(f) APPLICATION TO SHORT-TERM LIMITED DURA-
6 TION INSURANCE.—

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

9 “(A) a reference to ‘health insurance cov-
10 erage’ with respect to such coverage offered in
11 the individual market shall be deemed to in-
12 clude short-term limited duration insurance;
13 and

14 “(B) a reference to ‘health insurance
15 issuer’ with respect to health insurance cov-
16 erage offered in the individual market shall be
17 deemed to include an issuer of short-term lim-
18 ited duration insurance.

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

1 the contract between such individual and the health
2 insurance issuer shall specify whether the individual
3 opted for renewability or no renewability.”.

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

8 **SEC. 109. PROMOTING HEALTH PLANS THAT COVER INDI-**
9 **VIDUALS IN MORE THAN ONE STATE.**

10 There are appropriated, out of amounts in the Treas-
11 ury not otherwise appropriated, \$10,000,000 to be made
12 available by December 31, 2020, to the Center for Medi-
13 care & Medicaid Innovation to fund new research or pilot
14 programs dedicated to pursuing viable methods of enroll-
15 ing individuals in health insurance programs that cross
16 State lines.

17 **SEC. 110. RESTORING THE APPLICATION OF ANTITRUST**
18 **LAWS TO THE BUSINESS OF HEALTH INSUR-**
19 **ANCE.**

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

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

1 laws with respect to the business of health insurance (in-
2 cluding the business of dental insurance and limited-scope
3 dental benefits).

4 “(2) Paragraph (1) shall not apply with respect to
5 making a contract, or engaging in a combination or con-
6 spiracy—

7 “(A) to collect, compile, or disseminate histor-
8 ical loss data;

9 “(B) to determine a loss development factor ap-
10 plicable to historical loss data;

11 “(C) to perform actuarial services if such con-
12 tract, combination, or conspiracy does not involve a
13 restraint of trade; or

14 “(D) to develop or disseminate a standard in-
15 surance policy form (including a standard addendum
16 to an insurance policy form and standard termi-
17 nology in an insurance policy form) if such contract,
18 combination, or conspiracy is not to adhere to such
19 standard form or require adherence to such standard
20 form.

21 “(3) For purposes of this subsection—

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

1 Act (15 U.S.C. 45) to the extent that such section
2 5 applies to unfair methods of competition;

3 “(B) the term ‘business of health insurance (in-
4 cluding the business of dental insurance and limited-
5 scope dental benefits)’ does not include—

6 “(i) the business of life insurance (includ-
7 ing annuities); or

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

10 “(I) any insurance or benefits defined
11 as ‘excepted benefits’ under paragraph (1),
12 subparagraph (B) or (C) of paragraph (2),
13 or paragraph (3) of section 9832(c) of the
14 Internal Revenue Code of 1986 (26 U.S.C.
15 9832(c)) whether offered separately or in
16 combination with insurance or benefits de-
17 scribed in paragraph (2)(A) of such sec-
18 tion; and

19 “(II) any other line of insurance that
20 is classified as property or casualty insur-
21 ance under State law;

22 “(C) the term ‘historical loss data’ means infor-
23 mation respecting claims paid, or reserves held for
24 claims reported, by any person engaged in the busi-
25 ness of insurance; and

1 “(D) the term ‘loss development factor’ means
2 an adjustment to be made to reserves held for losses
3 incurred for claims reported by any person engaged
4 in the business of insurance, for the purpose of
5 bringing such reserves to an ultimate paid basis.”.

6 (b) RELATED PROVISION.—For purposes of section
7 5 of the Federal Trade Commission Act (15 U.S.C. 45)
8 to the extent such section applies to unfair methods of
9 competition, section 3(c) of the McCarran-Ferguson Act
10 shall apply with respect to the business of health insurance
11 without regard to whether such business is carried on for
12 profit, notwithstanding the definition of “Corporation”
13 contained in section 4 of the Federal Trade Commission
14 Act.

15 **SEC. 111. HEALTH PLANS CREATED UNDER PPACA OR OF-**
16 **FERED THROUGH EXCHANGES TO BE ONLY**
17 **HEALTH PLANS FEDERAL GOVERNMENT MAY**
18 **MAKE AVAILABLE TO PRESIDENT, VICE**
19 **PRESIDENT, MEMBERS OF CONGRESS, AND**
20 **FEDERAL EMPLOYEES.**

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

24 (1) in the subparagraph heading, by striking
25 “MEMBERS OF CONGRESS” and inserting “PRESI-

1 DENT, VICE PRESIDENT, MEMBERS OF CONGRESS,
2 AND FEDERAL EMPLOYEES”;

3 (2) in clause (i), in the matter preceding sub-
4 clause (I)—

5 (A) by striking “Members of Congress and
6 congressional staff” and inserting “the Presi-
7 dent, Vice President, Members of Congress, and
8 Federal employees”; and

9 (B) by striking “a Member of Congress or
10 congressional staff” and inserting “the Presi-
11 dent, the Vice President, a Member of Con-
12 gress, or a Federal employee”; and

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

15 “(II) FEDERAL EMPLOYEE.—The
16 term ‘Federal employee’ means—

17 “(aa) an ‘employee’, as such
18 term is defined in section 2105 of
19 title 5, United States Code; and

20 “(bb) includes an individual
21 to whom subsection (c) or (f) of
22 such section 2105 pertains
23 (whether or not such individual
24 satisfies item (aa)).”.

1 **SEC. 112. COST-SHARING REDUCTIONS.**

2 (a) COST-SHARING REDUCTION PAYMENTS.—Section
3 1402 of the Patient Protection and Affordable Care Act
4 (42 U.S.C. 18071) is amended by adding at the end the
5 following new subsection:

6 “(g) FUNDING.—

7 “(1) APPROPRIATIONS.—There is appropriated,
8 from any money in the Treasury not otherwise ap-
9 propriated, such sums as may be necessary to, sub-
10 ject to paragraph (2), provide health benefits cov-
11 erage through payment to issuers (under this section
12 or through advance payment by the Secretary of the
13 Treasury under section 1412(c)(3)) of the amounts
14 computed under this section for each of plan years
15 2019 through 2022.

16 “(2) ADJUSTMENTS.—Notwithstanding any
17 other provision of law, payments and other actions
18 for adjustments to obligations incurred prior to De-
19 cember 31, 2020, may be made through December
20 31, 2021.

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

1 the same extent as if such amounts for each such
2 year were appropriated under such division.”.

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

15 (1) enrolled in qualified health plans (as defined
16 in section 36B of the Internal Revenue Code of
17 1986) offered by such issuers, and

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

20 **SEC. 113. HEALTH SAVINGS ACCOUNTS.**

21 (a) NO HIGH DEDUCTIBLE HEALTH PLANS RE-
22 QUIRED FOR HEALTH SAVINGS ACCOUNT CONTRIBU-
23 TIONS.—

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

1 qualified health plan” after “high deductible health
2 plan” each place such term appears.

3 (2) QUALIFIED HEALTH PLAN DEFINED.—Sec-
4 tion 223(c) of such Code is amended to read as fol-
5 lows:

6 “(c) ELIGIBLE INDIVIDUAL.—For purposes of this
7 section—

8 “(1) IN GENERAL.—The term ‘eligible indi-
9 vidual’ means, with respect to any month, any indi-
10 vidual if such individual is covered under a qualified
11 health plan as of the 1st day of such month.

12 “(2) QUALIFIED HEALTH PLAN.—The term
13 ‘qualified health plan’ has the meaning given such
14 term in section 36B.”.

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

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

19 “(B) ABORTIONS.—

20 “(i) PAYMENTS FOR HEALTH INSUR-
21 ANCE WITH ABORTION COVERAGE.—The
22 term ‘qualified medical expense’ shall not
23 include amounts paid for insurance that
24 includes coverage for abortions.

1 “(ii) PAYMENTS FOR ABORTIONS.—
2 The term ‘qualified medical expense’ shall
3 not include amounts paid for an abortion.

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

7 “(I) if the pregnancy is the result
8 of an act of rape or incest, or

9 “(II) in the case where a woman
10 suffers from a physical disorder, phys-
11 ical injury, or physical illness that
12 would, as certified by a physician,
13 place the woman in danger of death
14 unless an abortion is performed, in-
15 cluding a life-endangering physical
16 condition caused by or arising from
17 the pregnancy itself.”.

18 (2) CONFORMING AMENDMENT.—Subsection
19 223(d)(2) is amended by striking subparagraph (C).

20 **SEC. 114. ADDING COPPER PLANS TO EXCHANGES.**

21 (a) IN GENERAL.—Section 1302 of the Patient Pro-
22 tection and Affordable Care Act (42 U.S.C. 18022) is
23 amended—

24 (1) in subsection (a)(3), by inserting “copper,”
25 after “either the”;

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

3 “(5) SPECIAL RULE FOR COPPER PLANS.—A
4 health plan in the copper level of coverage (as de-
5 scribed in subsection (d)(1)(E)) shall be deemed to
6 meet the requirements of this subsection.”;

7 (3) in subsection (d)—

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

10 “(E) COPPER LEVEL.—A plan in the cop-
11 per level shall provide a level of coverage that
12 is designed to provide benefits that are actuari-
13 ally equivalent to 50 percent of the full actu-
14 arial value of the benefits provided under the
15 plan.”; and

16 (B) in paragraph (4)—

17 (i) by inserting “copper,” after “any
18 reference to a”; and

19 (ii) by inserting “copper,” after “pro-
20 viding a”; and

21 (4) in subsection (e)(1), by inserting “copper,”
22 after “not providing a”.

23 (b) EFFECTIVE DATE.—The amendments made by
24 this section shall apply with respect to plan years begin-
25 ning on or after January 1, 2020.

1 **SEC. 115. ELIMINATING FEHBP ELIGIBILITY FOR ANNU-**
 2 **ITANTS.**

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

5 (1) in the matter preceding paragraph (1), by
 6 striking “An” and inserting “Consistent with the
 7 last sentence of this subsection, an”; and

8 (2) by adding at the end the following: “. An
 9 individual who is entitled to benefits under part A
 10 of title XVIII of the Social Security Act (42 U.S.C.
 11 1395c et seq.) by reason of section 226 or 226A of
 12 such Act (42 U.S.C. 426, 426–1), or otherwise eligi-
 13 ble to enroll under such part pursuant to section
 14 1818 or 1818A of such Act (42 U.S.C. 1395i–2,
 15 1395i–2a), and who first becomes an annuitant after
 16 the date of enactment of this sentence may not con-
 17 tinue enrollment in any health benefits plan under
 18 this chapter.”.

19 **Subtitle B—Association Health**
 20 **Plans**

21 **SEC. 121. RULES GOVERNING ASSOCIATION HEALTH**
 22 **PLANS.**

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

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

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

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

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

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

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

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

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

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

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

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

6 “(1) A plan which offered such coverage on the
7 date of the enactment of this section.

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

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

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

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

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

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

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

24 “(2) RULES OF OPERATION AND FINANCIAL
25 CONTROLS.—The board of trustees has in effect

1 rules of operation and financial controls, based on a
2 3-year plan of operation, adequate to carry out the
3 terms of the plan and to meet all requirements of
4 this title applicable to the plan.

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

8 “(A) BOARD MEMBERSHIP.—

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

17 “(ii) LIMITATION.—

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

24 “(II) LIMITED EXCEPTION FOR
25 PROVIDERS OF SERVICES SOLELY ON

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

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

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

23 “(B) SOLE AUTHORITY.—The board has
24 sole authority under the plan to approve appli-
25 cations for participation in the plan and to con-

1 tract with a service provider to administer the
2 day-to-day affairs of the plan.

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

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

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

17 The Secretary may by regulation define for purposes of
18 this subsection the terms ‘franchiser’, ‘franchise network’,
19 and ‘franchisee’.

20 **“SEC. 804. PARTICIPATION AND COVERAGE REQUIRE-**
21 **MENTS.**

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

1 “(1) each participating employer must be—

2 “(A) a member of the sponsor,

3 “(B) the sponsor, or

4 “(C) an affiliated member of the sponsor
5 with respect to which the requirements of sub-
6 section (b) are met,

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

16 “(2) all individuals commencing coverage under
17 the plan after certification under this part must
18 be—

19 “(A) active or retired owners (including
20 self-employed individuals), officers, directors, or
21 employees of, or partners in, participating em-
22 ployers; or

23 “(B) the beneficiaries of individuals de-
24 scribed in subparagraph (A).

1 “(b) COVERAGE OF PREVIOUSLY UNINSURED EM-
2 PLOYEES.—In the case of an association health plan in
3 existence on the date of the enactment of this section, an
4 affiliated member of the sponsor of the plan may be of-
5 fered coverage under the plan as a participating employer
6 only if—

7 “(1) the affiliated member was an affiliated
8 member on the date of certification under this part;
9 or

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

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

1 would, but for such exclusion on such basis, be eligible
2 for coverage under the plan.

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

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

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

18 “(3) the applicable requirements of sections
19 701, 702, and 703 are met with respect to the plan.

20 **“SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN**
21 **DOCUMENTS, CONTRIBUTION RATES, AND**
22 **BENEFIT OPTIONS.**

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

1 “(1) CONTENTS OF GOVERNING INSTRU-
2 MENTS.—The instruments governing the plan in-
3 clude a written instrument, meeting the require-
4 ments of an instrument required under section
5 402(a)(1), which—

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

11 “(B) provides that the sponsor of the plan
12 is to serve as plan sponsor (referred to in sec-
13 tion 3(16)(B)); and

14 “(C) incorporates the requirements of sec-
15 tion 806.

16 “(2) CONTRIBUTION RATES MUST BE NON-
17 DISCRIMINATORY.—

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

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

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

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

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

21 “(3) FLOOR FOR NUMBER OF COVERED INDI-
22 VIDUALS WITH RESPECT TO CERTAIN PLANS.—If
23 any benefit option under the plan does not consist
24 of health insurance coverage, the plan has as of the

1 beginning of the plan year not fewer than 1,000 par-
2 ticipants and beneficiaries.

3 “(4) MARKETING REQUIREMENTS.—

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

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

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

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

18 **“SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS**
19 **FOR SOLVENCY FOR PLANS PROVIDING**
20 **HEALTH BENEFITS IN ADDITION TO HEALTH**
21 **INSURANCE COVERAGE.**

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

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

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

4 “(A) establishes and maintains reserves
5 with respect to such additional benefit options,
6 in amounts recommended by the qualified actu-
7 ary, consisting of—

8 “(i) a reserve sufficient for unearned
9 contributions;

10 “(ii) a reserve sufficient for benefit li-
11 abilities which have been incurred, which
12 have not been satisfied, and for which risk
13 of loss has not yet been transferred, and
14 for expected administrative costs with re-
15 spect to such benefit liabilities;

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

18 “(iv) a reserve sufficient for a margin
19 of error and other fluctuations, taking into
20 account the specific circumstances of the
21 plan; and

22 “(B) establishes and maintains aggregate
23 and specific excess/stop loss insurance and sol-
24 vency indemnification, with respect to such ad-

1 ditional benefit options for which risk of loss
2 has not yet been transferred, as follows:

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

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

1 “(iii) The plan shall secure indem-
2 nification insurance for any claims which
3 the plan is unable to satisfy by reason of
4 a plan termination.

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

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

20 “(1) \$500,000, or

21 “(2) such greater amount (but not greater than
22 \$2,000,000) as may be set forth in regulations pre-
23 scribed by the applicable authority, considering the
24 level of aggregate and specific excess/stop loss insur-
25 ance provided with respect to such plan and other

1 factors related to solvency risk, such as the plan’s
2 projected levels of participation or claims, the nature
3 of the plan’s liabilities, and the types of assets avail-
4 able to assure that such liabilities are met.

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

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

19 “(e) ALTERNATIVE MEANS OF COMPLIANCE.—The
20 applicable authority may permit an association health plan
21 described in subsection (a)(2) to substitute, for all or part
22 of the requirements of this section (except subsection
23 (a)(2)(B)(iii)), such security, guarantee, hold-harmless ar-
24 rangement, or other financial arrangement as the applica-
25 ble authority determines to be adequate to enable the plan

1 to fully meet all its financial obligations on a timely basis
2 and is otherwise no less protective of the interests of par-
3 ticipants and beneficiaries than the requirements for
4 which it is substituted. The applicable authority may take
5 into account, for purposes of this subsection, evidence pro-
6 vided by the plan or sponsor which demonstrates an as-
7 sumption of liability with respect to the plan. Such evi-
8 dence may be in the form of a contract of indemnification,
9 lien, bonding, insurance, letter of credit, recourse under
10 applicable terms of the plan in the form of assessments
11 of participating employers, security, or other financial ar-
12 rangement.

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

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

17 “(A) IN GENERAL.—In the case of an as-
18 sociation health plan described in subsection
19 (a)(2), the requirements of this subsection are
20 met if the plan makes payments into the Asso-
21 ciation Health Plan Fund under this subpara-
22 graph when they are due. Such payments shall
23 consist of annual payments in the amount of
24 \$5,000, and, in addition to such annual pay-
25 ments, such supplemental payments as the Sec-

1 retary may determine to be necessary under
2 paragraph (2). Payments under this paragraph
3 are payable to the Fund at the time determined
4 by the Secretary. Initial payments are due in
5 advance of certification under this part. Pay-
6 ments shall continue to accrue until a plan's as-
7 sets are distributed pursuant to a termination
8 procedure.

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

15 “(C) CONTINUED DUTY OF THE SEC-
16 RETARY.—The Secretary shall not cease to
17 carry out the provisions of paragraph (2) on ac-
18 count of the failure of a plan to pay any pay-
19 ment when due.

20 “(2) PAYMENTS BY SECRETARY TO CONTINUE
21 EXCESS/STOP LOSS INSURANCE COVERAGE AND IN-
22 DEMNIFICATION INSURANCE COVERAGE FOR CER-
23 TAIN PLANS.—In any case in which the applicable
24 authority determines that there is, or that there is
25 reason to believe that there will be: (A) A failure to

1 take necessary corrective actions under section
2 809(a) with respect to an association health plan de-
3 scribed in subsection (a)(2); or (B) a termination of
4 such a plan under section 809(b) or 810(b)(8) (and,
5 if the applicable authority is not the Secretary, cer-
6 tifies such determination to the Secretary), the Sec-
7 retary shall determine the amounts necessary to
8 make payments to an insurer (designated by the
9 Secretary) to maintain in force excess/stop loss in-
10 surance coverage or indemnification insurance cov-
11 erage for such plan, if the Secretary determines that
12 there is a reasonable expectation that, without such
13 payments, claims would not be satisfied by reason of
14 termination of such coverage. The Secretary shall, to
15 the extent provided in advance in appropriation
16 Acts, pay such amounts so determined to the insurer
17 designated by the Secretary.

18 “(3) ASSOCIATION HEALTH PLAN FUND.—

19 “(A) IN GENERAL.—There is established
20 on the books of the Treasury a fund to be
21 known as the ‘Association Health Plan Fund’.
22 The Fund shall be available for making pay-
23 ments pursuant to paragraph (2). The Fund
24 shall be credited with payments received pursu-
25 ant to paragraph (1)(A), penalties received pur-

1 suant to paragraph (1)(B); and earnings on in-
2 vestments of amounts of the Fund under sub-
3 paragraph (B).

4 “(B) INVESTMENT.—Whenever the Sec-
5 retary determines that the moneys of the fund
6 are in excess of current needs, the Secretary
7 may request the investment of such amounts as
8 the Secretary determines advisable by the Sec-
9 retary of the Treasury in obligations issued or
10 guaranteed by the United States.

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

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

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

23 “(B) which is guaranteed renewable; and

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

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

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

16 “(B) which is guaranteed renewable; and

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

20 “(h) INDEMNIFICATION INSURANCE.—For purposes
21 of this section, the term ‘indemnification insurance’
22 means, in connection with an association health plan, a
23 contract—

24 “(1) under which an insurer (meeting such min-
25 imum standards as the applicable authority may pre-

1 scribe by regulation) provides for payment to the
2 plan with respect to claims under the plan which the
3 plan is unable to satisfy by reason of a termination
4 pursuant to section 809(b) (relating to mandatory
5 termination);

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

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

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

17 “(j) SOLVENCY STANDARDS WORKING GROUP.—

18 “(1) IN GENERAL.—Within 90 days after the
19 date of the enactment of this section, the applicable
20 authority shall establish a Solvency Standards Work-
21 ing Group. In prescribing the initial regulations
22 under this section, the applicable authority shall
23 take into account the recommendations of such
24 Working Group.

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

7 “(A) A representative of the National As-
8 sociation of Insurance Commissioners.

9 “(B) A representative of the American
10 Academy of Actuaries.

11 “(C) A representative of the State govern-
12 ments, or their interests.

13 “(D) A representative of existing self-in-
14 sured arrangements, or their interests.

15 “(E) A representative of associations of
16 the type referred to in section 801(b)(1), or
17 their interests.

18 “(F) A representative of multiemployer
19 plans that are group health plans, or their in-
20 terests.

21 **“SEC. 807. REQUIREMENTS FOR APPLICATION AND RE-**
22 **LATED REQUIREMENTS.**

23 “(a) FILING FEE.—Under the procedure prescribed
24 pursuant to section 802(a), an association health plan
25 shall pay to the applicable authority at the time of filing

1 an application for certification under this part a filing fee
2 in the amount of \$5,000, which shall be available in the
3 case of the Secretary, to the extent provided in appropria-
4 tion Acts, for the sole purpose of administering the certifi-
5 cation procedures applicable with respect to association
6 health plans.

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

13 “(1) IDENTIFYING INFORMATION.—The names
14 and addresses of—

15 “(A) the sponsor; and

16 “(B) the members of the board of trustees
17 of the plan.

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

23 “(3) BONDING REQUIREMENTS.—Evidence pro-
24 vided by the board of trustees that the bonding re-
25 quirements of section 412 will be met as of the date

1 of the application or (if later) commencement of op-
2 erations.

3 “(4) PLAN DOCUMENTS.—A copy of the docu-
4 ments governing the plan (including any bylaws and
5 trust agreements), the summary plan description,
6 and other material describing the benefits that will
7 be provided to participants and beneficiaries under
8 the plan.

9 “(5) AGREEMENTS WITH SERVICE PRO-
10 VIDERS.—A copy of any agreements between the
11 plan and contract administrators and other service
12 providers.

13 “(6) FUNDING REPORT.—In the case of asso-
14 ciation health plans providing benefits options in ad-
15 dition to health insurance coverage, a report setting
16 forth information with respect to such additional
17 benefit options determined as of a date within the
18 120-day period ending with the date of the applica-
19 tion, including the following:

20 “(A) RESERVES.—A statement, certified
21 by the board of trustees of the plan, and a
22 statement of actuarial opinion, signed by a
23 qualified actuary, that all applicable require-
24 ments of section 806 are or will be met in ac-

1 cordance with regulations which the applicable
2 authority shall prescribe.

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

17 “(C) CURRENT AND PROJECTED VALUE OF
18 ASSETS AND LIABILITIES.—A statement of ac-
19 tuarial opinion signed by a qualified actuary,
20 which sets forth the current value of the assets
21 and liabilities accumulated under the plan and
22 a projection of the assets, liabilities, income,
23 and expenses of the plan for the 12-month pe-
24 riod referred to in subparagraph (B). The in-

1 come statement shall identify separately the
2 plan’s administrative expenses and claims.

3 “(D) COSTS OF COVERAGE TO BE
4 CHARGED AND OTHER EXPENSES.—A state-
5 ment of the costs of coverage to be charged, in-
6 cluding an itemization of amounts for adminis-
7 tration, reserves, and other expenses associated
8 with the operation of the plan.

9 “(E) OTHER INFORMATION.—Any other
10 information as may be determined by the appli-
11 cable authority, by regulation, as necessary to
12 carry out the purposes of this part.

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

23 “(d) NOTICE OF MATERIAL CHANGES.—In the case
24 of any association health plan certified under this part,
25 descriptions of material changes in any information which

1 was required to be submitted with the application for the
2 certification under this part shall be filed in such form
3 and manner as shall be prescribed by the applicable au-
4 thority by regulation. The applicable authority may re-
5 quire by regulation prior notice of material changes with
6 respect to specified matters which might serve as the basis
7 for suspension or revocation of the certification.

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

21 “(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The
22 board of trustees of each association health plan which
23 provides benefits options in addition to health insurance
24 coverage and which is applying for certification under this
25 part or is certified under this part shall engage, on behalf

1 of all participants and beneficiaries, a qualified actuary
2 who shall be responsible for the preparation of the mate-
3 rials comprising information necessary to be submitted by
4 a qualified actuary under this part. The qualified actuary
5 shall utilize such assumptions and techniques as are nec-
6 essary to enable such actuary to form an opinion as to
7 whether the contents of the matters reported under this
8 part—

9 “(1) are in the aggregate reasonably related to
10 the experience of the plan and to reasonable expecta-
11 tions; and

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

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

16 **“SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TER-**
17 **MINATION.**

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

24 “(1) provides to the participants and bene-
25 ficiaries a written notice of intent to terminate stat-

1 qualified actuary engaged by the plan, and such actuary
2 shall, not later than the end of the next following month,
3 make such recommendations to the board for corrective
4 action as the actuary determines necessary to ensure com-
5 pliance with section 806. Not later than 30 days after re-
6 ceiving from the actuary recommendations for corrective
7 actions, the board shall notify the applicable authority (in
8 such form and manner as the applicable authority may
9 prescribe by regulation) of such recommendations of the
10 actuary for corrective action, together with a description
11 of the actions (if any) that the board has taken or plans
12 to take in response to such recommendations. The board
13 shall thereafter report to the applicable authority, in such
14 form and frequency as the applicable authority may speci-
15 fy to the board, regarding corrective action taken by the
16 board until the requirements of section 806 are met.

17 “(b) MANDATORY TERMINATION.—In any case in
18 which—

19 “(1) the applicable authority has been notified
20 under subsection (a) (or by an issuer of excess/stop
21 loss insurance or indemnity insurance pursuant to
22 section 806(a)) of a failure of an association health
23 plan which is or has been certified under this part
24 and is described in section 806(a)(2) to meet the re-
25 quirements of section 806 and has not been notified

1 by the board of trustees of the plan that corrective
2 action has restored compliance with such require-
3 ments; and

4 “(2) the applicable authority determines that
5 there is a reasonable expectation that the plan will
6 continue to fail to meet the requirements of section
7 806,

8 the board of trustees of the plan shall, at the direction
9 of the applicable authority, terminate the plan and, in the
10 course of the termination, take such actions as the appli-
11 cable authority may require, including satisfying any
12 claims referred to in section 806(a)(2)(B)(iii) and recov-
13 ering for the plan any liability under subsection
14 (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure
15 that the affairs of the plan will be, to the maximum extent
16 possible, wound up in a manner which will result in timely
17 provision of all benefits for which the plan is obligated.

18 **“SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOL-**
19 **VENT ASSOCIATION HEALTH PLANS PRO-**
20 **VIDING HEALTH BENEFITS IN ADDITION TO**
21 **HEALTH INSURANCE COVERAGE.**

22 “(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR
23 INSOLVENT PLANS.—Whenever the Secretary determines
24 that an association health plan which is or has been cer-
25 tified under this part and which is described in section

1 806(a)(2) will be unable to provide benefits when due or
2 is otherwise in a financially hazardous condition, as shall
3 be defined by the Secretary by regulation, the Secretary
4 shall, upon notice to the plan, apply to the appropriate
5 United States district court for appointment of the Sec-
6 retary as trustee to administer the plan for the duration
7 of the insolvency. The plan may appear as a party and
8 other interested persons may intervene in the proceedings
9 at the discretion of the court. The court shall appoint such
10 Secretary trustee if the court determines that the trustee-
11 ship is necessary to protect the interests of the partici-
12 pants and beneficiaries or providers of medical care or to
13 avoid any unreasonable deterioration of the financial con-
14 dition of the plan. The trusteeship of such Secretary shall
15 continue until the conditions described in the first sen-
16 tence of this subsection are remedied or the plan is termi-
17 nated.

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

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

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

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

8 “(4) to require the sponsor, the plan adminis-
9 trator, any participating employer, and any employee
10 organization representing plan participants to fur-
11 nish any information with respect to the plan which
12 the Secretary as trustee may reasonably need in
13 order to administer the plan;

14 “(5) to collect for the plan any amounts due the
15 plan and to recover reasonable expenses of the trust-
16 eeship;

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

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

24 “(8) to terminate the plan (or provide for its
25 termination in accordance with section 809(b)) and

1 liquidate the plan assets, to restore the plan to the
2 responsibility of the sponsor, or to continue the
3 trusteeship;

4 “(9) to provide for the enrollment of plan par-
5 ticipants and beneficiaries under appropriate cov-
6 erage options; and

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

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

15 “(1) the sponsor and plan administrator;

16 “(2) each participant;

17 “(3) each participating employer; and

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

21 “(d) ADDITIONAL DUTIES.—Except to the extent in-
22 consistent with the provisions of this title, or as may be
23 otherwise ordered by the court, the Secretary, upon ap-
24 pointment as trustee under this section, shall be subject
25 to the same duties as those of a trustee under section 704

1 of title 11, United States Code, and shall have the duties
2 of a fiduciary for purposes of this title.

3 “(e) OTHER PROCEEDINGS.—An application by the
4 Secretary under this subsection may be filed notwith-
5 standing the pendency in the same or any other court of
6 any bankruptcy, mortgage foreclosure, or equity receiver-
7 ship proceeding, or any proceeding to reorganize, conserve,
8 or liquidate such plan or its property, or any proceeding
9 to enforce a lien against property of the plan.

10 “(f) JURISDICTION OF COURT.—

11 “(1) IN GENERAL.—Upon the filing of an appli-
12 cation for the appointment as trustee or the issuance
13 of a decree under this section, the court to which the
14 application is made shall have exclusive jurisdiction
15 of the plan involved and its property wherever lo-
16 cated with the powers, to the extent consistent with
17 the purposes of this section, of a court of the United
18 States having jurisdiction over cases under chapter
19 11 of title 11, United States Code. Pending an adju-
20 dication under this section such court shall stay, and
21 upon appointment by it of the Secretary as trustee,
22 such court shall continue the stay of, any pending
23 mortgage foreclosure, equity receivership, or other
24 proceeding to reorganize, conserve, or liquidate the
25 plan, the sponsor, or property of such plan or spon-

1 sor, and any other suit against any receiver, conser-
2 vator, or trustee of the plan, the sponsor, or prop-
3 erty of the plan or sponsor. Pending such adjudica-
4 tion and upon the appointment by it of the Sec-
5 retary as trustee, the court may stay any proceeding
6 to enforce a lien against property of the plan or the
7 sponsor or any other suit against the plan or the
8 sponsor.

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

16 “(g) PERSONNEL.—In accordance with regulations
17 which shall be prescribed by the Secretary, the Secretary
18 shall appoint, retain, and compensate accountants, actu-
19 aries, and other professional service personnel as may be
20 necessary in connection with the Secretary’s service as
21 trustee under this section.

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

23 “(a) IN GENERAL.—Notwithstanding section 514, a
24 State may impose by law a contribution tax on an associa-
25 tion health plan described in section 806(a)(2), if the plan

1 commenced operations in such State after the date of the
2 enactment of this section.

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

7 “(1) such tax is computed by applying a rate to
8 the amount of premiums or contributions, with re-
9 spect to individuals covered under the plan who are
10 residents of such State, which are received by the
11 plan from participating employers located in such
12 State or from such individuals;

13 “(2) the rate of such tax does not exceed the
14 rate of any tax imposed by such State on premiums
15 or contributions received by insurers or health main-
16 tenance organizations for health insurance coverage
17 offered in such State in connection with a group
18 health plan;

19 “(3) such tax is otherwise nondiscriminatory;
20 and

21 “(4) the amount of any such tax assessed on
22 the plan is reduced by the amount of any tax or as-
23 sessment otherwise imposed by the State on pre-
24 miums, contributions, or both received by insurers or
25 health maintenance organizations for health insur-

1 ance coverage, aggregate excess/stop loss insurance
2 (as defined in section 806(g)(1)), specific excess/stop
3 loss insurance (as defined in section 806(g)(2)),
4 other insurance related to the provision of medical
5 care under the plan, or any combination thereof pro-
6 vided by such insurers or health maintenance organi-
7 zations in such State in connection with such plan.

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

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

10 “(1) GROUP HEALTH PLAN.—The term ‘group
11 health plan’ has the meaning provided in section
12 733(a)(1) (after applying subsection (b) of this sec-
13 tion).

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

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

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

22 “(5) APPLICABLE AUTHORITY.—The term ‘ap-
23 plicable authority’ means the Secretary, except that,
24 in connection with any exercise of the Secretary’s
25 authority regarding which the Secretary is required

1 under section 506(d) to consult with a State, such
2 term means the Secretary, in consultation with such
3 State.

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

7 “(7) INDIVIDUAL MARKET.—

8 “(A) IN GENERAL.—The term ‘individual
9 market’ means the market for health insurance
10 coverage offered to individuals other than in
11 connection with a group health plan.

12 “(B) TREATMENT OF VERY SMALL
13 GROUPS.—

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

21 “(ii) STATE EXCEPTION.—Clause (i)
22 shall not apply in the case of health insur-
23 ance coverage offered in a State if such
24 State regulates the coverage described in
25 such clause in the same manner and to the

1 same extent as coverage in the small group
2 market (as defined in section 2791(e)(5) of
3 the Public Health Service Act) is regulated
4 by such State.

5 “(8) PARTICIPATING EMPLOYER.—The term
6 ‘participating employer’ means, in connection with
7 an association health plan, any employer, if any indi-
8 vidual who is an employee of such employer, a part-
9 ner in such employer, or a self-employed individual
10 who is such employer (or any dependent, as defined
11 under the terms of the plan, of such individual) is
12 or was covered under such plan in connection with
13 the status of such individual as such an employee,
14 partner, or self-employed individual in relation to the
15 plan.

16 “(9) APPLICABLE STATE AUTHORITY.—The
17 term ‘applicable State authority’ means, with respect
18 to a health insurance issuer in a State, the State in-
19 surance commissioner or official or officials des-
20 ignated by the State to enforce the requirements of
21 title XXVII of the Public Health Service Act for the
22 State involved with respect to such issuer.

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

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

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

6 “(B) in the case of a sponsor with mem-
7 bers which consist of associations, a person who
8 is a member of any such association and elects
9 an affiliated status with the sponsor, or

10 “(C) in the case of an association health
11 plan in existence on the date of the enactment
12 of this section, a person eligible to be a member
13 of the sponsor or one of its member associa-
14 tions.

15 “(12) LARGE EMPLOYER.—The term ‘large em-
16 ployer’ means, in connection with a group health
17 plan with respect to a plan year, an employer who
18 employed an average of at least 51 employees on
19 business days during the preceding calendar year
20 and who employs at least 2 employees on the first
21 day of the plan year.

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

1 “(b) RULES OF CONSTRUCTION.—

2 “(1) EMPLOYERS AND EMPLOYEES.—For pur-
3 poses of determining whether a plan, fund, or pro-
4 gram is an employee welfare benefit plan which is an
5 association health plan, and for purposes of applying
6 this title in connection with such plan, fund, or pro-
7 gram so determined to be such an employee welfare
8 benefit plan—

9 “(A) in the case of a partnership, the term
10 ‘employer’ (as defined in section 3(5)) includes
11 the partnership in relation to the partners, and
12 the term ‘employee’ (as defined in section 3(6))
13 includes any partner in relation to the partner-
14 ship; and

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

19 “(2) PLANS, FUNDS, AND PROGRAMS TREATED
20 AS EMPLOYEE WELFARE BENEFIT PLANS.—In the
21 case of any plan, fund, or program which was estab-
22 lished or is maintained for the purpose of providing
23 medical care (through the purchase of insurance or
24 otherwise) for employees (or their dependents) cov-
25 ered thereunder and which demonstrates to the Sec-

1 retary that all requirements for certification under
2 this part would be met with respect to such plan,
3 fund, or program if such plan, fund, or program
4 were a group health plan, such plan, fund, or pro-
5 gram shall be treated for purposes of this title as an
6 employee welfare benefit plan on and after the date
7 of such demonstration.”.

8 (b) CONFORMING AMENDMENTS TO PREEMPTION
9 RULES.—

10 (1) Section 514(b)(6) of such Act (29 U.S.C.
11 1144(b)(6)) is amended by adding at the end the
12 following new subparagraph:

13 “(E) The preceding subparagraphs of this paragraph
14 do not apply with respect to any State law in the case
15 of an association health plan which is certified under part
16 8.”.

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

19 (A) in subsection (b)(4), by striking “Sub-
20 section (a)” and inserting “Subsections (a) and
21 (f)”;

22 (B) in subsection (b)(5), by striking “sub-
23 section (a)” in subparagraph (A) and inserting
24 “subsection (a) of this section and subsections
25 (a)(2)(B) and (b) of section 805”, and by strik-

1 ing “subsection (a)” in subparagraph (B) and
2 inserting “subsection (a) of this section or sub-
3 section (a)(2)(B) or (b) of section 805”; and

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

6 “(f)(1) Except as provided in subsection (b)(4), the
7 provisions of this title shall supersede any and all State
8 laws insofar as they may now or hereafter preclude, or
9 have the effect of precluding, a health insurance issuer
10 from offering health insurance coverage in connection with
11 an association health plan which is certified under part
12 8.

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

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

1 such other employers are participating employers in
2 such plan.

3 “(B) In any case in which health insurance cov-
4 erage of any policy type is offered in a State under
5 an association health plan certified under part 8 and
6 the filing, with the applicable State authority (as de-
7 fined in section 812(a)(9)), of the policy form in
8 connection with such policy type is approved by such
9 State authority, the provisions of this title shall su-
10 percede any and all laws of any other State in which
11 health insurance coverage of such type is offered, in-
12 sofar as they may preclude, upon the filing in the
13 same form and manner of such policy form with the
14 applicable State authority in such other State, the
15 approval of the filing in such other State.

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

20 “(A) providing solvency standards or similar
21 standards regarding the adequacy of insurer capital,
22 surplus, reserves, or contributions, or

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

1 “(4) For additional provisions relating to association
2 health plans, see subsections (a)(2)(B) and (b) of section
3 805.

4 “(5) For purposes of this subsection, the term ‘asso-
5 ciation health plan’ has the meaning provided in section
6 801(a), and the terms ‘health insurance coverage’, ‘par-
7 ticipating employer’, and ‘health insurance issuer’ have
8 the meanings provided such terms in section 812, respec-
9 tively.”.

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

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

14 (B) in clause (ii), by inserting “and which
15 does not provide medical care (within the mean-
16 ing of section 733(a)(2)),” after “arrange-
17 ment,”, and by striking “title.” and inserting
18 “title, and”; and

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

21 “(iii) subject to subparagraph (E), in the case
22 of any other employee welfare benefit plan which is
23 a multiple employer welfare arrangement and which
24 provides medical care (within the meaning of section

1 733(a)(2)), any law of any State which regulates in-
2 surance may apply.”.

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

5 (A) by striking “Nothing” and inserting
6 “(1) Except as provided in paragraph (2), noth-
7 ing”; and

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

10 “(2) Nothing in any other provision of law enacted
11 on or after the date of the enactment of this paragraph
12 shall be construed to alter, amend, modify, invalidate, im-
13 pair, or supersede any provision of this title, except by
14 specific cross-reference to the affected section.”.

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

20 (d) DISCLOSURE OF SOLVENCY PROTECTIONS RE-
21 LATED TO SELF-INSURED AND FULLY INSURED OPTIONS
22 UNDER ASSOCIATION HEALTH PLANS.—Section 102(b)
23 of such Act (29 U.S.C. 102(b)) is amended by adding at
24 the end the following: “An association health plan shall
25 include in its summary plan description, in connection

1 with each benefit option, a description of the form of sol-
 2 vency or guarantee fund protection secured pursuant to
 3 this Act or applicable State law, if any.”.

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

6 (f) REPORT TO THE CONGRESS REGARDING CERTIFI-
 7 CATION OF SELF-INSURED ASSOCIATION HEALTH
 8 PLANS.—Not later than January 1, 2022, the Secretary
 9 of Labor shall report to the Committee on Education and
 10 Labor of the House of Representatives and the Committee
 11 on Health, Education, Labor, and Pensions of the Senate
 12 the effect association health plans have had, if any, on
 13 reducing the number of uninsured individuals.

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

“PART 8. RULES GOVERNING ASSOCIATION HEALTH PLANS

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

1 **SEC. 122. CLARIFICATION OF TREATMENT OF SINGLE EM-**
2 **PLOYER ARRANGEMENTS.**

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

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

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

19 “(iii)(I) in any case in which the benefit re-
20 ferred to in subparagraph (A) consists of medical
21 care (as defined in section 812(a)(2)), the deter-
22 mination of whether a trade or business is under
23 ‘common control’ with another trade or business
24 shall be determined under regulations of the Sec-
25 retary applying principles consistent and coextensive
26 with the principles applied in determining whether

1 employees of two or more trades or businesses are
2 treated as employed by a single employer under sec-
3 tion 4001(b), except that, for purposes of this para-
4 graph, an interest of greater than 25 percent may
5 not be required as the minimum interest necessary
6 for common control, or

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

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

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

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

1 **SEC. 123. ENFORCEMENT PROVISIONS RELATING TO ASSO-**
2 **CIATION HEALTH PLANS.**

3 (a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL
4 MISREPRESENTATIONS.—Section 501 of the Employee
5 Retirement Income Security Act of 1974 (29 U.S.C. 1131)
6 is amended by adding at the end the following new sub-
7 section:

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

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

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

1 “(3) being a plan or arrangement described in
2 section 3(40)(A)(i),
3 shall, upon conviction, be imprisoned not more than 5
4 years, be fined under title 18, United States Code, or
5 both.”.

6 (b) CEASE ACTIVITIES ORDERS.—Section 502 of the
7 Employee Retirement Income Security Act of 1974 (29
8 U.S.C. 1132) is amended by adding at the end the fol-
9 lowing new subsection:

10 “(n) ASSOCIATION HEALTH PLAN CEASE AND DE-
11 SIST ORDERS.—

12 “(1) IN GENERAL.—Subject to paragraph (2),
13 upon application by the Secretary showing the oper-
14 ation, promotion, or marketing of an association
15 health plan (or similar arrangement providing bene-
16 fits consisting of medical care (as defined in section
17 733(a)(2))) that—

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

24 “(B) is an association health plan certified
25 under part 8 and is not operating in accordance

1 with the requirements under part 8 for such
2 certification,
3 a district court of the United States shall enter an
4 order requiring that the plan or arrangement cease
5 activities.

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

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

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

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

24 (c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—
25 Section 503 of the Employee Retirement Income Security

1 Act of 1974 (29 U.S.C. 1133) is amended by inserting
 2 “(a) IN GENERAL.—” before “In accordance”, and by
 3 adding at the end the following new subsection:

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

10 **SEC. 124. COOPERATION BETWEEN FEDERAL AND STATE**
 11 **AUTHORITIES.**

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

15 “(d) CONSULTATION WITH STATES WITH RESPECT
 16 TO ASSOCIATION HEALTH PLANS.—

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

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

24 “(B) the Secretary’s authority to certify
 25 association health plans under part 8 in accord-

1 ance with regulations of the Secretary applica-
2 ble to certification under part 8.

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

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

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

19 **SEC. 125. EFFECTIVE DATE AND TRANSITIONAL AND**
20 **OTHER RULES.**

21 (a) EFFECTIVE DATE.—The amendments made by
22 this Act shall take effect 1 year after the date of the enact-
23 ment of this Act. The Secretary of Labor shall first issue
24 all regulations necessary to carry out the amendments

1 made by this Act within 1 year after the date of the enact-
2 ment of this Act.

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

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

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

1 (B) the requirements of sections 801(a)
2 and 803(a) of the Employee Retirement Income
3 Security Act of 1974 shall be deemed met with
4 respect to such arrangement;

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

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

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

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

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

22 The provisions of this subsection shall cease to apply
23 with respect to any such arrangement at such time
24 after the date of the enactment of this Act as the

1 applicable requirements of this subsection are not
2 met with respect to such arrangement.

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

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

19 **Subtitle C—Tax-Related Provisions**

20 **SEC. 131. PREMIUM ASSISTANCE ADJUSTMENT TO RE-** 21 **FLECT AGE.**

22 (a) MODIFICATION OF APPLICABLE PERCENTAGE.—
23 Section 36B(b)(3)(A) of the Internal Revenue Code of
24 1986 is amended to read as follows:

25 “(A) APPLICABLE PERCENTAGE.—

1 “(i) IN GENERAL.—The applicable
 2 percentage for any taxable year shall be
 3 the percentage such that the applicable
 4 percentage for any taxpayer whose house-
 5 hold income is within an income tier speci-
 6 fied in the following table shall increase, on
 7 a sliding scale in a linear manner, from the
 8 initial percentage to the final percentage
 9 specified in such table for such income tier
 10 with respect to a taxpayer of the age in-
 11 volved:

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

12 “(ii) AGE DETERMINATIONS.—

13 “(I) IN GENERAL.—For purposes

14 of clause (i), the age of the taxpayer

15 taken into account under clause (i)

16 with respect to any taxable year is the

17 age attained by such taxpayer before

18 the close of such taxable year.

1 “(II) JOINT RETURNS.—In the
2 case of a joint return, the age of the
3 older spouse shall be taken into ac-
4 count under clause (i).

5 “(iii) INDEXING.—In the case of any
6 taxable year beginning after calendar year
7 2021, the initial and final percentages con-
8 tained in clause (i) shall be adjusted to re-
9 flect—

10 “(I) the excess (if any) of the
11 rate of premium growth for the period
12 beginning with calendar year 2013
13 and ending with calendar year 2020,
14 over the rate of income growth for
15 such period, and

16 “(II) in addition to any adjust-
17 ment under subclause (I), the excess
18 (if any) of the rate of premium
19 growth for calendar year 2020, over
20 the rate of growth in the consumer
21 price index for calendar year 2020.

22 “(iv) FAILSAFE.—Clause (iii)(II) shall
23 apply only if the aggregate amount of pre-
24 mium tax credits under this section and
25 cost-sharing reductions under section 1402

1 of the Patient Protection and Affordable
2 Care Act for calendar year 2018 exceeds
3 an amount equal to 0.504 percent of the
4 gross domestic product for such calendar
5 year.”.

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

9 **SEC. 132. REPEAL OF ANNUAL FEE ON HEALTH INSURANCE**
10 **PROVIDERS.**

11 (a) IN GENERAL.—The Patient Protection and Af-
12 fordable Care Act is amended by striking section 9010.

13 (b) EFFECTIVE DATE.—The amendments made by
14 this section shall apply with respect to calendar years be-
15 ginning after December 31, 2019.

16 **SEC. 133. REPEAL OF MEDICAL DEVICE EXCISE TAX.**

17 (a) IN GENERAL.—Chapter 32 of the Internal Rev-
18 enue Code of 1986 is amended by striking subchapter E.

19 (b) CONFORMING AMENDMENTS.—

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

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

1 (c) CLERICAL AMENDMENT.—The table of sub-
 2 chapters for chapter 32 of such Code is amended by strik-
 3 ing the item relating to subchapter E.

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

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

9 (a) IN GENERAL.—Section 106 of the Internal Rev-
 10 enue Code of 1986 is amended by adding at the end the
 11 following new subsection:

12 “(h) LIMITATION.—

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

17 “(A) \$10,200 for self-only coverage, and

18 “(B) \$27,500 for all other coverage.

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

22 “(A) such dollar amount, multiplied by—

23 “(B) the cost-of-living adjustment deter-
 24 mined under section 1(f)(3) for such calendar
 25 year, determined

1 “(i) by substituting ‘calendar year
2 2020’ for ‘calendar year 2016’ in subpara-
3 graph (A)(ii) thereof, and

4 “(ii) by substituting for the C–CPI–U
5 referred to in section 1(f)(3)(A) the
6 amount that such CPI would have been if
7 the annual percentage increase in CPI with
8 respect to each year after 2020 and before
9 2031 had been one percentage point great-
10 er.

11 “(3) TERMS RELATED TO CPI.—

12 “(A) ANNUAL PERCENTAGE INCREASE.—
13 For purposes of subparagraph (B)(ii)(II), the
14 term ‘annual percentage increase’ means the
15 percentage (if any) by which C–CPI–U for any
16 year exceeds the C–CPI–U for the prior year.

17 “(B) OTHER TERMS.—Terms used in this
18 paragraph which are also used in section
19 1(f)(3) shall have the same meanings as when
20 used in such section.”.

21 (b) REPEAL OF EMPLOYER-SPONSORED HEALTH
22 COVERAGE EXCISE TAX.—The Internal Revenue Code of
23 1986 is amended by striking section 4980I.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to taxable years begin-
3 ning after December 31, 2020.

4 **SEC. 135. INCLUSION OF CERTAIN OVER-THE-COUNTER**
5 **MEDICAL PRODUCTS AS QUALIFIED MEDICAL**
6 **EXPENSES.**

7 (a) HSAS.—Section 223(d)(2) of the Internal Rev-
8 enue Code of 1986 is amended—

9 (1) by striking the last sentence of subpara-
10 graph (A) and inserting the following: “For pur-
11 poses of this subparagraph, amounts paid for men-
12 strual care products shall be treated as paid for
13 medical care.”, and

14 (2) by adding at the end the following new sub-
15 paragraph:

16 “(D) MENSTRUAL CARE PRODUCT.—For
17 purposes of this paragraph, the term ‘menstrual
18 care product’ means a tampon, pad, liner, cup,
19 sponge, or similar product used by women with
20 respect to menstruation or other genital-tract
21 secretions.”.

22 (b) ARCHER MSAS.—Section 220(d)(2)(A) of such
23 Code is amended by striking the last sentence and insert-
24 ing the following: “For purposes of this subparagraph,
25 amounts paid for menstrual care products (as defined in

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

3 (c) HEALTH FLEXIBLE SPENDING ARRANGEMENTS
4 AND HEALTH REIMBURSEMENT ARRANGEMENTS.—Sec-
5 tion 106 of such Code is amended by striking subsection
6 (f) and inserting the following new subsection:

7 “(f) REIMBURSEMENTS FOR MENSTRUAL CARE
8 PRODUCTS.—For purposes of this section and section
9 105, expenses incurred for menstrual care products (as
10 defined in section 223(d)(2)(D)) shall be treated as in-
11 curred for medical care.”.

12 (d) EFFECTIVE DATES.—

13 (1) DISTRIBUTIONS FROM HEALTH SAVINGS AC-
14 COUNTS.—The amendments made by subsections (a)
15 and (b) shall apply to amounts paid after December
16 31, 2020.

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

20 **SEC. 136. REPEAL OF LIMITATION ON HEALTH FLEXIBLE**
21 **SPENDING ARRANGEMENTS.**

22 (a) IN GENERAL.—Section 125 of the Internal Rev-
23 enue Code of 1986 is amended by striking subsection (i).

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

4 **SEC. 137. MEDICARE PART D TAX DEDUCTION.**

5 (a) IN GENERAL.—Section 139A of the Internal Rev-
6 enue Code of 1986 is amended by adding at the end the
7 following: “This section shall not be taken into account
8 for purposes of determining whether any deduction is al-
9 lowable with respect to any cost taken into account in de-
10 termining such payment.”.

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

14 **SEC. 138. REPEAL OF NET INVESTMENT INCOME TAX.**

15 (a) IN GENERAL.—Subtitle A of the Internal Rev-
16 enue Code of 1986 is amended by striking chapter 2A.

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

20 **SEC. 139. BASIS FOR PURPOSES OF DETERMINING GAIN OR**
21 **LOSS.**

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

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

3 **SEC. 140. DEDUCTION FOR QUALIFIED CHARITY CARE.**

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

7 **“SEC. 199B. QUALIFIED CHARITY CARE.**

8 “(a) IN GENERAL.—There shall be allowed as a de-
9 duction for the taxable year an amount equal to—

10 “(1) in the case of a direct primary care physi-
11 cian, an amount equal to the sum of—

12 “(A) the fee (as published on a publicly
13 available website of such physician) for physi-
14 cians’ services that are qualified charity care
15 furnished by such taxpayer during such year,
16 and

17 “(B) for each visit by a patient to such
18 physician during which qualified charity care is
19 furnished, half of so much of the lowest sub-
20 scription fee of such physician that is attrib-
21 utable to a month, and

22 “(2) in the case of any other individual, the un-
23 reimbursed Medicare-based value of qualified charity
24 care furnished by such taxpayer during such year.

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

1 “(1) UNREIMBURSED MEDICARE-BASED
2 VALUE.—The term ‘unreimbursed Medicare-based
3 value’ means, with respect to physicians’ services,
4 the amount payable for such services under the phy-
5 sician fee schedule established under section 1848 of
6 the Social Security Act.

7 “(2) QUALIFIED CHARITY CARE.—The term
8 ‘qualified charity care’ means physicians’ services
9 that are furnished—

10 “(A) without expectation of reimburse-
11 ment, and

12 “(B) to an individual enrolled—

13 “(i) under a State plan under title
14 XIX of the Social Security Act (or a waiv-
15 er of such plan), or

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

19 “(3) DIRECT PRIMARY CARE PHYSICIAN.—The
20 term ‘direct primary care physician’ means a physi-
21 cian (as defined in section 1861(r) of the Social Se-
22 curity Act) who provides primary care—

23 “(A) to individuals who have paid a peri-
24 odic subscription fee, and

1 cian, or attending medical personnel supporting such phy-
2 sician, if such act or omission—

3 “(1) occurs in the course of furnishing qualified
4 charity care (as such term is defined in section
5 199B of the Internal Revenue Code of 1986); and

6 “(2) was not grossly negligent.

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

12 “(c) DEFINITIONS.—In this section:

13 “(1) PHYSICIAN.—The term ‘physician’ has the
14 meaning given such term by section 1861(r) of the
15 Social Security Act.

16 “(2) ATTENDING MEDICAL PERSONNEL.—The
17 term ‘attending medical personnel’ means an indi-
18 vidual who is licensed to directly support a physician
19 in furnishing medical services.”.

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

1 **TITLE II—MEDICARE AND**
2 **MEDICAID REFORMS**
3 **Subtitle A**

4 **SEC. 201. FLEXIBLE BLOCK GRANT OPTION FOR STATES.**

5 Title XIX of the Social Security Act is amended—

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

7 (A) in subsection (a), in the matter before
8 paragraph (1), by inserting “and section
9 1903A(a)” after “except as otherwise provided
10 in this section”; and

11 (B) in subsection (d)(1), by striking “to
12 which” and inserting “to which, subject to sec-
13 tion 1903A(a),”; and

14 (2) by inserting after such section 1903 the fol-
15 lowing new section:

16 **“SEC. 1903A. FLEXIBLE BLOCK GRANT OPTION FOR STATES.**

17 “(a) IN GENERAL.—In the case of a State that elects
18 the option of applying this section for a 10-fiscal-year pe-
19 riod (beginning no earlier than fiscal year 2020 and, at
20 the State option, for any succeeding 10-fiscal-year period)
21 and that has a plan approved by the Secretary under sub-
22 section (b) to carry out the option for such period—

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

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

5 “(2) the payment under this section may only
6 be used consistent with the State plan under sub-
7 section (b) for block grant health care assistance (as
8 defined in subsection (g)); and

9 “(3) with respect to block grant individuals
10 within the applicable block grant category for the
11 State for which block grant health care assistance is
12 made available under this section, such assistance
13 shall be instead of medical assistance otherwise pro-
14 vided to the individual under this title.

15 “(b) STATE PLAN FOR ADMINISTERING BLOCK
16 GRANT OPTION.—

17 “(1) IN GENERAL.—No payment shall be made
18 under this section to a State pursuant to an election
19 for a 10-fiscal-year period under subsection (a) un-
20 less the State has a plan, approved under paragraph
21 (2), for such period that specifies—

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

1 “(B) the conditions for eligibility of block
2 grant individuals within such applicable block
3 grant category for block grant health care as-
4 sistance under the option, which shall be in-
5 stead of other conditions for eligibility under
6 this title, except that in the case of a State that
7 has elected the applicable block grant category
8 described in—

9 “(i) paragraph (1) of subsection (f),
10 the plan must provide for eligibility for
11 pregnant women and children required to
12 be provided medical assistance under sub-
13 sections (a)(10)(A)(i) and (e)(4) of section
14 1902; or

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

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

1 ration, and scope, cost-sharing, and methods of
2 delivery for medical assistance otherwise re-
3 quired under this title, except that the plan
4 must provide for assistance for—

5 “(i) hospital care;

6 “(ii) surgical care and treatment;

7 “(iii) medical care and treatment;

8 “(iv) obstetrical and prenatal care and
9 treatment;

10 “(v) prescribed drugs, medicines, and
11 prosthetic devices;

12 “(vi) other medical supplies and serv-
13 ices; and

14 “(vii) health care for children under
15 18 years of age.

16 “(2) REVIEW AND APPROVAL.—A plan de-
17 scribed in paragraph (1) shall be deemed approved
18 by the Secretary unless the Secretary determines,
19 within 30 days after the date of the Secretary’s re-
20 ceipt of the plan, that the plan is incomplete or actu-
21 arially unsound and, with respect to such plan and
22 its implementation under this section, the require-
23 ments of paragraphs (1), (10)(B), (17), and (23) of
24 section 1902(a) shall not apply.

25 “(c) AMOUNT OF BLOCK GRANT FUNDS.—

1 “(1) FOR INITIAL FISCAL YEAR.—The block
2 grant amount under this subsection for a State for
3 the initial fiscal year in the first 10-fiscal-year pe-
4 riod is equal to an amount determined by the Sec-
5 retary to equal the per capita spending on the popu-
6 lation covered by the State plan established in sub-
7 section (b) of section 1903A.

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

17 “(3) AVAILABILITY OF ROLLOVER FUNDS.—The
18 block grant amount under this subsection for a
19 State for a fiscal year shall remain available to the
20 State for expenditures under this section for the suc-
21 ceeding fiscal year but only if an election is in effect
22 under this section for the State in such succeeding
23 fiscal year.

24 “(d) FEDERAL PAYMENT AND STATE RESPONSI-
25 BILITY.—The Secretary shall pay to each State with an

1 election in effect under this section for a fiscal year, from
2 its block grant amount under subsection (e) available for
3 such fiscal year, an amount for each quarter of such fiscal
4 year equal to the enhanced FMAP described in the first
5 sentence of section 2105(b) of the total amount expended
6 under the State plan under this section during such quar-
7 ter, and the State is responsible for the balance of funds
8 to carry out such plan.

9 “(e) BLOCK GRANT INDIVIDUAL DEFINED.—In this
10 section, the term ‘block grant individual’ means, with re-
11 spect to a State for a 10-fiscal-year period, an individual
12 who is within an applicable block grant category for the
13 State and such period.

14 “(f) APPLICABLE BLOCK GRANT CATEGORY DE-
15 FINED.—In this section, the term ‘applicable block grant
16 category’ means with respect to a State for a 10-fiscal-
17 year period, either of the following as specified by the
18 State for such period in its plan under subsection
19 (b)(1)(A):

20 “(1) ELDERLY, BLIND, DISABLED.—Both of the
21 following categories:

22 “(A) ELDERLY.—Individuals who are 65
23 years of age or older.

24 “(B) BLIND AND DISABLED.—Individuals
25 (not described in the previous subparagraph)

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

3 “(2) ELDERLY, BLIND, DISABLED, AND OTH-
4 ERS.—All of the following categories:

5 “(A) ELDERLY.—Individuals who are 65
6 years of age or older.

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

11 “(C) CHILDREN.—Individuals (not de-
12 scribed in a previous subparagraph) who are
13 children under 19 years of age.

14 “(D) EXPANSION ENROLLEES.—Individ-
15 uals (not described in a previous subparagraph)
16 for whom the amounts expended for medical as-
17 sistance are subject to an increase or change in
18 the Federal medical assistance percentage
19 under subsection (y) or (z)(2), respectively, of
20 section 1905.

21 “(E) OTHER NONELDERLY, NONDISABLED,
22 NON-EXPANSION ADULTS.—Individuals who are
23 not described in any of the previous subpara-
24 graphs and whose income does not exceed 60
25 percent of the poverty line (as defined in section

1 2110(c)(5)) applicable to a family of the size in-
2 volved.

3 “(g) BLOCK GRANT HEALTH CARE ASSISTANCE.—

4 In this section, the term ‘block grant health care assist-
5 ance’ means assistance for health-care-related items and
6 medical services for block grant individuals within the ap-
7 plicable block grant category for the State and 10-fiscal-
8 year period involved who are low-income individuals (as
9 defined by the State).

10 “(h) AUDITING.—As a condition of receiving funds
11 under this section, a State shall contract with an inde-
12 pendent entity to conduct audits of its expenditures made
13 with respect to activities funded under this section for
14 each fiscal year for which the State elects to apply this
15 section to ensure that such funds are used consistent with
16 this section and shall make such audits available to the
17 Secretary upon the request of the Secretary.”.

18 **SEC. 202. MEDICAID ELIGIBILITY DETERMINATIONS.**

19 (a) STATE FLEXIBILITY TO USE CONTRACTORS TO
20 MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF
21 STATE.—Section 1902(a)(5) of the Social Security Act
22 (42 U.S.C. 1396a(a)(5)) is amended by inserting before
23 the semicolon at the end the following: “, but such deter-
24 minations of eligibility may be made, at the option of a
25 State, under a contract with another State or local agency

1 or a contractor so long as the contract does not provide
2 incentives for the agency or contractor to delay eligibility
3 determinations or to deny eligibility for individuals other-
4 wise eligible for medical assistance”.

5 (b) FREQUENCY OF ELIGIBILITY REDETERMINA-
6 TIONS.—Section 1902(e)(14) of the Social Security Act
7 (42 U.S.C. 1396a(e)(14)) is amended by adding at the
8 end the following:

9 “(L) FREQUENCY OF ELIGIBILITY REDE-
10 TERMINATIONS.—Beginning on October 1,
11 2019, and notwithstanding subparagraph (H),
12 in the case of an individual whose eligibility for
13 medical assistance under the State plan under
14 this title (or a waiver of such plan) is deter-
15 mined based on the application of modified ad-
16 justed gross income under subparagraph (A)
17 and who is so eligible on the basis of clause
18 (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection
19 (a)(10)(A), at the option of the State, the State
20 plan may provide that the individual’s eligibility
21 shall be redetermined every 6 months (or such
22 shorter number of months as the State may
23 elect).”.

1 **SEC. 203. LOWERING SAFE HARBOR THRESHOLD WITH RE-**
2 **SPECT TO STATE TAXES ON HEALTH CARE**
3 **PROVIDERS.**

4 Section 1903(w)(4)(C)(ii) of the Social Security Act
5 (42 U.S.C. 1396b(w)(4)(C)(ii)) is amended—

6 (1) by striking “of fiscal years beginning” and
7 inserting “of fiscal years—

8 “(I) beginning”; and

9 (2) by striking “it appears.” and inserting the
10 following: “it appears;

11 “(II) beginning on or after January 1,
12 2020, and before January 1, 2030, ‘4 percent’
13 shall be substituted for ‘6 percent’ each place it
14 appears;

15 “(III) beginning on or after January 1,
16 2030, and before January 1, 2035, ‘3 percent’
17 shall be substituted for ‘6 percent’ each place it
18 appears;

19 “(IV) beginning on or after January 1,
20 2035, and before January 1, 2040, ‘2 percent’
21 shall be substituted for ‘6 percent’ each place it
22 appears;

23 “(V) beginning on or after January 1,
24 2040, and before January 1, 2045, ‘1 percent’
25 shall be substituted for ‘6 percent’ each place it
26 appears; and

1 “(VI) beginning on or after January 1,
2 2045, ‘0 percent’ shall be substituted for ‘6 per-
3 cent’ each place it appears.”.

4 **SEC. 204. INCOME LIMITATIONS FOR REFUNDABLE CRED-**
5 **ITS FOR COVERAGE UNDER A QUALIFIED**
6 **HEALTH PLAN.**

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

14 (b) **EFFECTIVE DATE.**—The amendments made by
15 this section shall apply with respect to taxable years begin-
16 ning after the date of the enactment of this Act.

17 **Subtitle B—Medicare**

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

20 (a) **IN GENERAL.**—Section 1834 of the Social Secu-
21 rity Act (42 U.S.C. 1395m) is amended by adding at the
22 end the following new subsection:

23 “(x) **OFF-CAMPUS PROVIDER-BASED DEPARTMENT**
24 **SITE NEUTRAL PAYMENT.**—

1 “(1) IN GENERAL.—With respect to items and
2 services furnished in an off-campus provider-based
3 department, payment under this section for such
4 items and services shall be the amount determined
5 under the fee schedule under section 1848 for such
6 items and services furnished if furnished in a physi-
7 cian office setting.

8 “(2) OFF-CAMPUS PROVIDER-BASED DEPART-
9 MENT.—For purposes of this subsection, the term
10 ‘off-campus provider-based department’ has such
11 meaning as specified by the Secretary.”.

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

15 **SEC. 222. ELIMINATION OF MEDICARE ELIGIBILITY FOR**
16 **CERTAIN INDIVIDUALS.**

17 (a) ENROLLMENT PROHIBITION.—

18 (1) PART B.—Section 1836 of the Social Secu-
19 rity Act (42 U.S.C. 1395o) is amended by striking
20 the period at the end and inserting “, except that an
21 individual who attains age 65 on or after January
22 1, 2030, and is an individual who, upon attaining
23 such age, has earned \$10,000,000 or more in life-
24 time wages, shall not be eligible to so enroll.”.

1 (2) PART D.—Section 1860D–1(a)(3)(A) of
2 such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amend-
3 ed by striking the period at the end and inserting
4 “, excluding an individual who, upon attaining age
5 65, has earned \$10,000,000 or more in lifetime
6 wages.”.

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

10 “(aa) ADDITIONAL LIMITATION ON NEWLY ELIGI-
11 BLE BENEFICIARIES.—

12 “(1) IN GENERAL.—Notwithstanding any other
13 provision of this section, on or after January 1,
14 2030, a medicare supplemental policy may not be
15 sold or issued to a targeted newly eligible Medicare
16 beneficiary.

17 “(2) TARGETED NEWLY ELIGIBLE MEDICARE
18 BENEFICIARY.—For purposes of this subsection, the
19 term ‘targeted newly eligible Medicare beneficiary’
20 means an individual who, upon attaining the age of
21 65, has earned \$10,000,000 or more in lifetime
22 wages.”.

23 **SEC. 223. MEDICARE COVERAGE OF BAD DEBT.**

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

1 (1) in subparagraph (T)—

2 (A) in clause (iv), by striking “and” at the
3 end;

4 (B) in clause (v)—

5 (i) by striking “during fiscal year”
6 and inserting “during fiscal years”;

7 (ii) by striking “or a subsequent fiscal
8 year” and inserting “through 2020”; and

9 (iii) by striking the period at the end
10 and inserting “, and”; and

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

13 “(vi) for cost reporting periods beginning dur-
14 ing fiscal year 2021 or a subsequent fiscal year, by
15 the percent applicable for cost reporting periods be-
16 ginning during the previous fiscal year, increased
17 (through fiscal year 2024) by 10 percentage
18 points.”;

19 (2) in subparagraph (V)—

20 (A) in clause (i)—

21 (i) in subclause (III), by striking
22 “and” at the end;

23 (ii) in subclause (IV)—

1 (I) by striking “during fiscal
2 year” and inserting “during fiscal
3 years 2015 through 2020”; and

4 (II) by striking the period at the
5 end and inserting “; and”; and

6 (iii) by adding at the end the fol-
7 lowing new subclause:

8 “(V) for cost reporting periods beginning
9 during fiscal year 2021 or a subsequent fiscal
10 year, the percent applicable for cost reporting
11 periods beginning during the previous fiscal
12 year, increased (through fiscal year 2024) by
13 10 percentage points.”; and

14 (B) in clause (ii)—

15 (i) in subclause (III), by striking
16 “and” at the end; and

17 (ii) in subclause (IV)—

18 (I) by striking “a subsequent fis-
19 cal year” and inserting “fiscal years
20 2015 through 2020”;

21 (II) by striking the period at the
22 end and inserting “; and”; and

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

1 “(V) for cost reporting periods beginning
2 during fiscal year 2021 or a subsequent fiscal
3 year, shall be reduced by the percent applicable
4 for cost reporting periods beginning during the
5 previous fiscal year, increased (through fiscal
6 year 2024) by 10 percentage points.”; and

7 (3) in subparagraph (W)(i)—

8 (A) in subclause (II), by striking “and” at
9 the end;

10 (B) in subclause (III)—

11 (i) by striking “during a subsequent
12 fiscal year” and inserting “during fiscal
13 years 2015 through 2020”; and

14 (ii) by striking the period at the end
15 and inserting “; and”; and

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

18 “(IV) for cost reporting periods beginning dur-
19 ing fiscal year 2021 or a subsequent fiscal year, by
20 the percent applicable for cost reporting periods be-
21 ginning during the previous fiscal year, increased
22 (through fiscal year 2024) by 10 percentage
23 points.”.

1 **Subtitle C—Medical Malpractice**
2 **Reform**

3 **SEC. 231. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

4 (a) STATUTE OF LIMITATIONS.—

5 (1) IN GENERAL.—Except as provided in para-
6 graph (2), the time for the commencement of a
7 health care lawsuit shall be, whichever occurs first of
8 the following:

9 (A) Three years after the date of the oc-
10 currence of the breach or tort.

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

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

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

24 (A) upon proof of fraud;

25 (B) intentional concealment; or

1 (C) the presence of a foreign body, which
2 has no therapeutic or diagnostic purpose or ef-
3 fect, in the person of the injured person.

4 (3) ACTIONS BY A MINOR.—Actions by a minor
5 shall be commenced within 3 years after the date of
6 the occurrence of the breach or tort or 3 years after
7 the date of the medical or health care treatment that
8 is the subject of the claim is completed (whichever
9 occurs first) except that actions by a minor under
10 the full age of 6 years shall be commenced within 3
11 years after the date of the occurrence of the breach
12 or tort, 3 years after the date of the medical or
13 health care treatment that is the subject of the claim
14 is completed, or 1 year after the injury is discovered,
15 or through the use of reasonable diligence should
16 have been discovered, or prior to the minor’s 8th
17 birthday, whichever provides a longer period. Such
18 time limitation shall be tolled for minors for any pe-
19 riod during which a parent or guardian and a health
20 care provider have committed fraud or collusion in
21 the failure to bring an action on behalf of the in-
22 jured minor.

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

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

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

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

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

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

14 **SEC. 232. COMPENSATING PATIENT INJURY.**

15 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL
16 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any
17 health care lawsuit, nothing in this Act shall limit a claim-
18 ant’s recovery of the full amount of the available economic
19 damages, notwithstanding the limitation in subsection (b).

20 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
21 health care lawsuit, the amount of noneconomic damages,
22 if available, shall not exceed \$250,000, regardless of the
23 number of parties against whom the action is brought or
24 the number of separate claims or actions brought with re-
25 spect to the same injury.

1 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
2 DAMAGES.—For purposes of applying the limitation in
3 subsection (b), future noneconomic damages shall not be
4 discounted to present value. The jury shall not be in-
5 formed about the maximum award for noneconomic dam-
6 ages. An award for noneconomic damages in excess of
7 \$250,000 shall be reduced either before the entry of judg-
8 ment, or by amendment of the judgment after entry of
9 judgment, and such reduction shall be made before ac-
10 counting for any other reduction in damages required by
11 law. If separate awards are rendered for past and future
12 noneconomic damages and the combined awards exceed
13 \$250,000, the future noneconomic damages shall be re-
14 duced first.

15 (d) FAIR SHARE RULE.—In any health care lawsuit,
16 each party shall be liable for that party's several share
17 of any damages only and not for the share of any other
18 person. Each party shall be liable only for the amount of
19 damages allocated to such party in direct proportion to
20 such party's percentage of responsibility. Whenever a
21 judgment of liability is rendered as to any party, a sepa-
22 rate judgment shall be rendered against each such party
23 for the amount allocated to such party. For purposes of
24 this section, the trier of fact shall determine the propor-

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

3 (e) STATE FLEXIBILITY.—No provision of this sec-
4 tion shall be construed to preempt any State law (whether
5 effective before, on, or after the date of the enactment of
6 this Act) that specifies a particular monetary amount of
7 economic or noneconomic damages (or the total amount
8 of damages) that may be awarded in a health care lawsuit,
9 regardless of whether such monetary amount is greater
10 or lesser than is provided for under this section.

11 **SEC. 233. MAXIMIZING PATIENT RECOVERY.**

12 (a) COURT SUPERVISION OF SHARE OF DAMAGES
13 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
14 suit, the court shall supervise the arrangements for pay-
15 ment of damages to protect against conflicts of interest
16 that may have the effect of reducing the amount of dam-
17 ages awarded that are actually paid to claimants. In par-
18 ticular, in any health care lawsuit in which the attorney
19 for a party claims a financial stake in the outcome by vir-
20 tue of a contingent fee, the court shall have the power
21 to restrict the payment of a claimant's damage recovery
22 to such attorney, and to redirect such damages to the
23 claimant based upon the interests of justice and principles
24 of equity. In no event shall the total of all contingent fees

1 for representing all claimants in a health care lawsuit ex-
2 ceed the following limits:

3 (1) Forty percent of the first \$50,000 recovered
4 by the claimant(s).

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

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

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

11 (b) APPLICABILITY.—The limitations in this section
12 shall apply whether the recovery is by judgment, settle-
13 ment, mediation, arbitration, or any other form of alter-
14 native dispute resolution. In a health care lawsuit involv-
15 ing a minor or incompetent person, a court retains the
16 authority to authorize or approve a fee that is less than
17 the maximum permitted under this section. The require-
18 ment for court supervision in the first two sentences of
19 subsection (a) applies only in civil actions.

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

1 **SEC. 234. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
2 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
3 **SUITS.**

4 (a) **IN GENERAL.**—In any health care lawsuit, if an
5 award of future damages, without reduction to present
6 value, equaling or exceeding \$50,000 is made against a
7 party with sufficient insurance or other assets to fund a
8 periodic payment of such a judgment, the court shall, at
9 the request of any party, enter a judgment ordering that
10 the future damages be paid by periodic payments, in ac-
11 cordance with the Uniform Periodic Payment of Judg-
12 ments Act promulgated by the National Conference of
13 Commissioners on Uniform State Laws.

14 (b) **APPLICABILITY.**—This section applies to all ac-
15 tions which have not been first set for trial or retrial be-
16 fore the effective date of this Act.

17 (c) **STATE FLEXIBILITY.**—No provision of this sec-
18 tion shall be construed to preempt any State law (whether
19 effective before, on, or after the date of the enactment of
20 this Act) that specifies periodic payments for future dam-
21 ages at any amount other than \$50,000 or that mandates
22 such payments absent the request of either party.

23 **SEC. 235. PRODUCT LIABILITY FOR HEALTH CARE PRO-**
24 **VIDERS.**

25 A health care provider who prescribes, or who dis-
26 penses pursuant to a prescription, a medical product ap-

1 proved, licensed, or cleared by the Food and Drug Admin-
2 istration shall not be named as a party to a product liabil-
3 ity lawsuit involving such product and shall not be liable
4 to a claimant in a class action lawsuit against the manu-
5 facturer, distributor, or seller of such product.

6 **SEC. 236. DEFINITIONS.**

7 In this Act:

8 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
9 TEM; ADR.—The term “alternative dispute resolution
10 system” or “ADR” means a system that provides
11 for the resolution of health care lawsuits in a man-
12 ner other than through a civil action brought in a
13 State or Federal court.

14 (2) CLAIMANT.—The term “claimant” means
15 any person who brings a health care lawsuit, includ-
16 ing a person who asserts or claims a right to legal
17 or equitable contribution, indemnity, or subrogation,
18 arising out of a health care liability claim or action,
19 and any person on whose behalf such a claim is as-
20 serted or such an action is brought, whether de-
21 ceased, incompetent, or a minor.

22 (3) COLLATERAL SOURCE BENEFITS.—The
23 term “collateral source benefits” means any amount
24 paid or reasonably likely to be paid in the future to
25 or on behalf of the claimant, or any service, product,

1 or other benefit provided or reasonably likely to be
2 provided in the future to or on behalf of the claim-
3 ant, as a result of the injury or wrongful death, pur-
4 suant to—

5 (A) any State or Federal health, sickness,
6 income-disability, accident, or workers' com-
7 pensation law;

8 (B) any health, sickness, income-disability,
9 or accident insurance that provides health bene-
10 fits or income-disability coverage;

11 (C) any contract or agreement of any
12 group, organization, partnership, or corporation
13 to provide, pay for, or reimburse the cost of
14 medical, hospital, dental, or income-disability
15 benefits; and

16 (D) any other publicly or privately funded
17 program.

18 (4) CONTINGENT FEE.—The term “contingent
19 fee” includes all compensation to any person or per-
20 sons which is payable only if a recovery is effected
21 on behalf of one or more claimants.

22 (5) ECONOMIC DAMAGES.—The term “economic
23 damages” means objectively verifiable monetary
24 losses incurred as a result of the provision or use of
25 (or failure to provide or use) health care services or

1 medical products, such as past and future medical
2 expenses, loss of past and future earnings, cost of
3 obtaining domestic services, loss of employment, and
4 loss of business or employment opportunities, unless
5 otherwise defined under applicable State law. In no
6 circumstances shall damages for health care services
7 or medical products exceed the amount actually paid
8 or incurred by or on behalf of the claimant.

9 (6) FUTURE DAMAGES.—The term “future
10 damages” means any damages that are incurred
11 after the date of judgment, settlement, or other reso-
12 lution (including mediation, or any other form of al-
13 ternative dispute resolution).

14 (7) HEALTH CARE LAWSUIT.—The term
15 “health care lawsuit” means any health care liability
16 claim concerning the provision of goods or services
17 for which coverage was provided in whole or in part
18 via a Federal program, subsidy or tax benefit, or
19 any health care liability action concerning the provi-
20 sion of goods or services for which coverage was pro-
21 vided in whole or in part via a Federal program,
22 subsidy or tax benefit, brought in a State or Federal
23 court or pursuant to an alternative dispute resolu-
24 tion system, against a health care provider regard-
25 less of the theory of liability on which the claim is

1 based, or the number of claimants, plaintiffs, de-
2 fendants, or other parties, or the number of claims
3 or causes of action, in which the claimant alleges a
4 health care liability claim. Such term does not in-
5 clude a claim or action which is based on criminal
6 liability; which seeks civil fines or penalties paid to
7 Federal, State, or local government; or which is
8 grounded in antitrust.

9 (8) HEALTH CARE LIABILITY ACTION.—The
10 term “health care liability action” means a civil ac-
11 tion brought in a State or Federal court or pursuant
12 to an alternative dispute resolution system, against
13 a health care provider regardless of the theory of li-
14 ability on which the claim is based, or the number
15 of plaintiffs, defendants, or other parties, or the
16 number of causes of action, in which the claimant al-
17 leges a health care liability claim.

18 (9) HEALTH CARE LIABILITY CLAIM.—The
19 term “health care liability claim” means a demand
20 by any person, whether or not pursuant to ADR,
21 against a health care provider, including, but not
22 limited to, third-party claims, cross-claims, counter-
23 claims, or contribution claims, which are based upon
24 the provision or use of (or the failure to provide or
25 use) health care services or medical products, re-

1 regardless of the theory of liability on which the claim
2 is based, or the number of plaintiffs, defendants, or
3 other parties, or the number of causes of action.

4 (10) HEALTH CARE PROVIDER.—The term
5 “health care provider” means any person or entity
6 required by State or Federal laws or regulations to
7 be licensed, registered, or certified to provide health
8 care services, and being either so licensed, reg-
9 istered, or certified, or exempted from such require-
10 ment by other statute or regulation, as well as any
11 other individual or entity defined as a health care
12 provider, health care professional, or health care in-
13 stitution under State law.

14 (11) HEALTH CARE SERVICES.—The term
15 “health care services” means the provision of any
16 goods or services (including safety, professional, or
17 administrative services directly related to health
18 care) by a health care provider, or by any individual
19 working under the supervision of a health care pro-
20 vider, that relates to the diagnosis, prevention, or
21 treatment of any human disease or impairment, or
22 the assessment or care of the health of human
23 beings.

24 (12) MEDICAL PRODUCT.—The term “medical
25 product” means a drug, device, or biological product

1 intended for humans, and the terms “drug”, “de-
2 vice”, and “biological product” have the meanings
3 given such terms in sections 201(g)(1) and 201(h)
4 of the Federal Food, Drug and Cosmetic Act (21
5 U.S.C. 321(g)(1) and (h)) and section 351(a) of the
6 Public Health Service Act (42 U.S.C. 262(a)), re-
7 spectively, including any component or raw material
8 used therein, but excluding health care services.

9 (13) NONECONOMIC DAMAGES.—The term
10 “noneconomic damages” means damages for phys-
11 ical and emotional pain, suffering, inconvenience,
12 physical impairment, mental anguish, disfigurement,
13 loss of enjoyment of life, loss of society and compan-
14 ionship, loss of consortium (other than loss of do-
15 mestic service), hedonic damages, injury to reputa-
16 tion, and all other nonpecuniary losses of any kind
17 or nature incurred as a result of the provision or use
18 of (or failure to provide or use) health care services
19 or medical products, unless otherwise defined under
20 applicable State law.

21 (14) RECOVERY.—The term “recovery” means
22 the net sum recovered after deducting any disburse-
23 ments or costs incurred in connection with prosecu-
24 tion or settlement of the claim, including all costs
25 paid or advanced by any person. Costs of health care

1 incurred by the plaintiff and the attorneys' office
2 overhead costs or charges for legal services are not
3 deductible disbursements or costs for such purpose.

4 (15) REPRESENTATIVE.—The term “represent-
5 ative” means a legal guardian, attorney, person des-
6 igned to make decisions on behalf of a patient
7 under a medical power of attorney, or any person
8 recognized in law or custom as a patient’s agent.

9 (16) STATE.—The term “State” means each of
10 the several States, the District of Columbia, the
11 Commonwealth of Puerto Rico, the Virgin Islands,
12 Guam, American Samoa, the Northern Mariana Is-
13 lands, the Trust Territory of the Pacific Islands, and
14 any other territory or possession of the United
15 States, or any political subdivision thereof.

16 **SEC. 237. EFFECT ON OTHER LAWS.**

17 (a) VACCINE INJURY.—

18 (1) To the extent that title XXI of the Public
19 Health Service Act establishes a Federal rule of law
20 applicable to a civil action brought for a vaccine-re-
21 lated injury or death—

22 (A) this Act does not affect the application
23 of the rule of law to such an action; and

1 (B) any rule of law prescribed by this sub-
2 title in conflict with a rule of law of such title
3 XXI shall not apply to such action.

4 (2) If there is an aspect of a civil action
5 brought for a vaccine-related injury or death to
6 which a Federal rule of law under title XXI of the
7 Public Health Service Act does not apply, then this
8 subtitle or otherwise applicable law (as determined
9 under this subtitle) will apply to such aspect of such
10 action.

11 (b) OTHER FEDERAL LAW.—Except as provided in
12 this section, nothing in this subtitle shall be deemed to
13 affect any defense available to a defendant in a health care
14 lawsuit or action under any other provision of Federal law.

15 **SEC. 238. RULES OF CONSTRUCTION.**

16 (a) HEALTH CARE LAWSUITS.—Unless otherwise
17 specified in this subtitle, the provisions governing health
18 care lawsuits set forth in this subtitle preempt, subject to
19 subsections (b) and (c), State law to the extent that State
20 law prevents the application of any provisions of law estab-
21 lished by or under this subtitle. The provisions governing
22 health care lawsuits set forth in this subtitle supersede
23 chapter 171 of title 28, United States Code, to the extent
24 that such chapter—

1 (1) provides for a greater amount of damages
2 or contingent fees, a longer period in which a health
3 care lawsuit may be commenced, or a reduced appli-
4 cability or scope of periodic payment of future dam-
5 ages, than provided in this subtitle; or

6 (2) prohibits the introduction of evidence re-
7 garding collateral source benefits, or mandates or
8 permits subrogation or a lien on collateral source
9 benefits.

10 (b) PROTECTION OF STATES' RIGHTS AND OTHER
11 LAWS.—Any issue that is not governed by any provision
12 of law established by or under this subtitle (including
13 State standards of negligence) shall be governed by other-
14 wise applicable State or Federal law.

15 (c) STATE FLEXIBILITY.—No provision of this sub-
16 title shall be construed to preempt any defense available
17 to a party in a health care lawsuit under any other provi-
18 sion of State or Federal law.

19 **SEC. 239. EFFECTIVE DATE.**

20 This subtitle shall apply to any health care lawsuit
21 brought in a Federal or State court, or subject to an alter-
22 native dispute resolution system, that is initiated on or
23 after the date of the enactment of this subtitle, except that
24 any health care lawsuit arising from an injury occurring
25 prior to the date of the enactment of this subtitle shall

1 be governed by the applicable statute of limitations provi-
2 sions in effect at the time the cause of action accrued.

3 **SEC. 240. LIMITATION ON EXPERT WITNESS TESTIMONY.**

4 (a) IN GENERAL.—No person in a health care profes-
5 sion requiring licensure under the laws of a State shall
6 be competent to testify in any court of law to establish
7 the following facts—

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

15 (2) that the defendant acted with less than or
16 failed to act with ordinary and reasonable care in ac-
17 cordance with the recognized standard; and

18 (3) that as a proximate result of the defend-
19 ant's negligent act or omission, the claimant suf-
20 fered injuries which would not otherwise have oc-
21 curred,

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

1 or specialty in one of these States during the year pre-
2 ceding the date that the alleged injury or wrongful act
3 occurred.

4 (b) **APPLICABILITY.**—The requirements set forth in
5 subsection (a) shall also apply to expert witnesses testi-
6 fying for the defendant as rebuttal witnesses.

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

10 **SEC. 241. COMMUNICATIONS FOLLOWING UNANTICIPATED**
11 **OUTCOME.**

12 (a) **PROVIDER COMMUNICATIONS.**—In any health
13 care liability action, any and all statements, affirmations,
14 gestures, or conduct expressing apology, fault, sympathy,
15 commiseration, condolence, compassion, or a general sense
16 of benevolence which are made by a health care provider
17 or an employee of a health care provider to the patient,
18 a relative of the patient, or a representative of the patient
19 and which relate to the discomfort, pain, suffering, injury,
20 or death of the patient as the result of the unanticipated
21 outcome of medical care shall be inadmissible for any pur-
22 pose as evidence of an admission of liability or as evidence
23 of an admission against interest.

24 (b) **STATE FLEXIBILITY.**—No provision of this sec-
25 tion shall be construed to preempt any State law (whether

1 effective before, on, or after the date of the enactment of
2 this Act) that makes additional communications inadmis-
3 sible as evidence of an admission of liability or as evidence
4 of an admission against interest.

5 **SEC. 242. EXPERT WITNESS QUALIFICATIONS.**

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

11 (1) If the party against whom or on whose be-
12 half the testimony is to be offered is or claims to be
13 a specialist, the expert witness shall specialize at the
14 time of the occurrence that is the basis for the law-
15 suit in the same specialty or claimed specialty as the
16 party against whom or on whose behalf the testi-
17 mony is to be offered. If the party against whom or
18 on whose behalf the testimony is to be offered is or
19 claims to be a specialist who is board certified, the
20 expert witness shall be a specialist who is board cer-
21 tified in that specialty or claimed specialty.

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

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

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

7 (B) The instruction of students in an ac-
8 credited health professional school or accredited
9 residency or clinical research program in the
10 same health profession as the defendant and, if
11 the defendant is or claims to be a specialist, in
12 an accredited health professional school or ac-
13 credited residency or clinical research program
14 in the same specialty or claimed specialty.

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

20 (A) Active clinical practice as a general
21 practitioner.

22 (B) Instruction of students in an accred-
23 ited health professional school or accredited
24 residency or clinical research program in the
25 same health profession as the defendant.

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

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

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

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

20 **SEC. 243. AFFIDAVIT OF MERIT.**

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

1 fessional who meets the requirements for an expert wit-
2 ness under section 242 of this Act. The affidavit of merit
3 shall certify that the health professional has reviewed the
4 notice and all medical records supplied to him or her by
5 the plaintiff's attorney concerning the allegations con-
6 tained in the notice and shall contain a statement of each
7 of the following:

8 (1) The applicable standard of practice or care.

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

13 (3) The actions that should have been taken or
14 omitted by the health professional or health facility
15 in order to have complied with the applicable stand-
16 ard of practice or care.

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

20 (5) A listing of the medical records reviewed.

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

1 days in which to file the affidavit required under sub-
2 section (a).

3 (c) STATE FLEXIBILITY.—No provision of this sec-
4 tion shall be construed to preempt any State law (whether
5 effective before, on, or after the date of the enactment of
6 this Act) that establishes additional requirements for the
7 filing of an affidavit of merit or similar pre-litigation docu-
8 mentation.

9 **SEC. 244. NOTICE OF INTENT TO COMMENCE LAWSUIT.**

10 (a) ADVANCE NOTICE.—A person shall not com-
11 mence a health care lawsuit against a health care provider
12 unless the person has given the health care provider 90
13 days written notice before the action is commenced.

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

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

1 **TITLE III—PRESCRIPTION DRUG**
2 **COMPETITION**
3 **Subtitle A—Eliminating Delays of**
4 **Generic Drugs and Biosimilar**
5 **Products**

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

8 (a) DEFINITIONS.—In this section—

9 (1) the term “covered product”—

10 (A) means—

11 (i) any drug approved under sub-
12 section (b) or (j) of section 505 of the Fed-
13 eral Food, Drug, and Cosmetic Act (21
14 U.S.C. 355) or biological product licensed
15 under subsection (a) or (k) of section 351
16 of the Public Health Service Act (42
17 U.S.C. 262);

18 (ii) any combination of a drug or bio-
19 logical product described in clause (i); or

20 (iii) when reasonably necessary to
21 demonstrate sameness, biosimilarity, or
22 interchangeability for purposes of section
23 505 of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 355), or section 351
25 of the Public Health Service Act (42

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

5 (B) does not include any drug or biological
6 product that the Secretary has determined to be
7 currently in shortage and that appears on the
8 drug shortage list in effect under section 506E
9 of the Federal Food, Drug, and Cosmetic Act
10 (21 U.S.C. 356e), unless the shortage will not
11 be promptly resolved—

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

15 (ii) as otherwise determined by the
16 Secretary;

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

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

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

3 (4) the term “license holder” means the holder
4 of an application approved under subsection (c) or
5 (j) of section 505 of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 355) or the holder of a li-
7 cense under subsection (a) or (k) of section 351 of
8 the Public Health Service Act (42 U.S.C. 262) for
9 a covered product;

10 (5) the term “REMS” means a risk evaluation
11 and mitigation strategy under section 505–1 of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355–1);

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

18 (7) the term “Secretary” means the Secretary
19 of Health and Human Services;

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

1 (9) the term “sufficient quantities” means an
2 amount of a covered product that allows the eligible
3 product developer to—

4 (A) conduct testing to support an applica-
5 tion—

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

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

13 (B) fulfill any regulatory requirements re-
14 lating to such an application for approval or li-
15 censing.

16 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-
17 CIENT QUANTITIES OF A COVERED PRODUCT.—

18 (1) IN GENERAL.—An eligible product developer
19 may bring a civil action against the license holder
20 for a covered product seeking relief under this sub-
21 section in an appropriate district court of the United
22 States alleging that the license holder has declined
23 to provide sufficient quantities of the covered prod-
24 uct to the eligible product developer on commercially
25 reasonable, market-based terms.

1 (2) ELEMENTS.—

2 (A) IN GENERAL.—To prevail in a civil ac-
3 tion brought under paragraph (1), an eligible
4 product developer shall prove, by a preponder-
5 ance of the evidence—

6 (i) that—

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

9 (II) if the covered product is sub-
10 ject to a REMS with ETASU—

11 (aa) the eligible product de-
12 veloper has obtained a covered
13 product authorization from the
14 Secretary in accordance with sub-
15 paragraph (B); and

16 (bb) the eligible product de-
17 veloper has provided a copy of
18 the covered product authorization
19 to the license holder;

20 (ii) that, as of the date on which the
21 civil action is filed, the product developer
22 has not obtained sufficient quantities of
23 the covered product on commercially rea-
24 sonable, market-based terms;

1 (iii) that the eligible product developer
2 has requested to purchase sufficient quan-
3 tities of the covered product from the li-
4 cense holder; and

5 (iv) that the license holder has not de-
6 livered to the eligible product developer
7 sufficient quantities of the covered product
8 on commercially reasonable, market-based
9 terms—

10 (I) for a covered product that is
11 not subject to a REMS with ETASU,
12 by the date that is 31 days after the
13 date on which the license holder re-
14 ceived the request for the covered
15 product; and

16 (II) for a covered product that is
17 subject to a REMS with ETASU, by
18 31 days after the later of—

19 (aa) the date on which the
20 license holder received the re-
21 quest for the covered product; or

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

1 issued by the Secretary in ac-
2 cordance with subparagraph (B).

3 (B) AUTHORIZATION FOR COVERED PROD-
4 UCT SUBJECT TO A REMS WITH ETASU.—

5 (i) REQUEST.—An eligible product de-
6 veloper may submit to the Secretary a
7 written request for the eligible product de-
8 veloper to be authorized to obtain suffi-
9 cient quantities of an individual covered
10 product subject to a REMS with ETASU.

11 (ii) AUTHORIZATION.—Not later than
12 90 days after the date on which a request
13 under clause (i) is received, the Secretary
14 shall, by written notice, authorize the eligi-
15 ble product developer to obtain sufficient
16 quantities of an individual covered product
17 subject to a REMS with ETASU for pur-
18 poses of—

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

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

4 (aa)(AA) submitted proto-
5 cols, informed consent docu-
6 ments, and informational mate-
7 rials for testing that include pro-
8 tections that provide safety pro-
9 tections comparable to those pro-
10 vided by the REMS for the cov-
11 ered product; or

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

15 (bb) met any other require-
16 ments the Secretary may estab-
17 lish.

18 (iii) NOTICE.—A covered product au-
19 thorization issued under this subparagraph
20 shall state that the provision of the covered
21 product by the license holder under the
22 terms of the authorization will not be a
23 violation of the REMS for the covered
24 product.

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

5 (A) that, on the date on which the eligible
6 product developer requested to purchase suffi-
7 cient quantities of the covered product from the
8 license holder—

9 (i) neither the license holder nor any
10 of its agents, wholesalers, or distributors
11 was engaged in the manufacturing or com-
12 mercial marketing of the covered product;
13 and

14 (ii) neither the license holder nor any
15 of its agents, wholesalers, or distributors
16 otherwise had access to inventory of the
17 covered product to supply to the eligible
18 product developer on commercially reason-
19 able, market-based terms; or

20 (B) that—

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

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

1 agents, distributors, or wholesalers to sell
2 covered products to eligible product devel-
3 opers; and

4 (iii) the covered product can be pur-
5 chased by the eligible product developer in
6 sufficient quantities on commercially rea-
7 sonable, market-based terms from the
8 agents, distributors, or wholesalers of the
9 license holder.

10 (4) REMEDIES.—

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

14 (i) order the license holder to provide
15 to the eligible product developer without
16 delay sufficient quantities of the covered
17 product on commercially reasonable, mar-
18 ket-based terms;

19 (ii) award to the eligible product de-
20 veloper reasonable attorney fees and costs
21 of the civil action; and

22 (iii) award to the eligible product de-
23 veloper a monetary amount sufficient to
24 deter the license holder from failing to pro-
25 vide other eligible product developers with

1 sufficient quantities of a covered product
2 on commercially reasonable, market-based
3 terms, if the court finds, by a preponderance of the evidence—
4

5 (I) that the license holder delayed
6 providing sufficient quantities of the
7 covered product to the eligible product
8 developer without a legitimate business justification; or
9

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

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

18 (i) beginning on—

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

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

1 date that is 31 days after the later
2 of—

3 (aa) the date on which the
4 license holder received the re-
5 quest; or

6 (bb) the date on which the
7 license holder received a copy of
8 the covered product authorization
9 issued by the Secretary in ac-
10 cordance with paragraph (2)(B);
11 and

12 (ii) ending on the date on which the
13 eligible product developer received suffi-
14 cient quantities of the covered product.

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

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

1 product during development or testing activities described
2 in this section, including transportation, handling, use, or
3 disposal of the covered product by the eligible product de-
4 veloper.

5 (d) RULE OF CONSTRUCTION.—

6 (1) DEFINITION.—In this subsection, the term
7 “antitrust laws”—

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

11 (B) includes section 5 of the Federal
12 Trade Commission Act (15 U.S.C. 45) to the
13 extent that such section applies to unfair meth-
14 ods of competition.

15 (2) ANTITRUST LAWS.—Nothing in this section
16 shall be construed to limit the operation of any pro-
17 vision of the antitrust laws.

18 **SEC. 302. REMS APPROVAL PROCESS FOR SUBSEQUENT**
19 **FILERS.**

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

22 (1) in subsection (g)(4)(B)—

23 (A) in clause (i) by striking “or” after the
24 semicolon;

1 (B) in clause (ii) by striking the period at
2 the end and inserting “; or”; and

3 (C) by adding at the end the following:

4 “(iii) accommodate different approved
5 risk evaluation and mitigation strategies
6 for a reference drug product and a drug
7 that is the subject of an abbreviated new
8 drug application.”; and

9 (2) in subsection (i)(1), by striking subpara-
10 graph (B) and inserting the following:

11 “(B) Elements to assure safe use, if re-
12 quired under subsection (f) for the listed drug
13 in accordance with the following:

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

17 “(I) a single, shared system with
18 the listed drug under subsection (f);
19 or

20 “(II) a different, comparable as-
21 pect of the elements to assure safe use
22 under subsection (f).

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

1 use a single, shared system under sub-
2 section (f), if the Secretary determines
3 that no different, comparable aspect of the
4 elements to assure safe use could satisfy
5 the requirements of subsection (f).”.

6 **Subtitle B—Increasing Access to**
7 **Drugs and Biosimilar Products**

8 **SEC. 311. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
9 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
10 **UCTS.**

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

14 **“SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
15 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
16 **UCTS.**

17 “(a) ESTABLISHMENT OF PROGRAM.—The Secretary
18 shall establish a program to expedite the development of,
19 and provide priority review under section 505(j) for, ge-
20 neric complex drug products.

21 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
22 generic complex drug product may request that the Sec-
23 retary designate such product for expedited development
24 and priority review under this section.

25 “(c) DESIGNATION PROCESS.—

1 “(1) IN GENERAL.—Not later than 60 calendar
2 days after the receipt of a request under subsection
3 (c), the Secretary shall determine whether the prod-
4 uct that is the subject of the request meets the cri-
5 teria under subsection (e) to be considered a generic
6 complex drug product. If the Secretary determines
7 that the product meets the criteria, the Secretary
8 shall designate the product for expedited develop-
9 ment and priority review.

10 “(2) REVIEW.—Review of a request under sub-
11 section (b) shall be undertaken by a team that is
12 composed of experienced staff and senior managers
13 of the Food and Drug Administration.

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

19 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
20 VIEW GUIDANCE.—

21 “(1) CONTENT.—Not later than December 31,
22 2021, the Secretary shall issue guidance on the im-
23 plementation of this section. Such guidance shall—

1 “(A) set forth the process by which a per-
2 son may seek a designation under subsection
3 (c);

4 “(B) provide a template for requests under
5 subsection (b);

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

9 “(D) identify the criteria and processes the
10 Secretary will use to expedite the development
11 and review of products designated under this
12 section.

13 “(2) PROCESS.—Prior to finalizing the guid-
14 ance under paragraph (1), the Secretary shall seek
15 public comment on a draft version of that guidance.

16 “(e) GENERIC COMPLEX DRUG PRODUCT DE-
17 FINED.—In this section, the term ‘generic complex drug
18 product’ means a product that represents a complex ther-
19 apy that consists of or includes a drug for approval under
20 section 505(j) and that—

21 “(1)(A) contains complex active ingredients
22 (such as peptides, polymeric compounds, complex
23 mixtures of active ingredients, and naturally sourced
24 ingredients);

1 “(B) is composed of complex formulations (such
2 as liposomes or colloids);

3 “(C) requires a complex route of delivery (such
4 as locally acting drugs such as dermatological prod-
5 ucts and complex ophthalmological products and otic
6 dosage forms that are formulated as suspensions,
7 emulsions, or gels); or

8 “(D) involves a complex dosage form (such as
9 transdermals, metered dose inhalers, or extended re-
10 lease injectables);

11 “(2) presents as a complex drug-device com-
12 bination product (such as auto injectors or metered
13 dose inhalers); or

14 “(3) is a product that would benefit from early
15 scientific engagement due to complexity or uncer-
16 tainty concerning the approval pathway under sec-
17 tion 505(j).”.

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

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

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

1 fewer than 3 available drugs exist for the treatment
2 of such disease or condition.”.

3 **SEC. 313. PREEMPTION OF STATE BARRIERS TO THE SUB-**
4 **STITUTION OF BIOSIMILAR PRODUCTS.**

5 No State, or any political subdivision thereof, may,
6 under any circumstances, prohibit a pharmacy or phar-
7 macist from dispensing, in place of a biological reference
8 product, any biosimilar that the Food and Drug Adminis-
9 tration has designated as an interchangeable product for
10 that biological reference product.

11 **Subtitle C—Limiting Exclusivity**
12 **Periods Delaying Competition**

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

15 (a) IN GENERAL.—Subsection (a) of section 527 of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360cc) is amended to read as follows:

18 “(a) EXCLUSIVITY.—

19 “(1) IN GENERAL.—Except as provided in sub-
20 section (b), if the Secretary approves an application
21 filed pursuant to section 505, or issues a license
22 under section 351 of the Public Health Service Act,
23 for a drug designated under section 526 for a rare
24 disease or condition, the Secretary may not approve
25 an application filed pursuant to section 505, or issue

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

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

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

15 “(B) in the case of a drug that has pre-
16 viously received a period of exclusivity under
17 paragraph (1), a single 3-year period of exclu-
18 sivity with respect to any subsequent designa-
19 tion of such drug under such section for any
20 other rare disease or condition.

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

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

4 (b) CONFORMING AMENDMENTS.—

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

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

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

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

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

1 striking “the 7-year period” and inserting “any ex-
2 clusivity period”.

3 (6) Section 351(m)(2)(B) of the Public Health
4 Service Act (42 U.S.C. 262) is amended by striking
5 “rather than 7 years” and inserting “or 3 years and
6 6 months, rather than 7 years or 3 years, respec-
7 tively”.

8 (7) Section 351(m)(3)(B) of the Public Health
9 Service Act (42 U.S.C. 262) is amended by striking
10 “rather than 7 years” and inserting “or 3 years and
11 6 months, rather than 7 years or 3 years, respec-
12 tively”.

13 **SEC. 322. LIMITING EXCLUSIVITY FOR BIOSIMILAR PROD-**
14 **UCTS.**

15 Paragraph (7) of section 351(k) of the Public Health
16 Service Act (42 U.S.C. 262(k)) is amended in subpara-
17 graph (A), by striking “12” and inserting “5”.

18 **Subtitle D—Congressional Review**
19 **of Agency Rulemaking**

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

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

1 **“CHAPTER 10—CONGRESSIONAL REVIEW**
2 **OF FOOD AND DRUG ADMINISTRATION**
3 **RULEMAKING**

“Sec.

“920. Applicability.

“921. Congressional review.

“922. Congressional approval procedure for major rules.

“923. Congressional disapproval procedure for nonmajor rules.

“924. Definitions.

“925. Judicial review.

“926. Exemption for monetary policy.

“927. Effective date of certain rules.

“928. Regulatory cut-go requirement.

“929. Review of rules currently in effect.

4 **“§ 920. Applicability**

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

7 **“§ 921. Congressional review**

8 “(a)(1)(A) Before a rule may take effect, the Food
9 and Drug Administration shall satisfy the requirements
10 of section 928 and shall publish in the Federal Register
11 a list of information on which the rule is based, including
12 data, scientific and economic studies, and cost-benefit
13 analyses, and identify how the public can access such in-
14 formation online, and shall submit to each House of the
15 Congress and to the Comptroller General a report con-
16 taining—

17 “(i) a copy of the rule;

18 “(ii) a concise general statement relating to the
19 rule;

1 “(iii) a classification of the rule as a major or
2 nonmajor rule, including an explanation of the clas-
3 sification specifically addressing each criteria for a
4 major rule contained within sections 924(2)(A),
5 924(2)(B), and 924(2)(C);

6 “(iv) a list of any other related regulatory ac-
7 tions intended to implement the same statutory pro-
8 vision or regulatory objective as well as the indi-
9 vidual and aggregate economic effects of those ac-
10 tions; and

11 “(v) the proposed effective date of the rule.

12 “(B) On the date of the submission of the report
13 under subparagraph (A), the Food and Drug Administra-
14 tion shall submit to the Comptroller General and make
15 available to each House of Congress—

16 “(i) a complete copy of the cost-benefit analysis
17 of the rule, if any, including an analysis of any jobs
18 added or lost, differentiating between public and pri-
19 vate sector jobs;

20 “(ii) the Food and Drug Administration’s ac-
21 tions pursuant to sections 603, 604, 605, 607, and
22 609 of this title;

23 “(iii) the Food and Drug Administration’s ac-
24 tions pursuant to sections 202, 203, 204, and 205
25 of the Unfunded Mandates Reform Act of 1995; and

1 “(iv) any other relevant information or require-
2 ments under any other Act and any relevant Execu-
3 tive orders.

4 “(C) Upon receipt of a report submitted under sub-
5 paragraph (A), each House shall provide copies of the re-
6 port to the chairman and ranking member of each stand-
7 ing committee with jurisdiction under the rules of the
8 House of Representatives or the Senate to report a bill
9 to amend the provision of law under which the rule is
10 issued.

11 “(2)(A) The Comptroller General shall provide a re-
12 port on each major rule to the committees of jurisdiction
13 by the end of 15 calendar days after the submission or
14 publication date. The report of the Comptroller General
15 shall include an assessment of the Food and Drug Admin-
16 istration’s compliance with procedural steps required by
17 paragraph (1)(B) and an assessment of whether the major
18 rule imposes any new limits or mandates on private-sector
19 activity.

20 “(B) The Food and Drug Administration shall co-
21 operate with the Comptroller General by providing infor-
22 mation relevant to the Comptroller General’s report under
23 subparagraph (A).

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

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

5 “(4) A nonmajor rule shall take effect as provided
6 by section 923 after submission to Congress under para-
7 graph (1).

8 “(5) If a joint resolution of approval relating to a
9 major rule is not enacted within the period provided in
10 subsection (b)(2), then a joint resolution of approval relat-
11 ing to the same rule may not be considered under this
12 chapter in the same Congress by either the House of Rep-
13 resentatives or the Senate.

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

17 “(2) If a joint resolution described in subsection (a)
18 is not enacted into law by the end of 70 session days or
19 legislative days, as applicable, beginning on the date on
20 which the report referred to in section 921(a)(1)(A) is re-
21 ceived by Congress (excluding days either House of Con-
22 gress is adjourned for more than 3 days during a session
23 of Congress), then the rule described in that resolution
24 shall be deemed not to be approved and such rule shall
25 not take effect.

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

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

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

12 “(B) necessary for the enforcement of criminal
13 laws;

14 “(C) necessary for national security; or

15 “(D) issued pursuant to any statute imple-
16 menting an international trade agreement.

17 “(3) An exercise by the President of the authority
18 under this subsection shall have no effect on the proce-
19 dures under section 922.

20 “(d)(1) In addition to the opportunity for review oth-
21 erwise provided under this chapter, in the case of any rule
22 for which a report was submitted in accordance with sub-
23 section (a)(1)(A) during the period beginning on the date
24 occurring—

1 “(A) in the case of the Senate, 60 session days;

2 or

3 “(B) in the case of the House of Representa-

4 tives, 60 legislative days,

5 before the date the Congress is scheduled to adjourn a

6 session of Congress through the date on which the same

7 or succeeding Congress first convenes its next session, sec-

8 tions 922 and 923 shall apply to such rule in the suc-

9 ceeding session of Congress.

10 “(2)(A) In applying sections 922 and 923 for pur-

11 poses of such additional review, a rule described under

12 paragraph (1) shall be treated as though—

13 “(i) such rule were published in the Federal

14 Register on—

15 “(I) in the case of the Senate, the 15th

16 session day; or

17 “(II) in the case of the House of Rep-

18 resentatives, the 15th legislative day,

19 after the succeeding session of Congress first con-

20 venes; and

21 “(ii) a report on such rule were submitted to

22 Congress under subsection (a)(1) on such date.

23 “(B) Nothing in this paragraph shall be construed

24 to affect the requirement under subsection (a)(1) that a

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

3 “(3) A rule described under paragraph (1) shall take
4 effect as otherwise provided by law (including other sub-
5 sections of this section).

6 **“§ 922. Congressional approval procedure for major**
7 **rules**

8 “(a)(1) For purposes of this section, the term ‘joint
9 resolution’ means only a joint resolution addressing a re-
10 port classifying a rule as major pursuant to section
11 921(a)(1)(A)(iii) that—

12 “(A) bears no preamble;

13 “(B) bears the following title (with blanks filled
14 as appropriate): ‘Approving the rule submitted by
15 _____ relating to _____.’;

16 “(C) includes after its resolving clause only the
17 following (with blanks filled as appropriate): ‘That
18 Congress approves the rule submitted by _____ re-
19 lating to _____.’; and

20 “(D) is introduced pursuant to paragraph (2).

21 “(2) After a House of Congress receives a report
22 classifying a rule as major pursuant to section
23 921(a)(1)(A)(iii), the majority leader of that House (or
24 his or her respective designee) shall introduce (by request,

1 if appropriate) a joint resolution described in paragraph
2 (1)—

3 “(A) in the case of the House of Representa-
4 tives, within 3 legislative days; and

5 “(B) in the case of the Senate, within 3 session
6 days.

7 “(3) A joint resolution described in paragraph (1)
8 shall not be subject to amendment at any stage of pro-
9 ceeding.

10 “(b) A joint resolution described in subsection (a)
11 shall be referred in each House of Congress to the commit-
12 tees having jurisdiction over the provision of law under
13 which the rule is issued.

14 “(c) In the Senate, if the committee or committees
15 to which a joint resolution described in subsection (a) has
16 been referred have not reported it at the end of 15 session
17 days after its introduction, such committee or committees
18 shall be automatically discharged from further consider-
19 ation of the resolution and it shall be placed on the cal-
20 endar. A vote on final passage of the resolution shall be
21 taken on or before the close of the 15th session day after
22 the resolution is reported by the committee or committees
23 to which it was referred, or after such committee or com-
24 mittees have been discharged from further consideration
25 of the resolution.

1 “(d)(1) In the Senate, when the committee or com-
2 mittees to which a joint resolution is referred have re-
3 ported, or when a committee or committees are discharged
4 (under subsection (c)) from further consideration of a
5 joint resolution described in subsection (a), it is at any
6 time thereafter in order (even though a previous motion
7 to the same effect has been disagreed to) for a motion
8 to proceed to the consideration of the joint resolution, and
9 all points of order against the joint resolution (and against
10 consideration of the joint resolution) are waived. The mo-
11 tion is not subject to amendment, or to a motion to post-
12 pone, or to a motion to proceed to the consideration of
13 other business. A motion to reconsider the vote by which
14 the motion is agreed to or disagreed to shall not be in
15 order. If a motion to proceed to the consideration of the
16 joint resolution is agreed to, the joint resolution shall re-
17 main the unfinished business of the Senate until disposed
18 of.

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

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

3 “(3) In the Senate, immediately following the conclu-
4 sion of the debate on a joint resolution described in sub-
5 section (a), and a single quorum call at the conclusion of
6 the debate if requested in accordance with the rules of the
7 Senate, the vote on final passage of the joint resolution
8 shall occur.

9 “(4) Appeals from the decisions of the Chair relating
10 to the application of the rules of the Senate to the proce-
11 dure relating to a joint resolution described in subsection
12 (a) shall be decided without debate.

13 “(e) In the House of Representatives, if any com-
14 mittee to which a joint resolution described in subsection
15 (a) has been referred has not reported it to the House
16 at the end of 15 legislative days after its introduction,
17 such committee shall be discharged from further consider-
18 ation of the joint resolution, and it shall be placed on the
19 appropriate calendar. On the second and fourth Thursdays
20 of each month it shall be in order at any time for the
21 Speaker to recognize a Member who favors passage of a
22 joint resolution that has appeared on the calendar for at
23 least 5 legislative days to call up that joint resolution for
24 immediate consideration in the House without intervention
25 of any point of order. When so called up a joint resolution

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

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

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

15 “(B) the procedure in the receiving House shall
16 be the same as if no joint resolution had been re-
17 ceived from the other House until the vote on pas-
18 sage, when the joint resolution received from the
19 other House shall supplant the joint resolution of
20 the receiving House.

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

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

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

3 “(h) This section and section 923 are enacted by
4 Congress—

5 “(1) as an exercise of the rulemaking power of
6 the Senate and House of Representatives, respec-
7 tively, and as such is deemed to be part of the rules
8 of each House, respectively, but applicable only with
9 respect to the procedure to be followed in that
10 House in the case of a joint resolution described in
11 subsection (a) and superseding other rules only
12 where explicitly so; and

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

18 **“§ 923. Congressional disapproval procedure for**
19 **nonmajor rules**

20 “(a) For purposes of this section, the term ‘joint res-
21 olution’ means only a joint resolution introduced in the
22 period beginning on the date on which the report referred
23 to in section 921(a)(1)(A) is received by Congress and
24 ending 60 days thereafter (excluding days either House
25 of Congress is adjourned for more than 3 days during a

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

6 “(b) A joint resolution described in subsection (a)
7 shall be referred to the committees in each House of Con-
8 gress with jurisdiction.

9 “(c) In the Senate, if the committee to which is re-
10 ferred a joint resolution described in subsection (a) has
11 not reported such joint resolution (or an identical joint
12 resolution) at the end of 15 session days after the date
13 of introduction of the joint resolution, such committee may
14 be discharged from further consideration of such joint res-
15 olution upon a petition supported in writing by 30 Mem-
16 bers of the Senate, and such joint resolution shall be
17 placed on the calendar.

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

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

10 “(2) In the Senate, debate on the joint resolution,
11 and on all debatable motions and appeals in connection
12 therewith, shall be limited to not more than 10 hours,
13 which shall be divided equally between those favoring and
14 those opposing the joint resolution. A motion to further
15 limit debate is in order and not debatable. An amendment
16 to, or a motion to postpone, or a motion to proceed to
17 the consideration of other business, or a motion to recom-
18 mit the joint resolution is not in order.

19 “(3) In the Senate, immediately following the conclu-
20 sion of the debate on a joint resolution described in sub-
21 section (a), and a single quorum call at the conclusion of
22 the debate if requested in accordance with the rules of the
23 Senate, the vote on final passage of the joint resolution
24 shall occur.

1 “(4) Appeals from the decisions of the Chair relating
2 to the application of the rules of the Senate to the proce-
3 dure relating to a joint resolution described in subsection
4 (a) shall be decided without debate.

5 “(e) In the Senate, the procedure specified in sub-
6 section (c) or (d) shall not apply to the consideration of
7 a joint resolution respecting a nonmajor rule—

8 “(1) after the expiration of the 60 session days
9 beginning with the applicable submission or publica-
10 tion date; or

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

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

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

23 “(2) With respect to a joint resolution described
24 in subsection (a) of the House receiving the joint
25 resolution—

1 “(A) the procedure in that House shall be
2 the same as if no joint resolution had been re-
3 ceived from the other House; but

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

6 **“§ 924. Definitions**

7 “For purposes of this chapter:

8 “(1) The term ‘major rule’ means any rule of
9 the Food and Drug Administration, including an in-
10 terim final rule, that the Administrator of the Office
11 of Information and Regulatory Affairs of the Office
12 of Management and Budget finds has resulted in or
13 is likely to result in—

14 “(A) an annual cost on the economy of
15 \$100,000,000 or more, adjusted annually for
16 inflation;

17 “(B) a major increase in costs or prices for
18 consumers, individual industries, Federal,
19 State, or local government agencies, or geo-
20 graphic regions; or

21 “(C) significant adverse effects on competi-
22 tion, employment, investment, productivity, in-
23 novation, or on the ability of United States-
24 based enterprises to compete with foreign-based
25 enterprises in domestic and export markets.

1 “(2) The term ‘nonmajor rule’ means any rule
2 of the Food and Drug Administration that is not a
3 major rule.

4 “(3) The term ‘rule’ has the meaning given
5 such term in section 551, except that such term does
6 not include—

7 “(A) any rule of particular applicability;

8 “(B) any rule relating to agency manage-
9 ment or personnel; or

10 “(C) any rule of agency organization, pro-
11 cedure, or practice that does not substantially
12 affect the rights or obligations of non-agency
13 parties.

14 “(4) The term ‘submission date or publication
15 date’, except as otherwise provided in this chapter,
16 means—

17 “(A) in the case of a major rule, the date
18 on which the Congress receives the report sub-
19 mitted under section 921(a)(1); and

20 “(B) in the case of a nonmajor rule, the
21 later of—

22 “(i) the date on which the Congress
23 receives the report submitted under section
24 921(a)(1); and

1 “(ii) the date on which the nonmajor
2 rule is published in the Federal Register, if
3 so published.

4 **“§ 925. Judicial review**

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

7 “(b) Notwithstanding subsection (a), a court may de-
8 termine whether the Food and Drug Administration has
9 completed the necessary requirements under this chapter
10 for a rule to take effect.

11 “(c) The enactment of a joint resolution of approval
12 under section 922 shall not be interpreted to serve as a
13 grant or modification of statutory authority by Congress
14 for the promulgation of a rule, shall not extinguish or af-
15 fect any claim, whether substantive or procedural, against
16 any alleged defect in a rule, and shall not form part of
17 the record before the court in any judicial proceeding con-
18 cerning a rule except for purposes of determining whether
19 or not the rule is in effect.

20 **“§ 926. Exemption for monetary policy**

21 “Nothing in this chapter shall apply to rules that con-
22 cern monetary policy proposed or implemented by the
23 Board of Governors of the Federal Reserve System or the
24 Federal Open Market Committee.

1 **“§ 927. Effective date of certain rules**

2 “Notwithstanding section 921, any rule other than a
3 major rule which the Food and Drug Administration for
4 good cause finds (and incorporates the finding and a brief
5 statement of reasons therefore in the rule issued) that no-
6 tice and public procedure thereon are impracticable, un-
7 necessary, or contrary to the public interest, shall take ef-
8 fect at such time as the Food and Drug Administration
9 determines.

10 **“§ 928. Regulatory cut-go requirement**

11 “In making any new rule, the Food and Drug Admin-
12 istration shall identify a rule or rules that may be amend-
13 ed or repealed to completely offset any annual costs of
14 the new rule to the United States economy. Before the
15 new rule may take effect, the Food and Drug Administra-
16 tion shall make each such repeal or amendment. In mak-
17 ing such an amendment or repeal, the Food and Drug Ad-
18 ministration shall comply with the requirements of sub-
19 chapter II of chapter 5, but the Food and Drug Adminis-
20 tration may consolidate proceedings under subchapter
21 with proceedings on the new rule.

22 **“§ 929. Review of rules currently in effect**

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

1 percent of eligible rules made by the Food and Drug Ad-
2 ministration for review, and shall submit a report includ-
3 ing each such eligible rule in the same manner as a report
4 under section 921(a)(1). Section 921, section 922, and
5 section 923 shall apply to each such rule, subject to sub-
6 section (c) of this section. No eligible rule previously des-
7 ignated may be designated again.

8 “(b) SUNSET FOR ELIGIBLE RULES NOT EX-
9 TENDED.—Beginning after the date that is 10 years after
10 the date of enactment of this section, if Congress has not
11 enacted a joint resolution of approval for that eligible rule,
12 that eligible rule shall not continue in effect.

13 “(c) CONSOLIDATION; SEVERABILITY.—In applying
14 sections 921, 922, and 923 to eligible rules under this sec-
15 tion, the following shall apply:

16 “(1) The words ‘take effect’ shall be read as
17 ‘continue in effect’.

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

1 “(3) It shall be in order to consider any amend-
2 ment that provides for specific conditions on which
3 the approval of a particular eligible rule included in
4 the joint resolution is contingent.

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

8 “(d) DEFINITION.—In this section, the term ‘eligible
9 rule’ means a rule that is in effect as of the date of enact-
10 ment of this section.”.

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

16 “(E) BUDGETARY EFFECTS OF RULES
17 SUBJECT TO SECTION 922 OF TITLE 5, UNITED
18 STATES CODE.—Any rules subject to the con-
19 gressional approval procedure set forth in sec-
20 tion 922 of chapter 8 of title 5, United States
21 Code, affecting budget authority, outlays, or re-
22 ceipts shall be assumed to be effective unless it
23 is not approved in accordance with such sec-
24 tion.”.

1 (c) GOVERNMENT ACCOUNTABILITY OFFICE STUDY
2 OF RULES.—

3 (1) IN GENERAL.—The Comptroller General of
4 the United States shall conduct a study to deter-
5 mine, as of the date of the enactment of this Act—

6 (A) how many rules (as such term is de-
7 fined in section 924 of title 5, United States
8 Code) of the Food and Drug Administration
9 were in effect;

10 (B) how many major rules (as such term
11 is defined in section 924 of title 5, United
12 States Code) of the Food and Drug Administra-
13 tion were in effect; and

14 (C) the total estimated economic cost im-
15 posed by all such rules.

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

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

1 **SEC. 332. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**
2 **OF RULES.**

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

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

9 (2) how many major rules (as such term is de-
10 fined in section 804 of title 5, United States Code)
11 were in effect; and

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

14 (b) REPORT.—Not later than 1 year after the date
15 of the enactment of this Act, the Comptroller General of
16 the United States shall submit a report to Congress that
17 contains the findings of the study conducted under sub-
18 section (a).

19 **Subtitle E—Medicare Prescription**
20 **Drug Competition**

21 **SEC. 341. MEDICARE DRUG COVERAGE.**

22 Notwithstanding any other provision of law, the Sec-
23 retary of Health and Human Services may alter the reim-
24 bursement mechanism for prescription drugs provided
25 through the Medicare Part B program by reimbursing at

1 a rate that, based on ASP+6% in the year of implementa-
2 tion of this Act, grows at CPI.

3 **SEC. 342. PBM TRANSPARENCY AND ELIMINATION OF DIR**
4 **FEES.**

5 (a) PROHIBITING MEDICARE PDP SPONSORS AND
6 MA-PD ORGANIZATIONS FROM RETROACTIVELY REDUC-
7 ING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHAR-
8 MACIES.—

9 (1) IN GENERAL.—Section 1860D–12(b)(4)(A)
10 of the Social Security Act (42 U.S.C. 1395w–
11 112(b)(4)(A)) is amended by adding at the end the
12 following new clause:

13 “(iv) PROHIBITING RETROACTIVE RE-
14 DUCTIONS IN PAYMENTS ON CLEAN
15 CLAIMS.—Each contract entered into with
16 a PDP sponsor under this part with re-
17 spect to a prescription drug plan offered
18 by such sponsor shall provide that after
19 the date of receipt of a clean claim sub-
20 mitted by a pharmacy, the PDP sponsor
21 (or an agent of the PDP sponsor) may not
22 retroactively reduce payment on such claim
23 directly or indirectly through aggregated
24 effective rate or otherwise except in the
25 case such claim is found to not be a clean

1 claim (such as in the case of a claim lack-
2 ing required substantiating documentation)
3 during the course of a routine audit as
4 permitted pursuant to written agreement
5 between the PDP sponsor (or such an
6 agent) and such pharmacy. The previous
7 sentence shall not prohibit any retroactive
8 increase in payment to a pharmacy pursu-
9 ant to a written agreement between a PDP
10 sponsor (or an agent of such sponsor) and
11 such pharmacy.”.

12 (2) EFFECTIVE DATE.—The amendment made
13 by subsection (a) shall apply with respect to con-
14 tracts entered into on or after January 1, 2021.

15 (b) ELIMINATION OF DIR FEES.—

16 (1) PHARMACY BENEFITS MANAGER STAND-
17 ARDS UNDER THE MEDICARE PROGRAM FOR PRE-
18 SCRIPTIION DRUG PLANS AND MA-PD PLANS.—

19 (A) IN GENERAL.—Section 1860D–12(b)
20 of the Social Security Act (42 U.S.C. 1395w–
21 112(b)) is amended by adding at the end the
22 following new paragraph:

23 “(7) PHARMACY BENEFITS MANAGER TRANS-
24 PARENCY REQUIREMENTS.—Each contract entered
25 into with a PDP sponsor under this part with re-

1 spect to a prescription drug plan offered by such
2 sponsor or with an MA organization offering an
3 MA–PD plan under part C shall provide that the
4 sponsor or organization, respectively, may not enter
5 into a contract with any pharmacy benefits manager
6 (referred to in this paragraph as a ‘PBM’) to man-
7 age the prescription drug coverage provided under
8 such plan, or to control the costs of the prescription
9 drug coverage under such plan, unless the PBM ad-
10 heres to the following criteria when handling person-
11 ally identifiable utilization and claims data or other
12 sensitive patient data:

13 “(A) The PBM may not transmit any per-
14 sonally identifiable utilization, protected health
15 information, or claims data, with respect to a
16 plan enrollee, to a pharmacy owned by a PBM
17 if the plan enrollee has not voluntarily elected
18 in writing or via secure electronic means to fill
19 that particular prescription at the PBM-owned
20 pharmacy.

21 “(B) The PBM may not require that a
22 plan enrollee use a retail pharmacy, mail order
23 pharmacy, specialty pharmacy, or other phar-
24 macy entity providing pharmacy services in
25 which the PBM has an ownership interest or

1 that has an ownership interest in the PBM, or
2 provide an incentive to a plan enrollee to en-
3 courage the enrollee to use a retail pharmacy,
4 mail order pharmacy, specialty pharmacy, or
5 other pharmacy entity providing pharmacy serv-
6 ices in which the PBM has an ownership inter-
7 est or that has an ownership interest in the
8 PBM, if the incentive is applicable only to such
9 pharmacies.”.

10 (B) REGULAR UPDATE OF PRESCRIPTION
11 DRUG PRICING STANDARD.—Paragraph (6) of
12 section 1860D–12(b) of the Social Security Act
13 (42 U.S.C. 1395w–112(b)) is amended to read
14 as follows:

15 “(6) REGULAR UPDATE OF PRESCRIPTION
16 DRUG PRICING STANDARD.—

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

1 “(i) update such standard not less fre-
2 quently than once every 7 days, beginning
3 with an initial update on January 1 of
4 each year, to accurately reflect the market
5 price of acquiring the drug;

6 “(ii) disclose to applicable pharmacies
7 and the contracting entities of such phar-
8 macies the sources used for making any
9 such update immediately without require-
10 ment of request;

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

18 “(iv) establish a process to appeal, in-
19 vestigate, and resolve disputes regarding
20 individual drug prices that are less than
21 the pharmacy acquisition price for such
22 drug, which must be adjudicated within 7
23 days of the pharmacy filing its appeal; and

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

1 parable easily accessible and complete
2 spreadsheet format.

3 “(B) PRESCRIPTION DRUG PRICING
4 STANDARD DEFINED.—For purposes of sub-
5 paragraph (A), a standard for reimbursement
6 of a pharmacy is any methodology or formula
7 for varying the pricing of a drug or drugs dur-
8 ing the term of the pharmacy reimbursement
9 contract that is based on the cost of the drug
10 involved, including drug pricing references and
11 amounts that are based upon average wholesale
12 price, wholesale average cost, average manufac-
13 turer price, average sales price, maximum al-
14 lowable cost (MAC), or other costs, whether
15 publicly available or not.”.

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

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

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

1 section (a)(2)(E)(ii), the Secretary shall ensure that a con-
2 tract entered into with a TRICARE managed care support
3 contractor includes requirements described in section
4 1860D–12(b)(6) of the Social Security Act (42 U.S.C.
5 1395w–112(b)(6)) to ensure the provision of information
6 regarding the pricing standard for prescription drugs.”.

7 (3) PRESCRIPTION DRUG TRANSPARENCY IN
8 THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-
9 GRAM.—

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

13 “(p) A contract may not be made or a plan approved
14 under this chapter under which a carrier has an agree-
15 ment with a pharmacy benefits manager (in this sub-
16 section referred to as a ‘PBM’) to manage prescription
17 drug coverage or to control the costs of the prescription
18 drug coverage unless the carrier and PBM adhere to the
19 following criteria:

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

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

3 “(2) The PBM may not require that an indi-
4 vidual enrolled under such contract or plan use a re-
5 tail pharmacy, mail order pharmacy, specialty phar-
6 macy, or other pharmacy entity providing pharmacy
7 services in which the PBM has an ownership interest
8 or that has an ownership interest in the PBM or
9 provide an incentive to a plan enrollee to encourage
10 the enrollee to use a retail pharmacy, mail order
11 pharmacy, specialty pharmacy, or other pharmacy
12 entity providing pharmacy services in which the
13 PBM has an ownership interest or that has an own-
14 ership interest in the PBM, if the incentive is appli-
15 cable only to such pharmacies.

16 “(q)(1) If a contract made or plan approved under
17 this chapter provides for a standard for reimbursement
18 (as described in paragraph (2)) with respect to a prescrip-
19 tion drug plan, such contract or plan shall provide that
20 the applicable carrier—

21 “(A) update such standard not less frequently
22 than once every 7 days, beginning with an initial up-
23 date on January 1 of each year, to accurately reflect
24 the market price of acquiring the drug;

1 “(B) disclose to applicable pharmacies and the
2 contracting entities of such pharmacies the sources
3 used for making any such update immediately with-
4 out requirement of request;

5 “(C) if the source for such a standard for reim-
6 bursement is not publicly available, disclose to the
7 applicable pharmacies and contracting entities of
8 such pharmacies all individual drug prices to be so
9 updated in advance of the use of such prices for the
10 reimbursement of claims;

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

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

19 “(2) For purposes of paragraph (1), a standard for
20 reimbursement of a pharmacy is any methodology or for-
21 mula for varying the pricing of a drug or drugs during
22 the term of the pharmacy reimbursement contract that is
23 based on the cost of the drug involved, including drug prie-
24 ing references and amounts that are based upon average
25 wholesale price, wholesale average cost, average manufac-

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

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

8 **SEC. 343. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT**
9 **FOR SINGLE SOURCE DRUGS AND INNO-**
10 **VATOR MULTIPLE SOURCE DRUGS.**

11 Section 1927(c)(2)(D) of the Social Security Act (42
12 U.S.C. 1396r-8(c)(2)(D)) is amended by inserting after
13 “December 31, 2009,” the following: “and before Decem-
14 ber 31, 2024,”.

15 **SEC. 344. REGULATION OF MANUFACTURER-SPONSORED**
16 **COPAY CONTRIBUTIONS.**

17 Notwithstanding any other provision of law, the Sec-
18 retary of Health and Human Services may establish a
19 mechanism prohibiting drug manufacturers from contrib-
20 uting financially to patient copays, and establish a system
21 of penalizing such behavior.

1 **SEC. 345. DATA REPORTING TO IMPROVE THE TRANS-**
2 **PARENCY REGARDING HOW 340B HOSPITAL**
3 **COVERED ENTITIES PROVIDE CARE FOR PA-**
4 **TIENTS.**

5 Section 340B of the Public Health Service Act (42
6 U.S.C. 256b) is amended by adding at the end the fol-
7 lowing new subsection:

8 “(f) DATA REPORTING TO IMPROVE THE TRANS-
9 PARENCY REGARDING HOW HOSPITAL COVERED ENTI-
10 TIES PROVIDE CARE FOR PATIENTS.—

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

19 “(A) The following information:

20 “(i) With respect to such covered enti-
21 ty and with respect to each child site of
22 such entity (as referenced in paragraph
23 (11)), the number and percentage of indi-
24 viduals who are dispensed or administered
25 drugs that are subject to an agreement
26 under this section, organized by form of

1 health insurance coverage of such individ-
2 uals (including at least by the Medicare
3 program under title XVIII of the Social
4 Security Act, the Medicaid program under
5 title XIX of such Act, health insurance
6 coverage offered in the individual or group
7 market or a group health plan (as such
8 terms are defined in section 2791), and
9 uninsured).

10 “(ii) With respect to each such child
11 site of such entity, the total costs incurred
12 at each such site and the cost incurred at
13 each such site for charity care as defined
14 in line 23 of worksheet S-10 to the Medi-
15 care cost report or in any successor form.

16 “(B) The aggregate amount of gross reim-
17 bursement received by each such covered entity
18 (including child sites of such entity) described
19 in such subparagraph (L) or (M) for all drugs
20 purchased that are subject to an agreement
21 under this section and the entity’s aggregate
22 acquisition cost for such drugs.

23 “(C) In the case of covered entity de-
24 scribed in subparagraph (L) of subsection
25 (a)(4), at the time of application and recertifi-

1 cation (and at least annually thereafter), the
2 contract that is the basis for eligibility under
3 the requirement under clause (i) of such sub-
4 paragraph and any modifications to such con-
5 tract for purposes of review by the Secretary.

6 “(D) With respect to such covered entity
7 and with respect to each child site of such enti-
8 ty, the name of all third-party vendors or other
9 similar entities that the covered entity contracts
10 with to provide services associated with the pro-
11 gram under this section.

12 “(2) AVAILABILITY OF INFORMATION.—

13 “(A) IN GENERAL.—The Secretary shall
14 make data reported by covered entities under
15 subparagraphs (A), (C), and (D) of paragraph
16 (1) available on the public website of the De-
17 partment of Health and Human Services in an
18 electronic and searchable format, which may in-
19 clude the 340B Office of Pharmacy Affairs In-
20 formation System or a successor to such sys-
21 tem.

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

1 covered entities described in subparagraphs (L)
2 and (M) of subsection (a)(4) and child sites of
3 such covered entities. In carrying out this para-
4 graph, with respect to data reported pursuant
5 to paragraph (1)(C), the Secretary shall ensure
6 that any proprietary information shall be re-
7 dacted from contracts submitted pursuant to
8 such paragraph (1)(C) before posting such
9 data.

10 “(3) INTERIM FINAL REGULATIONS.—The Sec-
11 retary shall issue interim final regulations no later
12 than the date that is 6 months after the date of the
13 enactment of this subsection, to carry out this sub-
14 section and shall finalize such regulations prior to
15 the end of the moratorium period to which sub-
16 section (a)(11) applies.

17 “(4) REPORTS TO CONGRESS.—

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

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

3 “(B) GAO REPORTS.—

4 “(i) INITIAL REPORT.—Not later than
5 1 year after the date of the enactment of
6 this subsection, the Comptroller General of
7 the United States shall submit to Congress
8 a report—

9 “(I) analyzing the State and local
10 government contracts intended to sat-
11 isfy the requirement under subsection
12 (a)(4)(L)(i) for a covered entity to
13 qualify as an entity described in sub-
14 paragraph (L) of subsection (a)(4);

15 “(II) assessing the amount of
16 care such contracts obligate such enti-
17 ty to provide to low-income individuals
18 ineligible for Medicare under title
19 XVIII of the Social Security Act and
20 Medicaid under title XIX of such Act;
21 and

22 “(III) analyzing how these con-
23 tracts define low-income individuals
24 and whether the Secretary reviews
25 such determinations.

1 “(ii) SUBSEQUENT REPORT.—Not
2 later than 2 years after the date of the en-
3 actment of this subsection, the Comptroller
4 General of the United States shall submit
5 to Congress a final report on the informa-
6 tion collected under paragraph (1)(B) re-
7 garding the difference between the aggre-
8 gate gross reimbursement and aggregate
9 acquisition costs received by each such cov-
10 ered entity (including child sites of such
11 entity) for drugs subject to an agreement
12 under this section.”.

13 **SEC. 346. REQUIRING 340B DRUG DISCOUNT PROGRAM RE-**
14 **PORTS BY DSH HOSPITAL COVERED ENTITIES**
15 **ON LOW-INCOME UTILIZATION RATE OF OUT-**
16 **PATIENT HOSPITAL SERVICES.**

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

19 (1) in subparagraph (B)(i), by inserting before
20 the period at the end the following: “, including,
21 with respect to such updates made on or after Janu-
22 ary 1, 2020, by requiring covered entities described
23 in subsection (a)(4)(L) to submit (and to so regu-
24 larly update) information described in subparagraph
25 (C)”;

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

3 “(C) INFORMATION ON LOW-INCOME UTI-
4 LIZATION RATE OF OUTPATIENT HOSPITAL
5 SERVICES.—

6 “(i) IN GENERAL.—For purposes of
7 subparagraph (B)(i), the information de-
8 scribed in this subparagraph, with respect
9 to a covered entity described in subsection
10 (a)(4)(L) and an update under such sub-
11 paragraph (B)(i), is—

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

15 “(II) the low-income outpatient
16 utilization rate of off-site outpatient
17 facilities, clinics, eligible off-site loca-
18 tions, and associated sites of such en-
19 tity identified as child sites of such
20 entity pursuant to the identification
21 system under subparagraph (B)(iv)
22 for the most recent fiscal year.

23 “(ii) LOW-INCOME OUTPATIENT UTI-
24 LIZATION RATE DEFINED.—In this sub-
25 paragraph, the term ‘low-income outpatient

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

5 “(I) clauses (i) and (ii) of sub-
6 paragraph (A) of such paragraph
7 shall be applied as if—

8 “(aa) each reference to ‘pa-
9 tient services’ were a reference to
10 ‘patient services furnished on an
11 outpatient basis’; and

12 “(bb) for purposes of clause
13 (i)(II) of this subparagraph, each
14 reference to ‘hospital’ were a ref-
15 erence to ‘off-site outpatient fa-
16 cilities, clinics, eligible off-site lo-
17 cations, and associated sites of
18 the hospital that are identified as
19 child sites of the hospital pursu-
20 ant to the identification system
21 under section 340B(d)(2)(B)(iv)
22 of the Public Health Service Act’;
23 and

1 “(II) clauses (i) and (ii) of sub-
2 paragraph (B) of such paragraph
3 shall be applied as if—

4 “(aa) each reference to ‘in-
5 patient hospital services’ were a
6 reference to ‘outpatient hospital
7 services’; and

8 “(bb) for purposes of clause
9 (i)(II) each reference to ‘hos-
10 pital’s charges’ were a reference
11 to ‘charges of the off-site out-
12 patient facilities, clinics, eligible
13 off-site locations, and associated
14 sites of the hospital that are
15 identified as child sites of the
16 hospital pursuant to the identi-
17 fication system under section
18 340B(d)(2)(B)(iv) of the Public
19 Health Service Act’.”.

20 (b) ANNUAL REPORTS.—Not later than January 1,
21 2021, and annually thereafter, the Administrator of the
22 Health Resources and Services Administration shall sub-
23 mit to Congress a report on information submitted by cov-
24 ered entities for the previous year pursuant to the amend-
25 ments made by subsection (a).

1 **TITLE IV—PROVIDER**
2 **COMPETITION**

3 **SEC. 401. HOSPITAL CONSOLIDATION.**

4 (a) **AUTHORIZATION OF APPROPRIATIONS.**—There is
5 authorized to be appropriated \$160,000,000 to the Fed-
6 eral Trade Commission to hire staff to investigate, as con-
7 sistent with the Sherman Antitrust Act and other relevant
8 Federal laws, anti-competitive mergers and practices
9 under such laws to the extent such mergers and practices
10 relate to providers of inpatient and outpatient health care
11 services, as defined by the Secretary of Health and
12 Human Services.

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

15 (1) **IN GENERAL.**—Section 1866(a) of the So-
16 cial Security Act (42 U.S.C. 1395cc(a)) is amend-
17 ed—

18 (A) in paragraph (1)—

19 (i) in subparagraph (X), by striking
20 “and” at the end;

21 (ii) in subparagraph (Y), by striking
22 the period at the end and inserting “;
23 and”; and

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

1 “(Z) subject to paragraph (4), in the case
2 of a hospital in an urban area and with respect
3 to which there is a Herfindahl-Hirschman Index
4 (HHI) of greater than 4,000 and in the case of
5 a hospital in a rural area and with respect to
6 which there is Herfindahl-Hirschman Index
7 (HHI) of greater than 5,000, to apply the reim-
8 bursement rate with respect to individuals (re-
9 gardless of whether such an individual is enti-
10 tled to or eligible for benefits under this title,
11 but excluding individuals eligible for medical as-
12 sistance under a State plan under title XIX)
13 furnished items and services at such hospital
14 that would be billable under this title for such
15 items and services if furnished by such hospital
16 to an individual entitled to or enrolled for bene-
17 fits under this title.”; and

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

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

1 “(B) For purposes of subparagraph (A), the
2 HRR market share of a hospital in a hospital refer-
3 ral region is equal to—

4 “(i) the total revenue of the hospital, di-
5 vided by

6 “(ii) the total revenue of all hospital in the
7 hospital referral region.”.

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

11 (c) GRANTS FOR HOSPITAL INFRASTRUCTURE IM-
12 PROVEMENT.—

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

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

23 (3) ELIGIBILITY.—

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

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

4 (B) ELIGIBLE STATE.—For purposes of
5 this subsection, the term “eligible State” means
6 a State that meets any one or more of the fol-
7 lowing qualifying criteria:

8 (i) The State does not have in effect
9 any State certificate of need law that re-
10 quires a health care provider to provide to
11 a regulatory body a certification that the
12 community needs the services provided by
13 the health care provider.

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

16 (I) allow advanced practice pro-
17 viders (such as nurse practitioners,
18 advanced practice registered nurses,
19 clinical nurse specialists, and physi-
20 cian assistants) to evaluate patients;
21 diagnose, order, and interpret diag-
22 nostic tests; and initiate and manage
23 treatments; or

24 (II) provide that the only jus-
25 tification for limiting the scope of

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

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

9 (4) FUNDING.—There is authorized to be ap-
10 propriated to carry out this subsection
11 \$1,000,000,000 for each of the fiscal years 2019
12 through 2028. Funds appropriated under this para-
13 graph shall remain available until expended.

14 **SEC. 402. PRICE TRANSPARENCY.**

15 Section 1866 of the Social Security Act (42 U.S.C.
16 1395cc), as amended by section 401, is further amended—

17 (1) in subsection (a)(1)—

18 (A) in subparagraph (Y), by striking
19 “and” at the end;

20 (B) in subparagraph (Z), by striking the
21 period at the end and inserting “; and”; and

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

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

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

3 “(1) REQUIREMENT RELATING TO PUBLISHING CER-
4 TAIN HOSPITAL PRICES.—

5 “(1) IN GENERAL.—For purposes of subsection
6 (a)(1)(AA), the requirement described in this sub-
7 section is, with respect to a hospital and year (begin-
8 ning with 2021), for the hospital to publicly post,
9 through the system established under paragraph (3),
10 for each service included in the list published under
11 paragraph (2) for such year, the volume-weighted
12 average price charged by the hospital to—

13 “(A) individuals enrolled during such year
14 in group health plans or health insurance cov-
15 erage offered in the individual or group market
16 (as such terms are defined in section 2791 of
17 the Public Health Service Act); and

18 “(B) individuals who are not enrolled in
19 any health insurance coverage or health benefits
20 plan and individuals who are enrolled in such
21 coverage or plan but such coverage or plan does
22 not provide benefits for the service.

23 “(2) SERVICES.—For purposes of subsection
24 (a)(1)(AA) and this subsection, the Secretary shall,
25 for 2021 and each subsequent year, publish a list of

1 the 100 services that are the most highly utilized in
2 a hospital-based setting.

3 “(3) STANDARDIZED DIGITAL REPORTING SYS-
4 TEM.—Not later than January 1, 2021, the Sec-
5 retary shall establish a standardized digital system
6 for purposes of paragraph (1).”.

7 **SEC. 403. REPEALING SHARED SAVINGS INCENTIVES FROM**
8 **MEDICARE SHARED SAVINGS PROGRAM.**

9 (a) IN GENERAL.—Section 1899 of the Social Secu-
10 rity Act (42 U.S.C. 1395jjj) is amended—

11 (1) in subsection (a)(1)—

12 (A) by striking subparagraph (B); and

13 (B) by striking “such program—

14 “(A) groups of providers” and inserting

15 “such program, groups of providers”;

16 (2) in subsection (b)(2)—

17 (A) in subparagraph (C), by striking “that

18 would allow the organization to receive and dis-

19 tribute payments for shared savings under sub-

20 section (d)(2) to participating providers of serv-

21 ices and suppliers”; and

22 (B) in subparagraph (E)—

23 (i) by striking “the implementation”

24 and inserting “and the implementation”;

25 and

1 (ii) by striking “, and the determina-
2 tion of payments for shared savings under
3 subsection (d)(2)”;

4 (3) in subsection (d)—

5 (A) in paragraph (1)—

6 (i) in subparagraph (A), by striking
7 “except” and all that follows through
8 “subparagraph (B)(i).”; and

9 (ii) by striking subparagraph (B); and

10 (B) by striking paragraph (2); and

11 (4) in subsection (g), by striking paragraph (4)

12 and redesignating paragraphs (5) and (6) as para-
13 graphs (4) and (5), respectively.

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

16 **SEC. 404. REPEAL OF HEALTH CARE REFORM PROVISIONS**

17 **LIMITING MEDICARE EXCEPTION TO THE**

18 **PROHIBITION ON CERTAIN PHYSICIAN RE-**

19 **FERRALS FOR HOSPITALS.**

20 Sections 6001 and 10601 of the Patient Protection
21 and Affordable Care Act (Public Law 111–148; 124 Stat.
22 684, 1005) and section 1106 of the Health Care and Edu-
23 cation Reconciliation Act of 2010 (Public Law 111–152;
24 124 Stat. 1049) are repealed and the provisions of law

1 amended by such sections are restored as if such sections
2 had never been enacted.

3 **SEC. 405. ADVISORY GROUP ON REDUCING BURDEN OF**
4 **HOSPITAL ADMINISTRATIVE REQUIREMENTS.**

5 (a) IN GENERAL.—Not later than January 1, 2021,
6 the Secretary of Health and Human Services shall convene
7 an advisory group to provide, in accordance with this sec-
8 tion, recommendations on ways the Federal Government
9 could reduce the burden of administrative requirements on
10 hospitals.

11 (b) RECOMMENDATIONS.—Not later than January 1,
12 2022, the advisory board convened under this section
13 shall—

14 (1) submit to the Secretary of Health and
15 Human Services recommendations described under
16 subsection (a) for executive action and any rec-
17 ommendations for State actions for potential consid-
18 eration in making grants under section 2(c) to
19 States; and

20 (2) submit to Congress recommendations de-
21 scribed under subsection (a) for legislative proposals.

22 (c) MEMBERSHIP.—The advisory board under this
23 section shall consist of the following members:

24 (1) Three representatives of companies that
25 have—

- 1 (A) geographically distributed workforces;
2 (B) at least 10,000 employees; and
3 (C) no more than 10 percent of such em-
4 ployees in any single State.

5 (2) Three representatives of health insurance
6 issuers and health plans, consisting of—

7 (A) one representative of for-profit health
8 insurance issuers and health plans with at least
9 20,000,000 enrollees in the employer-sponsored
10 market;

11 (B) one representative of non-profit health
12 insurance issuers and health plans operating in
13 at least 5 States; and

14 (C) one representative of non-profit health
15 insurance issuers and health plans operating in
16 a rural State (as defined by the Census Bu-
17 reau).

18 (3) Seven public policy experts in the field of
19 hospital consolidation.

20 **SEC. 406. AUTHORITY OF FEDERAL TRADE COMMISSION**
21 **OVER CERTAIN TAX-EXEMPT ORGANIZA-**
22 **TIONS.**

23 Section 4 of the Federal Trade Commission Act (15
24 U.S.C. 44) is amended, in the undesignated paragraph re-
25 lating to the definition of the term “Corporation”—

1 (1) by striking “, and any” and inserting “,
2 any”; and

3 (2) by inserting before the period at the end the
4 following: “, and any organization described in sec-
5 tion 501(c)(3) of the Internal Revenue Code of 1986
6 that is exempt from taxation under section 501(a) of
7 such Code”.

8 **TITLE V—DIGITAL HEALTH**
9 **CARE**

10 **SEC. 501. ACCESS OF INDIVIDUALS TO PROTECTED HEALTH**
11 **INFORMATION.**

12 The provisions of section 164.524 of title 45, Code
13 of Federal Regulations, as in effect on the day before the
14 date of the enactment of this Act, shall have the force and
15 effect of law.

16 **SEC. 502. EXPANSION OF COVERAGE OF TELEHEALTH**
17 **SERVICES.**

18 (a) COVERED SERVICES.—Section 1834(m)(4)(F)(i)
19 of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)(i))
20 is amended—

21 (1) by striking “and office” and inserting “of-
22 fice”; and

23 (2) by inserting: “respiratory services, audiology
24 services (as defined in section 1861(l)), outpatient
25 therapy services (including physical therapy, occupa-

1 tional therapy, and speech-language pathology serv-
2 ices)” after “the Secretary)),”.

3 (b) PROVIDERS.—Subsection (m) of section 1834 of
4 such Act (42 U.S.C. 1395m) is amended—

5 (1) in paragraph (1), by striking “or a practi-
6 tioner (described in section 1842(b)(18)(C))” and
7 inserting “, a practitioner (described in section
8 1842(b)(18)(C)), or an applicable professional (as
9 defined in paragraph (4)(G))”;

10 (2) by striking “physician or practitioner” each
11 time it appears in such subsection and inserting
12 “physician, practitioner, or applicable professional”;

13 (3) in paragraph (3)(A)—

14 (A) in the heading, by striking “PHYSI-
15 CIAN AND PRACTITIONER” and inserting “PHY-
16 SICIAN, PRACTITIONER, AND APPLICABLE PRO-
17 FESSIONAL”; and

18 (B) by striking “physicians or practi-
19 tioners” and inserting “physicians, practi-
20 tioners, or applicable professionals”; and

21 (4) in paragraph (4), by adding at the end the
22 following new subparagraph:

23 “(G) APPLICABLE PROFESSIONAL.—The
24 term ‘applicable professional’ means, with re-
25 spect to services furnished on or after the date

1 that is 6 months after the date of the enact-
2 ment of this subparagraph, a certified diabetes
3 educator or licensed—

4 “(i) respiratory therapist;

5 “(ii) audiologist;

6 “(iii) occupational therapist;

7 “(iv) physical therapist; or

8 “(v) speech language pathologist.”.

9 (c) HOME-BASED MONITORING SERVICES FOR CON-
10 GESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE
11 PULMONARY DISEASE.—

12 (1) COVERAGE OF REMOTE PATIENT MONI-
13 TORING SERVICES FOR CERTAIN CHRONIC HEALTH
14 CONDITIONS.—

15 (A) IN GENERAL.—Section 1861(s)(2) of
16 the Social Security Act (42 U.S.C. 1395x(s)(2))
17 is amended—

18 (i) in subparagraph (GG), by striking
19 “and” at the end;

20 (ii) in subparagraph (HH), by insert-
21 ing “and” at the end; and

22 (iii) by inserting after subparagraph
23 (HH) the following new subparagraph:

1 “(II) applicable remote patient monitoring
2 services (as defined in paragraph (1)(A) of sub-
3 section (iii));”.

4 (2) SERVICES DESCRIBED.—Section 1861 of
5 the Social Security Act (42 U.S.C. 1395x) is amend-
6 ed by adding at the end the following new sub-
7 section:

8 “(kkk) REMOTE PATIENT MONITORING SERVICES
9 FOR CHRONIC HEALTH CONDITIONS.—

10 “(1)(A) The term ‘applicable remote patient
11 monitoring services’ means remote patient moni-
12 toring services (as defined in subparagraph (B)) fur-
13 nished to provide for the monitoring, evaluation, and
14 management of an individual with a covered chronic
15 condition (as defined in paragraph (2)), insofar as
16 such services are for the management of such chron-
17 ic condition.

18 “(B) The term ‘remote patient monitoring serv-
19 ices’ means services furnished through remote pa-
20 tient monitoring technology (as defined in subpara-
21 graph (C)).

22 “(C) The term ‘remote patient monitoring tech-
23 nology’ means a coordinated system that uses one or
24 more home-based or mobile monitoring devices that
25 automatically transmit vital sign data or information

1 on activities of daily living and may include re-
2 sponses to assessment questions collected on the de-
3 vices wirelessly or through a telecommunications
4 connection to a server that complies with the Fed-
5 eral regulations (concerning the privacy of individ-
6 ually identifiable health information) promulgated
7 under section 264(c) of the Health Insurance Port-
8 ability and Accountability Act of 1996, as part of an
9 established plan of care for that patient that in-
10 cludes the review and interpretation of that data by
11 a health care professional.

12 “(2) For purposes of paragraph (1), the term
13 ‘covered chronic health condition’ means applicable
14 conditions (as defined in and applied under section
15 1886(q)(5)) when under chronic care management
16 (identified as of July 1, 2015, by HCPCS code
17 99490 (and as subsequently modified by the Sec-
18 retary)).

19 “(3)(A) Payment may be made under this part
20 for applicable remote patient monitoring services
21 provided to an individual during a period of up to
22 90 days and such additional period as provided for
23 under subparagraph (B).

24 “(B) The 90-day period described in subpara-
25 graph (A), with respect to an individual, may be re-

1 newed by the physician who provides chronic care
2 management to such individual if the individual con-
3 tinues to qualify for such management.”.

4 (3) PAYMENT UNDER THE PHYSICIAN FEE
5 SCHEDULE.—Section 1848 of the Social Security
6 Act (42 U.S.C. 1395w-4) is amended—

7 (A) in subsection (c)—

8 (i) in paragraph (2)(B)—

9 (I) in clause (ii)(II), by striking
10 “and (v)” and inserting “(v), and
11 (vii)”; and

12 (II) by adding at the end the fol-
13 lowing new clause:

14 “(vii) BUDGETARY TREATMENT OF
15 CERTAIN SERVICES.—The additional ex-
16 penditures attributable to services de-
17 scribed in section 1861(s)(2)(II) shall not
18 be taken into account in applying clause
19 (ii)(II).”; and

20 (ii) by adding at the end the following
21 new paragraph:

22 “(7) TREATMENT OF APPLICABLE REMOTE PA-
23 TIENT MONITORING SERVICES.—

24 “(A) In determining relative value units
25 for applicable remote patient monitoring serv-

1 ices (as defined in section 1861(iii)(1)(A)), the
2 Secretary, in consultation with appropriate phy-
3 sician groups, practitioner groups, and supplier
4 groups, shall take into consideration—

5 “(i) physician or practitioner re-
6 sources, including physician or practitioner
7 time and the level of intensity of services
8 provided, based on—

9 “(I) the frequency of evaluation
10 necessary to manage the individual
11 being furnished the services;

12 “(II) the complexity of the eval-
13 uation, including the information that
14 must be obtained, reviewed, and ana-
15 lyzed; and

16 “(III) the number of possible di-
17 agnoses and the number of manage-
18 ment options that must be considered;

19 “(ii) practice expense costs associated
20 with such services, including the direct
21 costs associated with installation and infor-
22 mation transmission, costs of remote pa-
23 tient monitoring technology (including
24 equipment and software), device delivery
25 costs, and resource costs necessary for pa-

1 tient monitoring and followup (but not in-
2 cluding costs of any related item or non-
3 physician service otherwise reimbursed
4 under this title); and

5 “(iii) malpractice expense resources.

6 “(B) Using the relative value units deter-
7 mined in subparagraph (A), the Secretary shall
8 provide for separate payment for such services
9 and shall not adjust the relative value units as-
10 signed to other services that might otherwise
11 have been determined to include such separately
12 paid remote patient monitoring services.”; and

13 (B) in subsection (j)(3), by inserting
14 “(2)(II),” after “health risk assessment),”.

15 **SEC. 503. STARK AND AKS EXEMPTIONS.**

16 Notwithstanding any other provision of law, the Sec-
17 retary of Health and Human Services may exempt value-
18 based arrangements, alternative payment models, and
19 technologies (as defined by the Secretary) from any provi-
20 sion of section 1128B or 1877 of the Social Security Act
21 for purposes of maintaining, analyzing, or transferring
22 electronic health records.

23 **SEC. 504. STARK TECHNICAL PENALTY.**

24 Notwithstanding any other provision of law, the Sec-
25 retary of Health and Human Services may institute a civil

1 monetary penalty for technical, nonegregious violations of
2 section 1877 of the Social Security Act in lieu of any pen-
3 alty otherwise applicable for such violations under such
4 section.

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