

116TH CONGRESS
2D SESSION

H. R. 8527

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 2, 2020

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

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 2020”.

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—MEDISAVE

Subtitle A—Medisave Accounts and Contributions

- Sec. 101. Establishment of Medisave accounts.
- Sec. 102. Consolidation of HSAs, HRAs, FSAs, and MSAs into Medisave accounts.
- Sec. 103. Health Reimbursement Arrangements and Other Account-Based Group Health Plans.
- Sec. 104. Cost-sharing reduction payments as eligible contributions.
- Sec. 105. Direct Primary Care.

Subtitle B—Assistance to Medisave Accounts

- Sec. 111. Support in implementation.
- Sec. 112. New corporations required to use Medisave.
- Sec. 113. Federal employee health benefits and Medisave.
- Sec. 114. Grants to States for consumer assistance.

TITLE II—IMPROVING PRIVATE HEALTH INSURANCE

Subtitle A—Maintaining Protections for Patients With Preexisting Conditions

- Sec. 201. Guaranteed availability of coverage; prohibiting discrimination.

Subtitle B—Expanding Coverage Options

- Sec. 211. Rules governing association health plans.
- Sec. 212. Clarification of treatment of single employer arrangements.
- Sec. 213. Enforcement provisions relating to association health plans.
- Sec. 214. Cooperation between Federal and State authorities.
- Sec. 215. Effective date and transitional and other rules.
- Sec. 216. Short-term limited duration insurance.

Subtitle C—Improving Commercial Health Insurance

- Sec. 221. Invisible Guaranteed Coverage Pool Reinsurance Program; tax on exchange plans.
- Sec. 222. Employer health insurance mandate repeal.
- Sec. 223. Refundable credits for coverage under a qualified health plan for individuals offered employer-sponsored insurance.
- Sec. 224. Inclusion in income of certain costs of employer-provided coverage under health plans.
- Sec. 225. Change in permissible age variation in health insurance premium rates.
- Sec. 226. Premium assistance adjustment to reflect age.
- Sec. 227. Premium assistance.
- Sec. 228. Adding copper plans to Exchanges.
- Sec. 229. Copper and bronze plans.
- Sec. 230. Waivers for State innovation.
- Sec. 231. Enrollment periods.
- Sec. 232. State-operated Exchanges flexibility for open enrollment periods.
- Sec. 233. Promoting health plans that cover individuals in more than one State.

TITLE III—COMPETITION, TRANSPARENCY AND ACCOUNTABILITY

Subtitle A—Provider and Insurer Competition

- Sec. 301. Hospital consolidation.
- Sec. 302. Authority of Federal Trade Commission over certain tax-exempt organizations.
- Sec. 303. Restoring the application of antitrust laws to the business of health insurance.
- Sec. 304. Leveling the playing field between payers and providers.
- Sec. 305. Increasing transparency by removing gag clauses on price and quality information.
- Sec. 306. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.
- Sec. 307. Repealing eligibility of certain ACOs.
- Sec. 308. Repeal of health care reform provisions limiting Medicare exception to the prohibition on certain physician referrals for hospitals.
- Sec. 309. Alternative payment model for certain shoppable procedures.

Subtitle B—Price Transparency

- Sec. 321. Price transparency.
- Sec. 322. Price transparency requirements.
- Sec. 323. Designation of nongovernmental, nonprofit transparency organizations to lower Americans' health care costs.
- Sec. 324. Protecting patients and improving the accuracy of provider directory information.
- Sec. 325. Ensuring enrollee access to cost-sharing information.
- Sec. 326. Access of individuals to protected health information.
- Sec. 327. Timely bills for patients.
- Sec. 328. Advisory group on reducing burden of hospital administrative requirements.
- Sec. 329. Data reporting to improve the transparency regarding how 340B hospital covered entities provide care for patients.
- Sec. 330. Requiring 340B drug discount program reports by DSH hospital covered entities on low-income utilization rate of outpatient hospital services.
- Sec. 331. Employer benefits reports.
- Sec. 332. Group health plan reporting requirements.
- Sec. 333. Government Accountability Office study on profit- and revenue-sharing in health care.

Subtitle C—Prescription Drug Competition and Innovation

- Sec. 341. Expedited development and priority review for generic complex drug products.
- Sec. 342. Preventing blocking of generic drugs.
- Sec. 343. Ensuring timely access to generics.
- Sec. 344. Preemption of State barriers to the substitution of biosimilar products.
- Sec. 345. Increasing pharmaceutical options to treat an unmet medical need.
- Sec. 346. Provisional approval of new human drugs.
- Sec. 347. Consolidating exclusivity periods for drugs treating rare diseases and conditions.
- Sec. 348. Exclusivity period for brand name biological products.
- Sec. 349. Protecting access to biological products.
- Sec. 350. Streamlining the transition of biological products.
- Sec. 351. Regulation of manufacturer-sponsored copay contributions.

- Sec. 352. Antitrust exemption for private health insurer issuers to negotiate wholesale acquisition prices of prescription drugs purchased from drug manufacturers.
- Sec. 353. Biological product innovation.
- Sec. 354. Clarifying the meaning of new chemical entity.
- Sec. 355. Prompt approval of drugs related to safety information.
- Sec. 356. Conditions of use for biosimilar biological products.
- Sec. 357. Education on biological products.
- Sec. 358. Congressional review of the Food and Drug Administration rule-making.
- Sec. 359. Government Accountability Office study of rules.

Subtitle D—Prescription Drug and Pharmacy Benefit Manager Transparency

- Sec. 361. Patent disclosure requirements.
- Sec. 362. Biological product patent transparency.
- Sec. 363. Orange Book modernization.
- Sec. 364. Modernizing the labeling of certain generic drugs.
- Sec. 365. Requirements with respect to prescription drug benefits.
- Sec. 366. PBM transparency and elimination of DIR fees.
- Sec. 367. Health plan oversight of pharmacy benefit manager services.
- Sec. 368. Study by Comptroller General of United States.

Subtitle E—Medicare and Medicaid Prescription Drug Reforms

- Sec. 371. Medicare part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.
- Sec. 372. Market based part B pricing index.
- Sec. 373. Innovation model testing of Medicare drug payments.
- Sec. 374. Modification of maximum rebate amount under Medicaid drug rebate program.

Subtitle F—Medical Malpractice Reform

- Sec. 381. Definitions.
- Sec. 382. Encouraging speedy resolution of claims.
- Sec. 383. Compensating patient injury.
- Sec. 384. Maximizing patient recovery.
- Sec. 385. Authorization of payment of future damages to claimants in health care lawsuits.
- Sec. 386. Product liability for health care providers.
- Sec. 387. Effect on other laws.
- Sec. 388. Limitation on expert witness testimony.
- Sec. 389. Expert witness qualifications.
- Sec. 390. Communications following unanticipated outcome.
- Sec. 391. Affidavit of merit.
- Sec. 392. Notice of intent to commence lawsuit.
- Sec. 393. Limitation on liability for volunteer health care professionals.
- Sec. 394. Rules of construction.
- Sec. 395. Effective date.

TITLE IV—MEDICARE AND MEDICAID REFORMS

Subtitle A—Medicaid Reforms

- Sec. 401. Medicaid payment reform.

- Sec. 402. Income limitations for refundable credits for coverage under a qualified health plan.
- Sec. 403. Medicaid eligibility determinations.
- Sec. 404. Lowering safe harbor threshold with respect to State taxes on health care providers.
- Sec. 405. Providing for State approval and implementation of specified waivers under the Medicaid program.
- Sec. 406. Deduction for qualified charity care.

Subtitle B—Medicare Reforms

- Sec. 411. Off-campus provider-based department Medicare site neutral payment.
- Sec. 412. Eliminating FEHBP eligibility for annuitants.
- Sec. 413. Elimination of Medicare eligibility for certain individuals.
- Sec. 414. Medicare part D tax deduction.
- Sec. 415. Repeal of net investment income tax.
- Sec. 416. Medicare coverage of bad debt.

Subtitle C—Medicare Choice and Competition

- Sec. 421. Competitive bidding and premiums under unified Medicare.
- Sec. 422. New unified eligibility and enrollment rules.
- Sec. 423. New benefit structure under unified Medicare.
- Sec. 424. Late enrollment penalty not to apply for months of any health coverage.
- Sec. 425. Medigap reform.
- Sec. 426. ACO revision.
- Sec. 427. Primary care options.
- Sec. 428. General provisions; effective date.

Subtitle D—Telehealth Improvements and Expansion

- Sec. 431. Expansion of coverage of telehealth services.
- Sec. 432. Expanding the use of telehealth through the waiver of certain requirements.
- Sec. 433. Expanding the use of telehealth for mental health services.
- Sec. 434. Use of telehealth in emergency medical care.
- Sec. 435. Improvements to the process for adding telehealth services.
- Sec. 436. Rural health clinics and Federally qualified health centers.
- Sec. 437. Native American health facilities.
- Sec. 438. Waiver of telehealth restrictions during national emergencies.
- Sec. 439. Use of telehealth in recertification for hospice care.
- Sec. 440. Clarification for fraud and abuse laws regarding technologies provided to beneficiaries.
- Sec. 441. Study and report on increasing access to telehealth services in the home.
- Sec. 442. Analysis of telehealth waivers in alternative payment models.
- Sec. 443. Model to allow additional health professionals to furnish telehealth services.
- Sec. 444. Testing of models to examine the use of telehealth under the Medicare program.

1 **TITLE I—MEDISAVE**
2 **Subtitle A—Medisave Accounts and**
3 **Contributions**

4 **SEC. 101. ESTABLISHMENT OF MEDISAVE ACCOUNTS.**

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

8 **“SEC. 530A. MEDISAVE ACCOUNTS.**

9 “(a) MEDISAVE ACCOUNT.—For purposes of this sec-
10 tion—

11 “(1) IN GENERAL.—The term ‘Medisave ac-
12 count’ means a trust created or organized in the
13 United States as a Medisave account exclusively for
14 the purpose of paying the qualified medical expenses
15 of the account beneficiary, but only if the written
16 governing instrument creating the trust meets the
17 following requirements:

18 “(A) Except in the case of a rollover con-
19 tribution described in subparagraph (A) or (B)
20 of subsection (e)(5), no contribution will be ac-
21 cepted—

22 “(i) unless it is in cash,

23 “(ii) to the extent such contribution,
24 when added to previous contributions to
25 the trust for the calendar year, exceeds the

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

3 “(iii) to the extent such contribution,
4 when added to the balance of the account,
5 exceeds the limitation amount specified in
6 subsection (b)(2).

7 “(B) The trustee is a bank (as defined in
8 section 408(n)), an insurance company (as de-
9 fined in section 816), or another person who
10 demonstrates to the satisfaction of the Sec-
11 retary that the manner in which such person
12 will administer the trust will be consistent with
13 the requirements of this section.

14 “(C) No part of the trust assets will be in-
15 vested in life insurance contracts.

16 “(D) The assets of the trust will not be
17 commingled with other property except in a
18 common trust fund or common investment
19 fund.

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

22 “(2) QUALIFIED MEDICAL EXPENSES.—

23 “(A) IN GENERAL.—The term ‘qualified
24 medical expenses’ means, with respect to an ac-
25 count beneficiary, amounts paid by such bene-

1 ficiary for medical care, but only to the extent
2 such amounts are not compensated for by in-
3 surance or otherwise—

4 “(i) for—

5 “(I) such individual,

6 “(II) the spouse of such indi-
7 vidual,

8 “(III) any dependent (as defined
9 in section 152, determined without re-
10 gard to subsections (b)(1), (b)(2), and
11 (d)(1)(B) thereof) of such individual,
12 and

13 “(IV) any individual who bears a
14 relationship to the account beneficiary
15 that is described in subparagraph (C)
16 or (D) of section 152(d) if the ac-
17 count beneficiary is or was a depend-
18 ent of such individual for any taxable
19 year ending before or with the taxable
20 year in which the individual attained
21 18 years of age, and

22 “(ii) if, on the date such medical care
23 was provided, such individual, spouse or
24 dependent to whom such care was provided

1 was covered under the qualified health in-
2 surance of the account beneficiary.

3 “(B) MODIFIED DEFINITION OF MEDICAL
4 CARE.—For purposes of subparagraph (A), the
5 term ‘medical care’ has the meaning given such
6 term by section 213(d), except that such term
7 includes—

8 “(i) a direct primary care service ar-
9 rangement, and

10 “(ii) predetermined level of access to
11 care from an integrated health plan.

12 “(3) ACCOUNT BENEFICIARY.—The term ‘ac-
13 count beneficiary’ means the individual on whose be-
14 half the Medisave account was established.

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

18 “(A) Section 219(d)(2) (relating to no de-
19 duction for rollovers).

20 “(B) Section 219(f)(3) (relating to time
21 when contributions deemed made).

22 “(C) Except as provided in section 106(d),
23 section 219(f)(5) (relating to employer pay-
24 ments).

1 “(D) Section 408(g) (relating to commu-
2 nity property laws).

3 “(E) Section 408(h) (relating to custodial
4 accounts).

5 “(b) LIMITATIONS.—

6 “(1) ANNUAL LIMITATION.—

7 “(A) IN GENERAL.—The limitation amount
8 specified in this paragraph is—

9 “(i) \$5,000 in the case of a qualified
10 health plan with an actuarial value of less
11 than 40 percent,

12 “(ii) \$4,300 in the case of a qualified
13 health plan with an actuarial value that is
14 40 percent or more and less than 75 per-
15 cent, and

16 “(iii) \$3,600 in the case of a qualified
17 health plan with an actuarial value that is
18 75 percent or more.

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

1 “(2) ACCOUNT ACCUMULATION LIMITATION.—
2 The limitation amount specified in this paragraph is
3 \$50,000.

4 “(3) INDEXING.—

5 “(A) IN GENERAL.—In the case of any
6 taxable year beginning in a calendar year after
7 2020, each dollar amount contained in para-
8 graph (1)(A) shall be increased by the medical
9 care cost adjustment of such amount for such
10 calendar year.

11 “(B) MEDICAL CARE COST ADJUST-
12 MENT.—For purposes of subparagraph (A), the
13 medical care cost adjustment for any calendar
14 year is the percentage (if any) by which—

15 “(i) the medical care component of
16 the C-CPI-U (as defined in section
17 1(f)(6)) for August of the preceding cal-
18 endar year, exceeds

19 “(ii) such component of the C-CPI-U
20 (as so defined) for August of 2019.

21 “(C) ROUNDING.—

22 “(i) ANNUAL LIMITATION.—If any in-
23 crease in a dollar amount contained in
24 paragraph (1)(A) determined under sub-
25 paragraph (A) is not a multiple of \$100,

1 such increase shall be rounded to the near-
2 est multiple of \$100.

3 “(ii) ACCOUNT LIMITATION.—If any
4 increase in the dollar amount contained in
5 paragraph (2) determined under subpara-
6 graph (A) is not a multiple of \$1,000, such
7 increase shall be rounded to the nearest
8 multiple of \$1,000.

9 “(4) COORDINATION WITH OTHER CONTRIBU-
10 TIONS.—The limitation which would (but for this
11 paragraph) apply under paragraphs (1) and (2) to
12 an individual for any taxable year shall be reduced
13 (but not below zero) by the sum of—

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

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

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

1 deposit the advance payment into the Medisave ac-
2 count of the account beneficiary.

3 “(c) DEFINITIONS AND SPECIAL RULES.—For pur-
4 poses of this section—

5 “(1) ELIGIBLE INDIVIDUAL.—

6 “(A) IN GENERAL.—The term ‘eligible in-
7 dividual’ means, with respect to any month—

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

11 “(ii) any individual whose household
12 income is greater than 250 percent of the
13 Federal poverty level—

14 “(I) if such individual is covered
15 under a qualified health plan with an
16 actuarial value not more than 80 per-
17 cent; or

18 “(II) if—

19 “(aa) such individual is cov-
20 ered under a high deductible
21 health plan as of the 1st day of
22 such month; and

23 “(bb) such individual is not,
24 while covered under a high de-

1 ductible health plan, covered
2 under any health plan—

3 “(AA) which is not a
4 high deductible health plan;
5 and

6 “(BB) which provides
7 coverage for any benefit
8 which is covered under the
9 high deductible health plan.

10 “(B) CERTAIN COVERAGE DIS-
11 REGARDED.—Subparagraph (A) shall be ap-
12 plied without regard to—

13 “(i) coverage for any benefit provided
14 by permitted insurance, and

15 “(ii) coverage (whether through insur-
16 ance or otherwise) for accidents, disability,
17 dental care, vision care, or long-term care.

18 “(C) SPECIAL RULE FOR INDIVIDUALS ELI-
19 GIBLE FOR CERTAIN VETERANS BENEFITS.—An
20 individual shall not fail to be treated as an eli-
21 gible individual for any period merely because
22 the individual receives hospital care or medical
23 services under any law administered by the Sec-
24 retary of Veterans Affairs for a service-con-

1 needed disability (within the meaning of section
2 101(16) of title 38, United States Code).

3 “(2) QUALIFIED HEALTH PLAN.—

4 “(A) IN GENERAL.—The term ‘qualified
5 health plan’ means a health plan that offers
6 health insurance coverage. Such term includes
7 entitlement to benefits under title XVIII or title
8 XIX of the Social Security Act.

9 “(B) EXCLUSION OF CERTAIN PLANS.—

10 Such term does not include a health plan if
11 substantially all of its coverage is disregarded
12 under paragraph (1)(B).

13 “(C) HEALTH INSURANCE COVERAGE.—

14 The term ‘health insurance coverage’ means
15 benefits consisting of medical care (provided di-
16 rectly, through insurance or reimbursement, or
17 otherwise and including items and services paid
18 for as medical care) under any hospital or med-
19 ical service policy or certificate, hospital or
20 medical service plan contract, or health mainte-
21 nance organization contract offered by a health
22 insurance issuer.

23 “(D) HEALTH INSURANCE ISSUER.—The

24 term ‘health insurance issuer’ means an insur-
25 ance company, insurance service, or insurance

1 organization (including a health maintenance
2 organization) which is licensed to engage in the
3 business of insurance in a State and which is
4 subject to State law which regulates insurance
5 (within the meaning of section 514(b)(2) of the
6 Employee Retirement Income Security Act of
7 1974 (29 U.S.C. 1144(b)(2))).

8 “(E) HEALTH MAINTENANCE ORGANIZA-
9 TION.—The term ‘health maintenance organiza-
10 tion’ means—

11 “(i) a Federally qualified health main-
12 tenance organization (as defined in section
13 1301(a) of the Public Health Service Act
14 (42 U.S.C. 300e(a))),

15 “(ii) an organization recognized under
16 State law as a health maintenance organi-
17 zation, or

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

22 “(3) PERMITTED INSURANCE.—The term ‘per-
23 mitted insurance’ means—

1 “(A) insurance if substantially all of the
2 coverage provided under such insurance relates
3 to—

4 “(i) liabilities incurred under workers’
5 compensation laws,

6 “(ii) tort liabilities,

7 “(iii) liabilities relating to ownership
8 or use of property, or

9 “(iv) such other similar liabilities as
10 the Secretary may specify by regulations,

11 “(B) insurance for a specified disease or
12 illness, and

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

15 “(4) FAMILY COVERAGE.—The term ‘family
16 coverage’ means any coverage other than self-only
17 coverage.

18 “(d) TAX TREATMENT OF ACCOUNTS.—

19 “(1) IN GENERAL.—A Medisave account is ex-
20 empt from taxation under this subtitle unless such
21 account has ceased to be a Medisave account. Not-
22 withstanding the preceding sentence, any Medisave
23 account is subject to the taxes imposed by section
24 511 (relating to imposition of tax on unrelated busi-
25 ness income of charitable, etc. organizations).

1 “(2) ACCOUNT TERMINATIONS.—Rules similar
2 to the rules of paragraphs (2) and (4) of section
3 408(e) shall apply to Medisave accounts, and any
4 amount treated as distributed under such rules shall
5 be treated as not used to pay qualified medical ex-
6 penses.

7 “(e) TAX TREATMENT OF DISTRIBUTIONS.—

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

13 “(2) INCLUSION OF AMOUNTS NOT USED FOR
14 QUALIFIED MEDICAL EXPENSES.—Any amount paid
15 or distributed out of a Medisave account which is
16 not used exclusively to pay the qualified medical ex-
17 penses of the account beneficiary shall be included in
18 the gross income of such beneficiary.

19 “(3) EXCESS CONTRIBUTIONS RETURNED BE-
20 FORE DUE DATE OF RETURN.—

21 “(A) IN GENERAL.—If any excess con-
22 tribution is contributed for a taxable year to
23 any Medisave account of an individual, para-
24 graph (2) shall not apply to distributions from
25 the Medisave accounts of such individual (to the

1 extent such distributions do not exceed the ag-
2 gregate excess contributions to all such ac-
3 counts of such individual for such year) if—

4 “(i) such distribution is received by
5 the individual on or before the last day
6 prescribed by law (including extensions of
7 time) for filing such individual’s return for
8 such taxable year, and

9 “(ii) such distribution is accompanied
10 by the amount of net income attributable
11 to such excess contribution.

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

15 “(B) EXCESS CONTRIBUTION.—For pur-
16 poses of subparagraph (A), the term excess con-
17 tribution means any contribution (other than a
18 rollover contribution described in paragraph
19 (5)) which exceeds the limitations specified in
20 subsection (b).

21 “(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT
22 USED FOR QUALIFIED MEDICAL EXPENSES.—

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

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

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

10 “(5) ROLLOVER CONTRIBUTION.—

11 “(A) IN GENERAL.—An amount is de-
12 scribed in this subparagraph as a rollover con-
13 tribution if it meets the requirements of clauses
14 (i) and (ii).

15 “(i) IN GENERAL.—Paragraph (2)
16 shall not apply to any amount paid or dis-
17 tributed from a Medisave account to the
18 account beneficiary to the extent the
19 amount received is paid into a Medisave
20 account for the benefit of such beneficiary
21 not later than the 60th day after the day
22 on which the beneficiary receives the pay-
23 ment or distribution.

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

1 clause (i) received by an individual from a
2 Medisave account if, at any time during
3 the 1-year period ending on the day of
4 such receipt, such individual received any
5 other amount described in clause (i) from
6 a Medisave account which was not includ-
7 ible in the individual's gross income be-
8 cause of the application of this paragraph.

9 “(B) ROLLOVER FROM FSA, ARCHER MSA,
10 AND HSA.—An amount is described in this sub-
11 paragraph for a calendar year as a rollover con-
12 tribution if the amount is the remaining balance
13 in a flexible spending account, Archer MSA, or
14 health savings account that is contributed to
15 the Medisave account for a taxable year ending
16 on or before one year after the date of the en-
17 actment of the Fair Care Act of 2020.

18 “(6) COORDINATION WITH MEDICAL EXPENSE
19 DEDUCTION.—For purposes of determining the
20 amount of the deduction under section 213, any pay-
21 ment or distribution out of a Medisave account for
22 qualified medical expenses shall not be treated as an
23 expense paid for medical care.

24 “(7) TRANSFER OF ACCOUNT INCIDENT TO DI-
25 VORCE.—The transfer of an individual's interest in

1 a Medisave account to an individual's spouse or
2 former spouse under a divorce or separation instru-
3 ment described in clause (i) of section 121(d)(3)(C)
4 shall not be considered a taxable transfer made by
5 such individual notwithstanding any other provision
6 of this subtitle, and such interest shall, after such
7 transfer, be treated as a Medisave account with re-
8 spect to which such spouse is the account bene-
9 ficiary.

10 “(8) TREATMENT AFTER DEATH OF ACCOUNT
11 BENEFICIARY.—

12 “(A) TREATMENT IF DESIGNATED BENE-
13 FICIARY IS SPOUSE.—If the account bene-
14 ficiary's surviving spouse acquires such bene-
15 ficiary's interest in a Medisave account by rea-
16 son of being the designated beneficiary of such
17 account at the death of the account beneficiary,
18 such Medisave account shall be treated as if the
19 spouse were the account beneficiary.

20 “(B) OTHER CASES.—

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

1 “(I) such account shall cease to
2 be a Medisave account as of the date
3 of death, and

4 “(II) an amount equal to the fair
5 market value of the assets in such ac-
6 count on such date shall be includible
7 if such person is not the estate of
8 such beneficiary, in such person’s
9 gross income for the taxable year
10 which includes such date, or if such
11 person is the estate of such bene-
12 ficiary, in such beneficiary’s gross in-
13 come for the last taxable year of such
14 beneficiary.

15 “(ii) SPECIAL RULES.—

16 “(I) REDUCTION OF INCLUSION
17 FOR PREDEATH EXPENSES.—The
18 amount includible in gross income
19 under clause (i) by any person (other
20 than the estate) shall be reduced by
21 the amount of qualified medical ex-
22 penses which were incurred by the de-
23 cedent before the date of the dece-
24 dent’s death and paid by such person
25 within 1 year after such date.

1 “(II) DEDUCTION FOR ESTATE
2 TAXES.—An appropriate deduction
3 shall be allowed under section 691(c)
4 to any person (other than the dece-
5 dent or the decedent’s spouse) with
6 respect to amounts included in gross
7 income under clause (i) by such per-
8 son.

9 “(f) REPORTS.—The Secretary may require—

10 “(1) the trustee of a Medisave account to make
11 such reports regarding such account to the Secretary
12 and to the account beneficiary with respect to con-
13 tributions, distributions, the return of excess con-
14 tributions, and such other matters as the Secretary
15 determines appropriate, and

16 “(2) any person who provides an individual with
17 a qualified health plan to make such reports to the
18 Secretary and to the account beneficiary with re-
19 spect to such plan as the Secretary determines ap-
20 propriate.

21 The reports required by this subsection shall be filed at
22 such time and in such manner and furnished to such indi-
23 viduals at such time and in such manner as may be re-
24 quired by the Secretary.

1 “(g) REGULATIONS AND GUIDANCE.—For purposes
2 of this section, the Secretary shall prescribe such regula-
3 tions or other guidance as the Secretary determines nec-
4 essary or appropriate to carry out this section, including
5 regulations or guidance on the methods acceptable to the
6 Secretary for determining qualified health plan actuarial
7 value.”.

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

“Sec. 530A. Medisave accounts.”.

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

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

16 (a) TREATMENT OF EMPLOYER PAYMENTS.—

17 (1) EXCLUSION LIMITED TO SELF-FUNDED
18 MAJOR MEDICAL PLAN OF EMPLOYERS.—Section
19 105(b) of the Internal Revenue Code of 1986 is
20 amended by striking “paid,” and inserting “paid
21 under a self-funded major medical plan of the em-
22 ployer”.

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

1 “(h) EXCLUSION NOT APPLICABLE TO HEALTH RE-
2 IMBURSEMENT ARRANGEMENTS.—Subsection (b) shall
3 not apply to health reimbursement arrangements.”.

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

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

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

10 (ii) by redesignating subsections (f)
11 and (g) as subsections (d) and (e), respec-
12 tively.

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

18 “(b) CONTRIBUTIONS TO MEDISAVE ACCOUNTS.—

19 “(1) IN GENERAL.—In the case of an employee
20 who is an eligible individual (as defined in section
21 530A(c)(1)), amounts contributed by such employ-
22 ee’s employer to any Medisave account (as defined in
23 section 530A(a)) of such employee shall be treated
24 as employer-provided coverage for medical expenses
25 under an accident or health plan to the extent such

1 amounts do not exceed the limitations specified in
2 clauses (ii) and (iii) of section 530A(a)(1)(A) (deter-
3 mined without regard to this subsection) which is
4 applicable to such employee for such taxable year
5 unless such employee is receiving and advance pay-
6 ment of the premium tax credit under section, then
7 such amounts shall not be treated as employer-pro-
8 vided coverage for medical expense under an acci-
9 dent or health plan and are subject to taxation as
10 personal income.

11 “(2) NO CONSTRUCTIVE RECEIPT.—No amount
12 shall be included in the gross income of any em-
13 ployee solely because the employee may choose be-
14 tween the contributions referred to in paragraph (1)
15 and employer contributions to another health plan of
16 the employer.

17 “(3) SPECIAL RULE FOR DEDUCTION OF EM-
18 PLOYER CONTRIBUTIONS.—Any employer contribu-
19 tion to a Medisave account, if otherwise allowable as
20 a deduction under this chapter, shall be allowed only
21 for the taxable year in which paid.

22 “(4) EMPLOYER MEDISAVE ACCOUNT CON-
23 TRIBUTIONS REQUIRED TO BE SHOWN ON RE-
24 TURN.—Every individual required to file a return
25 under section 6012 for the taxable year shall include

1 on such return the aggregate amount contributed by
2 employers to the Medisave accounts of such indi-
3 vidual or such individual's spouse for such taxable
4 year.

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

8 “(6) CROSS REFERENCE.—For penalty on fail-
9 ure by employer to make comparable contributions
10 to the Medisave accounts of comparable employees,
11 see section 4980G.”.

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

16 “(9) DISTRIBUTION FOR MEDISAVE ACCOUNT
17 FUNDING.—

18 “(A) IN GENERAL.—In the case of an indi-
19 vidual who is an eligible individual (as defined
20 in section 530A(e)(1)) and who elects the appli-
21 cation of this paragraph for a taxable year,
22 gross income of the individual for the taxable
23 year does not include a qualified Medisave ac-
24 count funding distribution to the extent such

1 distribution is otherwise includible in gross in-
2 come.

3 “(B) QUALIFIED MEDISAVE ACCOUNT
4 FUNDING DISTRIBUTION.—For purposes of this
5 paragraph, the term ‘qualified Medisave ac-
6 count funding distribution’ means a distribution
7 from an individual retirement plan (other than
8 a plan described in subsection (k) or (p)) of the
9 employee to the extent that—

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

13 “(ii) such distribution—

14 “(I) when added to previous con-
15 tributions to the Medisave account for
16 the calendar year does not exceed the
17 limitation amount specified in section
18 530A(b)(1), and

19 “(II) when added to the balance
20 of the Medisave account, exceeds the
21 limitation amount specified in section
22 530A(b)(2).

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

1 distribution during the lifetime of the indi-
2 vidual. Such an election, once made, shall be ir-
3 revocable.

4 “(D) APPLICATION OF SECTION 72.—Not-
5 withstanding section 72, in determining the ex-
6 tent to which an amount is treated as otherwise
7 includible in gross income for purposes of sub-
8 paragraph (A), the aggregate amount distrib-
9 uted from an individual retirement plan shall be
10 treated as includible in gross income to the ex-
11 tent that such amount does not exceed the ag-
12 gregate amount which would have been so in-
13 cludible if all amounts from all individual retire-
14 ment plans were distributed. Proper adjust-
15 ments shall be made in applying section 72 to
16 other distributions in such taxable year and
17 subsequent taxable years.”.

18 (5) FAILURE OF EMPLOYER TO MAKE COM-
19 PARABLE CONTRIBUTIONS.—

20 (A) Section 4980G(a) of such Code is
21 amended by striking “health savings account”
22 and inserting “Medisave account”.

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

1 savings accounts” and inserting “Medisave ac-
2 counts”.

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

5 (A) by striking paragraph (11) and redес-
6 ignating paragraphs (12) through (17) as para-
7 graphs (11) through (16), respectively, and

8 (B) by amending paragraph (11), as so re-
9 designated, to read as follows:

10 “(11) the amount contributed to any Medisave
11 account (as defined in section 530A) of such em-
12 ployee or such employee’s spouse,”.

13 (b) OTHER CONFORMING AMENDMENTS.—

14 (1) ARCHER MSAS.—Section 220(a) of such
15 Code is amended by adding at the end the following:

16 “No amount is allowed as a deduction under the
17 preceding sentence for any taxable year beginning
18 after one year after the date of the enactment of the
19 Fair Care Act of 2020.”.

20 (2) HEALTH SAVINGS ACCOUNTS.—Section
21 223(a) of such Code is amended by adding at the
22 end the following: “No amount is allowed as a de-
23 duction under the preceding sentence for any taxable
24 year beginning after one year after the date of the
25 enactment of the Fair Care Act of 2020.”.

1 (c) ROLLOVER OF FSA, ARCHER MSA, HSA TO
2 MEDISAVE ACCOUNT.—Notwithstanding any other provi-
3 sion of law, if the remaining balance in a health flexible
4 spending arrangement, Archer MSA, or health savings ac-
5 count is transferred to a Medisave account before the end
6 of any taxable year ending on or before one year after
7 the date of the enactment of the Fair Care Act of 2020,
8 such transfer shall be treated as a rollover to the Medisave
9 account under section 530A(e)(5)(B) of the Internal Rev-
10 enue Code of 1986 and the distribution from the health
11 flexible spending arrangement, Archer MSA, or health
12 savings account shall not be includible in gross income.

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

16 **SEC. 103. HEALTH REIMBURSEMENT ARRANGEMENTS AND**
17 **OTHER ACCOUNT-BASED GROUP HEALTH**
18 **PLANS.**

19 The rule published by the Internal Revenue Service,
20 the Employee Benefits Security Administration, and the
21 Health and Human Services Department relating to
22 “Health Reimbursement Arrangements and Other Ac-
23 count-Based Group Health Plans” (June 20, 2019) shall
24 have the force and effect of law. Health Reimbursement

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

3 **SEC. 104. COST-SHARING REDUCTION PAYMENTS AS ELIGI-**
4 **BLE CONTRIBUTIONS.**

5 (a) ALTERNATIVE WAIVER FOR STATE INNOVA-
6 TION.—Section 1332 of the Patient Protection and Af-
7 fordable Care Act (42 U.S.C. 18052) is amended by add-
8 ing at the end the following new subsection:

9 “(f) ALTERNATIVE WAIVER FOR STATE INNOVA-
10 TION.—

11 “(1) IN GENERAL.—Notwithstanding any pre-
12 ceding provision of this section, a State may apply
13 to the Secretary for the waiver of any requirement
14 of subsection (a)(2) with respect to health insurance
15 coverage within that State for plan years beginning
16 on or after January 1, 2022, if instead of complying
17 with section 1402 the State provides for the dis-
18 tribution of funding received under paragraph (2) to
19 Medisave accounts of qualifying individuals with re-
20 spect to such State. Such application shall be filed
21 at such time and in such manner as the Secretary
22 may require, and shall include such information as
23 the Secretary may require (including a 10-year
24 budget plan for such plan that is budget neutral for
25 the Federal Government).

1 “(2) PASS-THROUGH FUNDING.—With respect
2 to a State waiver under paragraph (1), under which,
3 due to the structure of such waiver, individuals in
4 the State would not qualify for cost-sharing reduc-
5 tions under section 1402 for which they would other-
6 wise be eligible, the Secretary shall provide for an al-
7 ternative means by which an amount is transferred
8 to the State equal to the aggregate amount of such
9 reductions that would have been paid on behalf of
10 the participants in the Exchanges established under
11 this title—

12 “(A) had the State not received such waiv-
13 er;

14 “(B) had references to ‘eligible insureds’
15 under section 1402 referred to ‘qualifying in-
16 sureds (as defined in section 1332(f))’;

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

20 “(i) the percentages specified in sub-
21 clauses (I), (II), and (III) of section
22 1402(c)(1)(B) were references to 84 per-
23 cent, 77 percent, and 63 percent, respec-
24 tively; and

1 “(ii) the references in subparagraphs
2 (A), (B), and (C) of section 1402(c)(2) to
3 94 percent, 87 percent, and 73 percent, re-
4 spectively, were references to 84 percent,
5 77 percent, and 63 percent, respectively;
6 and

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

10 “(i) the percentages specified in sub-
11 clauses (I), (II), and (III) of section
12 1402(c)(1)(B) were references to 74 per-
13 cent, 67 percent, and 53 percent, respec-
14 tively; and

15 “(ii) the references in subparagraphs
16 (A), (B), and (C) of section 1402(c)(2) to
17 94 percent, 87 percent, and 73 percent, re-
18 spectively, were references to 74 percent,
19 67 percent, and 53 percent, respectively.

20 The amount transferred pursuant to the previous
21 sentence shall be determined annually by the Sec-
22 retary, taking into consideration the experience of
23 other States with respect to participation in an Ex-
24 change and reductions provided under such provi-
25 sions to residents of the other States, and shall be

1 paid to the State for purposes of implementing such
2 waiver.

3 “(3) WAIVER CONSIDERATION AND TRANS-
4 PARENCY.—The provisions of paragraph (4) of sub-
5 section (a) shall apply to an application for a waiver
6 under paragraph (1) in the same manner as such
7 provisions apply with respect to an application for a
8 waiver under subsection (a)(1), except that, for pur-
9 poses of this paragraph, the provisions of subsection
10 (a)(4)(B)(ii) shall not apply.

11 “(4) DETERMINATIONS; TERM OF WAIVER.—
12 The provisions of subsections (d) and (e) shall apply
13 with respect to a determination with respect to an
14 application under paragraph (1), and with respect to
15 the term of a waiver under such paragraph, in the
16 same manner as such provisions apply with respect
17 to a determination with respect to an application
18 under subsection (a)(1), and with respect to the
19 term of a waiver under such subsection.

20 “(5) DEFINITIONS.—For purposes of this sub-
21 section:

22 “(A) MEDISAVE ACCOUNT.—The term
23 ‘Medisave account’ has the meaning given such
24 term in section 530A(a) of the Internal Rev-
25 enue Code of 1986.

1 “(B) QUALIFYING INSURED.—The term
2 ‘qualifying insured’ means, with respect to a
3 State and a year, an individual—

4 “(i) who is enrolled in a Medisave ac-
5 count;

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

9 “(iii) whose household income is not
10 more than 250 percent of the Federal pov-
11 erty line for a family of the size involved.”.

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

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

21 (1) in subparagraph (A) by striking the period
22 and inserting “, except in the case of a waiver de-
23 scribed in subsection (f).”; and

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

4 (d) APPROPRIATION FOR COST-SHARING PAY-
5 MENTS.—Section 1402 of the Patient Protection and Af-
6 fordable Care Act (42 U.S.C. 18071) is amended by add-
7 ing at the end the following new subsection:

8 “(g) FUNDING.—

9 “(1) APPROPRIATIONS.—Out of any funds in
10 the Treasury not otherwise appropriated, there is
11 appropriated such sums as may be necessary to,
12 subject to paragraph (2), provide health benefits
13 coverage through payment to issuers (under this sec-
14 tion or through advance payment by the Secretary
15 of the Treasury under section 1412(c)(3)) of the
16 amounts computed under this section for each of
17 plan years 2022 through 2026.

18 “(2) ADJUSTMENTS.—Notwithstanding any
19 other provision of law, payments and other actions
20 for adjustments to obligations incurred prior to De-
21 cember 31, 2022, may be made through December
22 31, 2022.

23 “(3) LIMITATION.—Amounts appropriated
24 under paragraph (1) for each of plan years 2022
25 through 2026 are subject to the requirements and

1 limitations under sections 506 and 507 of division H
2 of Public Law 115–31 in the same manner and to
3 the same extent as if such amounts for each such
4 year were appropriated under such division.”.

5 **SEC. 105. DIRECT PRIMARY CARE.**

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

9 “(D) TREATMENT OF DIRECT PRIMARY
10 CARE SERVICE ARRANGEMENTS.—

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

15 “(ii) DIRECT PRIMARY CARE SERVICE
16 ARRANGEMENT.—For purposes of this
17 paragraph—

18 “(I) IN GENERAL.—The term ‘di-
19 rect primary care service arrange-
20 ment’ means, with respect to any indi-
21 vidual, an arrangement under which
22 such individual is provided medical
23 care (as defined in section 213(d))
24 consisting solely of primary care serv-
25 ices provided by primary care practi-

1 tioners (as defined in section
2 1833(x)(2)(A) of the Social Security
3 Act, determined without regard to
4 clause (ii) thereof), if the sole com-
5 pensation for such care is a fixed peri-
6 odic fee.

7 “(II) LIMITATION.—With respect
8 to any individual for any month, such
9 term shall not include any arrange-
10 ment if the aggregate fees for all di-
11 rect primary care service arrange-
12 ments (determined without regard to
13 this subclause) with respect to such
14 individual for such month exceed
15 \$150 (twice such dollar amount in the
16 case of an individual with any direct
17 primary care service arrangement (as
18 so determined) that covers more than
19 one individual).

20 “(iii) CERTAIN SERVICES SPECIFI-
21 CALLY EXCLUDED FROM TREATMENT AS
22 PRIMARY CARE SERVICES.—For purposes
23 of this paragraph, the term ‘primary care
24 services’ shall not include—

1 “(I) procedures that require the
2 use of general anesthesia, and

3 “(II) laboratory services not typi-
4 cally administered in an ambulatory
5 primary care setting.

6 The Secretary, after consultation with the
7 Secretary of Health and Human Services,
8 shall issue regulations or other guidance
9 regarding the application of this clause.”.

10 (b) DIRECT PRIMARY CARE SERVICE ARRANGEMENT
11 FEES TREATED AS MEDICAL EXPENSES.—Section
12 223(d)(2)(C) is amended by striking “or” at the end of
13 clause (iii), by striking the period at the end of clause (iv)
14 and inserting “, or”, and by adding at the end the fol-
15 lowing new clause:

16 “(v) any direct primary care service arrangement.”.

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

19 (1) by inserting “, (c)(1)(D)(ii)(II),” after
20 “(b)(2),” each place such term appears, and

21 (2) in subparagraph (B), by inserting “and
22 (iii)” after “clause (ii)” in clause (i), by striking
23 “and” at the end of clause (i), by striking the period
24 at the end of clause (ii) and inserting “, and”, and

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

3 “(iii) in the case of the dollar amount
4 in subsection (c)(1)(D)(ii)(II) for taxable
5 years beginning in calendar years after
6 2020, calendar year 2019.”.

7 (d) REPORTING OF DIRECT PRIMARY CARE SERVICE
8 ARRANGEMENT FEES ON W-2.—Section 6051(a) of such
9 Code is amended by striking “and” at the end of para-
10 graph (16), by striking the period at the end of paragraph
11 (17) and inserting “, and”, and by inserting after para-
12 graph (17) the following new paragraph:

13 “(18) in the case of a direct primary care serv-
14 ice arrangement (as defined in section
15 223(c)(1)(D)(ii)) which is provided in connection
16 with employment, the aggregate fees for such ar-
17 rangement for such employee.”.

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

21 **Subtitle B—Assistance to Medisave** 22 **Accounts**

23 **SEC. 111. SUPPORT IN IMPLEMENTATION.**

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

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

9 (b) LIMITATION.—The aggregate amount allowed to
10 an individual as a credit under subsection (a) for all tax-
11 able years shall not exceed \$1,000.

12 (c) PORTION OF CREDIT REFUNDABLE.—For pur-
13 poses of this section—

14 (1) IN GENERAL.—For purposes of the Internal
15 Revenue Code of 1986, in the case of an eligible in-
16 dividual—

17 (A) INCREASE IN CREDIT RATE.—Sub-
18 section (a) shall be applied by substituting “\$1
19 for every \$1 contributed” for “\$1 for every \$3
20 contributed”.

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

1 (2) ELIGIBLE INDIVIDUAL.—

2 (A) IN GENERAL.—The term “eligible indi-
3 vidual” means, with respect to any taxable year,
4 a taxpayer whose household income for the tax-
5 able year does not exceed 400 percent of an
6 amount equal to the poverty line for a family of
7 the size involved.

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

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

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

18 (3) FAMILY SIZE, HOUSEHOLD INCOME, MODI-
19 FIED ADJUSTED GROSS INCOME, POVERTY LINE.—
20 The terms “family size”, “household income”,
21 “modified adjusted gross income”, and “poverty
22 line” have the meaning given such terms by section
23 36B(d) of such Code.

24 (d) DENIAL OF CREDIT TO DEPENDENTS.—No cred-
25 it shall be allowed under this section to any individual with

1 respect to whom a deduction under section 151 is allow-
2 able to another taxpayer for a taxable year beginning in
3 the calendar year in which such individual's taxable year
4 begins.

5 **SEC. 112. NEW CORPORATIONS REQUIRED TO USE**
6 **MEDISAVE.**

7 Notwithstanding any other provision of law, a cor-
8 poration incorporated after December 31, 2021, may not
9 receive tax benefits for offering employees health insur-
10 ance. The previous sentence shall not apply to Medisave
11 contributions offered by such a corporation.

12 **SEC. 113. FEDERAL EMPLOYEE HEALTH BENEFITS AND**
13 **MEDISAVE.**

14 (a) IN GENERAL.—Section 1312(d)(3)(D) of the Pa-
15 tient Protection and Affordable Care Act (42 U.S.C.
16 18032(d)(3)(D)) is amended—

17 (1) in the subparagraph heading, by striking
18 “MEMBERS OF CONGRESS” and inserting “PRESI-
19 DENT, VICE PRESIDENT, MEMBERS OF CONGRESS,
20 AND FEDERAL EMPLOYEES”;

21 (2) in clause (i), in the matter preceding sub-
22 clause (I)—

23 (A) by striking “Members of Congress and
24 congressional staff” and inserting “the Presi-

1 dent, Vice President, Members of Congress, and
2 Federal employees”; and

3 (B) by striking “a Member of Congress or
4 congressional staff” and inserting “the Presi-
5 dent, the Vice President, a Member of Con-
6 gress, or a Federal employee”; and

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

9 “(II) FEDERAL EMPLOYEE.—The
10 term ‘Federal employee’ means—

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

14 “(bb) includes an individual
15 to whom subsection (c) or (f) of
16 such section 2105 pertains
17 (whether or not such individual
18 satisfies item (aa)).”.

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

1 **SEC. 114. GRANTS TO STATES FOR CONSUMER ASSISTANCE.**

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

7 (b) APPLICATION.—An eligible entity shall submit an
8 application to the Administrator in such time and in such
9 manner as the Administrator may require, providing that
10 such application requires a demonstration of the existence
11 of a relationship with, or the ability to establish a relation-
12 ship with, an employer, employee, self-employed indi-
13 vidual, or consumer eligible to enroll in a Medisave ac-
14 count.

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

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

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

23 (3) facilitate enrollment in Medisave accounts;
24 and

25 (4) refer individuals enrolled in a Medisave ac-
26 count to the appropriate official, organization, or

1 State agency for the purpose of addressing a com-
2 plaint, grievance, or other question with respect to
3 such Medisave account.

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

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

13 (f) DEFINITIONS.—In this section:

14 (1) ADMINISTRATOR.—The term “Adminis-
15 trator” means the Administrator of the Centers for
16 Medicare & Medicaid Services.

17 (2) CONSUMER.—The term “consumer” means
18 an individual enrolled in, or seeking to enroll in, a
19 Medisave account.

20 (3) ELIGIBLE ENTITY.—The term “eligible enti-
21 ty” includes the following:

22 (A) A State.

23 (B) Trade.

24 (C) Industry.

25 (D) Professional associations.

1 (E) Commercial fishing industry organiza-
2 tions.

3 (F) Ranching and farming organizations.

4 (G) Community and consumer-focused
5 nonprofit groups.

6 (H) Chambers of Commerce.

7 (I) Unions.

8 (J) Small business development centers (as
9 defined in section 21 of the Small Business Act
10 (15 U.S.C. 648)).

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

13 (4) MEDISAVE ACCOUNT.—The term “Medisave
14 account” has the meaning given such term in section
15 530A(a) of the Internal Revenue Code of 1986 (as
16 added by section 2(a)).

17 (5) STATE.—The term “State” means each of
18 the several States, the District of Columbia, each
19 territory and possession of the United States, and
20 each federally recognized Indian Tribe.

1 **TITLE II—IMPROVING PRIVATE**
2 **HEALTH INSURANCE**
3 **Subtitle A—Maintaining Protec-**
4 **tions for Patients With Pre-**
5 **existing Conditions**

6 **SEC. 201. GUARANTEED AVAILABILITY OF COVERAGE; PRO-**
7 **HIBITING DISCRIMINATION.**

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

12 **“SEC. 196. GUARANTEED AVAILABILITY OF COVERAGE.**

13 “(a) GUARANTEED ISSUANCE OF COVERAGE IN THE
14 INDIVIDUAL AND GROUP MARKET.—Subject to sub-
15 sections (b) through (d), each health insurance issuer that
16 offers health insurance coverage in the individual or group
17 market in a State must accept every employer and indi-
18 vidual in the State that applies for such coverage.

19 “(b) ENROLLMENT.—

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

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

1 ance with the regulations promulgated under para-
2 graph (3), establish special enrollment periods for
3 qualifying events (under section 603 of the Em-
4 ployee Retirement Income Security Act of 1974).

5 “(3) REGULATIONS.—The Secretary shall pro-
6 mulgate regulations with respect to enrollment peri-
7 ods under paragraphs (1) and (2).

8 “(c) SPECIAL RULES FOR NETWORK PLANS.—

9 “(1) IN GENERAL.—In the case of a health in-
10 surance issuer that offers health insurance coverage
11 in the group and individual market through a net-
12 work plan, the issuer may—

13 “(A) limit the employers that may apply
14 for such coverage to those with eligible individ-
15 uals who live, work, or reside in the service area
16 for such network plan; and

17 “(B) within the service area of such plan,
18 deny such coverage to such employers and indi-
19 viduals if the issuer has demonstrated, if re-
20 quired, to the applicable State authority that—

21 “(i) it will not have the capacity to de-
22 liver services adequately to enrollees of any
23 additional groups or any additional individ-
24 uals because of its obligations to existing
25 group contract holders and enrollees; and

1 “(ii) it is applying this paragraph uni-
2 formly to all employers and individuals
3 without regard to the claims experience of
4 those individuals, employers and their em-
5 ployees (and their dependents), or any
6 health status-related factor relating to
7 such individuals, employees, and depend-
8 ents.

9 “(2) 180-DAY SUSPENSION UPON DENIAL OF
10 COVERAGE.—An issuer, upon denying health insur-
11 ance coverage in any service area in accordance with
12 paragraph (1)(B), may not offer coverage in the
13 group or individual market within such service area
14 for a period of 180 days after the date such cov-
15 erage is denied.

16 “(d) APPLICATION OF FINANCIAL CAPACITY LIM-
17 ITS.—

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

22 “(A) it does not have the financial reserves
23 necessary to underwrite additional coverage;
24 and

1 “(B) it is applying this paragraph uni-
2 formly to all employers and individuals in the
3 group or individual market in the State con-
4 sistent with applicable State law and without
5 regard to the claims experience of those individ-
6 uals, employers and their employees (and their
7 dependents) or any health status-related factor
8 relating to such individuals, employees, and de-
9 pendents.

10 “(2) 180-DAY SUSPENSION UPON DENIAL OF
11 COVERAGE.—A health insurance issuer upon denying
12 health insurance coverage in connection with group
13 health plans in accordance with paragraph (1) in a
14 State may not offer coverage in connection with
15 group health plans in the group or individual market
16 in the State for a period of 180 days after the date
17 such coverage is denied or until the issuer has dem-
18 onstrated to the applicable State authority, if re-
19 quired under applicable State law, that the issuer
20 has sufficient financial reserves to underwrite addi-
21 tional coverage, whichever is later. An applicable
22 State authority may provide for the application of
23 this subsection on a service-area-specific basis.

24 “(e) DEFINITIONS.—In this section and in sections
25 197 through 199A:

1 “(1) The term ‘Secretary’ means the Secretary
2 of Health and Human Services.

3 “(2) The terms ‘genetic information’, ‘genetic
4 test’, ‘group health plan’, ‘group market’, ‘health in-
5 surance coverage’, ‘health insurance issuer’, ‘group
6 health insurance coverage’, ‘individual health insur-
7 ance coverage’, ‘individual market’, and ‘under-
8 writing purpose’ have the meanings given such terms
9 in section 2791 of the Public Health Service Act.

10 **“SEC. 197. FAIR HEALTH INSURANCE PREMIUMS.**

11 “(a) PROHIBITING DISCRIMINATORY PREMIUM
12 RATES.—

13 “(1) IN GENERAL.—With respect to the pre-
14 mium rate charged by a health insurance issuer for
15 health insurance coverage offered in the individual
16 or small group market—

17 “(A) such rate shall vary with respect to
18 the particular plan or coverage involved only
19 by—

20 “(i) whether such plan or coverage
21 covers an individual or family;

22 “(ii) rating area, as established in ac-
23 cordance with paragraph (2);

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

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

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

11 “(2) RATING AREA.—

12 “(A) IN GENERAL.—Each State shall es-
13 tablish 1 or more rating areas within that State
14 for purposes of applying the requirements of
15 this title.

16 “(B) SECRETARIAL REVIEW.—The Sec-
17 retary shall review the rating areas established
18 by each State under subparagraph (A) to en-
19 sure the adequacy of such areas for purposes of
20 carrying out the requirements of this title. If
21 the Secretary determines a State’s rating areas
22 are not adequate, or that a State does not es-
23 tablish such areas, the Secretary may establish
24 rating areas for that State.

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

3 “(3) Claims experience.

4 “(4) Receipt of health care.

5 “(5) Medical history.

6 “(6) Genetic information.

7 “(7) Evidence of insurability (including condi-
8 tions arising out of acts of domestic violence).

9 “(8) Disability.

10 “(9) Any other health status-related factor de-
11 termined appropriate by the Secretary.

12 “(b) IN PREMIUM CONTRIBUTIONS.—

13 “(1) IN GENERAL.—A group health plan, and a
14 health insurance issuer offering group or individual
15 health insurance coverage, may not require any indi-
16 vidual (as a condition of enrollment or continued en-
17 rollment under the plan) to pay a premium or con-
18 tribution which is greater than such premium or
19 contribution for a similarly situated individual en-
20 rolled in the plan on the basis of any health status-
21 related factor in relation to the individual or to an
22 individual enrolled under the plan as a dependent of
23 the individual.

24 “(2) CONSTRUCTION.—Nothing in paragraph
25 (1) shall be construed—

1 “(A) to restrict the amount that an em-
2 ployer or individual may be charged for cov-
3 erage under a group health plan except as pro-
4 vided in paragraph (3) or individual health cov-
5 erage, as the case may be; or

6 “(B) to prevent a group health plan, and
7 a health insurance issuer offering group health
8 insurance coverage, from establishing premium
9 discounts or rebates or modifying otherwise ap-
10 plicable copayments or deductibles in return for
11 adherence to programs of health promotion and
12 disease prevention.

13 “(3) NO GROUP-BASED DISCRIMINATION ON
14 BASIS OF GENETIC INFORMATION.—

15 “(A) IN GENERAL.—For purposes of this
16 section, a group health plan, and health insur-
17 ance issuer offering group health insurance cov-
18 erage in connection with a group health plan,
19 may not adjust premium or contribution
20 amounts for the group covered under such plan
21 on the basis of genetic information.

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

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

9 “(c) GENETIC TESTING.—

10 “(1) LIMITATION ON REQUESTING OR REQUIR-
11 ING GENETIC TESTING.—A group health plan, and a
12 health insurance issuer offering health insurance
13 coverage in connection with a group health plan,
14 shall not request or require an individual or a family
15 member of such individual to undergo a genetic test.

16 “(2) RULE OF CONSTRUCTION.—Paragraph (1)
17 shall not be construed to limit the authority of a
18 health care professional who is providing health care
19 services to an individual to request that such indi-
20 vidual undergo a genetic test.

21 “(3) RULE OF CONSTRUCTION REGARDING PAY-
22 MENT.—

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

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

10 “(B) LIMITATION.—For purposes of sub-
11 paragraph (A), a group health plan, or a health
12 insurance issuer offering health insurance cov-
13 erage in connection with a group health plan,
14 may request only the minimum amount of in-
15 formation necessary to accomplish the intended
16 purpose.

17 “(4) RESEARCH EXCEPTION.—Notwithstanding
18 paragraph (1), a group health plan, or a health in-
19 surance issuer offering health insurance coverage in
20 connection with a group health plan, may request,
21 but not require, that a participant or beneficiary un-
22 dergo a genetic test if each of the following condi-
23 tions is met:

24 “(A) The request is made pursuant to re-
25 search that complies with part 46 of title 45,

1 Code of Federal Regulations, or equivalent Fed-
2 eral regulations, and any applicable State or
3 local law or regulations for the protection of
4 human subjects in research.

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

9 “(i) compliance with the request is
10 voluntary; and

11 “(ii) noncompliance will have no effect
12 on enrollment status or premium or con-
13 tribution amounts.

14 “(C) No genetic information collected or
15 acquired under this paragraph shall be used for
16 underwriting purposes.

17 “(D) The plan or issuer notifies the Sec-
18 retary in writing that the plan or issuer is con-
19 ducting activities pursuant to the exception pro-
20 vided for under this paragraph, including a de-
21 scription of the activities conducted.

22 “(E) The plan or issuer complies with such
23 other conditions as the Secretary may by regu-
24 lation require for activities conducted under this
25 paragraph.

1 “(d) PROHIBITION ON COLLECTION OF GENETIC IN-
2 FORMATION.—

3 “(1) IN GENERAL.—A group health plan, and a
4 health insurance issuer offering health insurance
5 coverage in connection with a group health plan,
6 shall not request, require, or purchase genetic infor-
7 mation for underwriting purposes.

8 “(2) PROHIBITION ON COLLECTION OF GE-
9 NETIC INFORMATION PRIOR TO ENROLLMENT.—A
10 group health plan, and a health insurance issuer of-
11 fering health insurance coverage in connection with
12 a group health plan, shall not request, require, or
13 purchase genetic information with respect to any in-
14 dividual prior to such individual’s enrollment under
15 the plan or coverage in connection with such enroll-
16 ment.

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

1 ment, or purchase is not in violation of paragraph
2 (1).

3 “(e) GENETIC INFORMATION OF A FETUS OR EM-
4 BRYO.—Any reference in this part to genetic information
5 concerning an individual or family member of an indi-
6 vidual shall—

7 “(1) with respect to such an individual or fam-
8 ily member of an individual who is a pregnant
9 woman, include genetic information of any fetus car-
10 ried by such pregnant woman; and

11 “(2) with respect to an individual or family
12 member utilizing an assisted reproductive tech-
13 nology, include genetic information of any embryo le-
14 gally held by the individual or family member.

15 “(f) PROGRAMS OF HEALTH PROMOTION OR DIS-
16 EASE PREVENTION.—

17 “(1) GENERAL PROVISIONS.—

18 “(A) GENERAL RULE.—For purposes of
19 subsection (b)(2)(B), a program of health pro-
20 motion or disease prevention (referred to in this
21 subsection as a ‘wellness program’) shall be a
22 program offered by an employer that is de-
23 signed to promote health or prevent disease
24 that meets the applicable requirements of this
25 subsection.

1 “(B) NO CONDITIONS BASED ON HEALTH
2 STATUS FACTOR.—If none of the conditions for
3 obtaining a premium discount or rebate or
4 other reward for participation in a wellness pro-
5 gram is based on an individual satisfying a
6 standard that is related to a health status fac-
7 tor, such wellness program shall not violate this
8 section if participation in the program is made
9 available to all similarly situated individuals
10 and the requirements of paragraph (2) are com-
11 plied with.

12 “(C) CONDITIONS BASED ON HEALTH STA-
13 TUS FACTOR.—If any of the conditions for ob-
14 taining a premium discount or rebate or other
15 reward for participation in a wellness program
16 is based on an individual satisfying a standard
17 that is related to a health status factor, such
18 wellness program shall not violate this section if
19 the requirements of paragraph (3) are complied
20 with.

21 “(2) WELLNESS PROGRAMS NOT SUBJECT TO
22 REQUIREMENTS.—If none of the conditions for ob-
23 taining a premium discount or rebate or other re-
24 ward under a wellness program as described in para-
25 graph (1)(B) are based on an individual satisfying

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

10 “(A) A program that reimburses all or
11 part of the cost for memberships in a fitness
12 center.

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

16 “(C) A program that encourages preven-
17 tive care related to a health condition through
18 the waiver of the copayment or deductible re-
19 quirement under group health plan for the costs
20 of certain items or services related to a health
21 condition (such as prenatal care or well-baby
22 visits).

23 “(D) A program that reimburses individ-
24 uals for the costs of smoking cessation pro-

1 grams without regard to whether the individual
2 quits smoking.

3 “(E) A program that provides a reward to
4 individuals for attending a periodic health edu-
5 cation seminar.

6 “(3) WELLNESS PROGRAMS SUBJECT TO RE-
7 QUIREMENTS.—If any of the conditions for obtaining
8 a premium discount, rebate, or reward under a
9 wellness program as described in paragraph (1)(C)
10 is based on an individual satisfying a standard that
11 is related to a health status factor, the wellness pro-
12 gram shall not violate this section if the following re-
13 quirements are complied with:

14 “(A) The reward for the wellness program,
15 together with the reward for other wellness pro-
16 grams with respect to the plan that requires
17 satisfaction of a standard related to a health
18 status factor, shall not exceed 30 percent of the
19 cost of employee-only coverage under the plan.
20 If, in addition to employees or individuals, any
21 class of dependents (such as spouses or spouses
22 and dependent children) may participate fully
23 in the wellness program, such reward shall not
24 exceed 30 percent of the cost of the coverage in
25 which an employee or individual and any de-

1 dependents are enrolled. For purposes of this
2 paragraph, the cost of coverage shall be deter-
3 mined based on the total amount of employer
4 and employee contributions for the benefit
5 package under which the employee is (or the
6 employee and any dependents are) receiving
7 coverage. A reward may be in the form of a dis-
8 count or rebate of a premium or contribution,
9 a waiver of all or part of a cost-sharing mecha-
10 nism (such as deductibles, copayments, or coin-
11 surance), the absence of a surcharge, or the
12 value of a benefit that would otherwise not be
13 provided under the plan. The Secretaries of
14 Labor, Health and Human Services, and the
15 Treasury may increase the reward available
16 under this subparagraph to up to 50 percent of
17 the cost of coverage if the Secretaries determine
18 that such an increase is appropriate.

19 “(B) The wellness program shall be rea-
20 sonably designed to promote health or prevent
21 disease. A program complies with the preceding
22 sentence if the program has a reasonable
23 chance of improving the health of, or preventing
24 disease in, participating individuals and it is
25 not overly burdensome, is not a subterfuge for

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

4 “(C) The plan shall give individuals eligible
5 for the program the opportunity to qualify for
6 the reward under the program at least once
7 each year.

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

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

15 “(I) for a reasonable alternative
16 standard (or waiver of the otherwise
17 applicable standard) for obtaining the
18 reward for any individual for whom,
19 for that period, it is unreasonably dif-
20 ficult due to a medical condition to
21 satisfy the otherwise applicable stand-
22 ard; and

23 “(II) for a reasonable alternative
24 standard (or waiver of the otherwise
25 applicable standard) for obtaining the

1 reward for any individual for whom,
2 for that period, it is medically inadvis-
3 able to attempt to satisfy the other-
4 wise applicable standard.

5 “(ii) If reasonable under the cir-
6 cumstances, the plan or issuer may seek
7 verification, such as a statement from an
8 individual’s physician, that a health status
9 factor makes it unreasonably difficult or
10 medically inadvisable for the individual to
11 satisfy or attempt to satisfy the otherwise
12 applicable standard.

13 “(E) The plan or issuer involved shall dis-
14 close in all plan materials describing the terms
15 of the wellness program the availability of a
16 reasonable alternative standard (or the possi-
17 bility of waiver of the otherwise applicable
18 standard) required under subparagraph (D). If
19 plan materials disclose that such a program is
20 available, without describing its terms, the dis-
21 closure under this subparagraph shall not be re-
22 quired.

1 **“SEC. 199. PROHIBITION OF PREEXISTING CONDITION EX-**
2 **CLUSIONS OR OTHER DISCRIMINATION**
3 **BASED ON HEALTH STATUS.**

4 “(a) IN GENERAL.—A group health plan and a health
5 insurance issuer offering group or individual health insur-
6 ance coverage may not impose any preexisting condition
7 exclusion with respect to such plan or coverage.

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

9 “(1) PREEXISTING CONDITION EXCLUSION.—

10 “(A) IN GENERAL.—The term ‘preexisting
11 condition exclusion’ means, with respect to cov-
12 erage, a limitation or exclusion of benefits relat-
13 ing to a condition based on the fact that the
14 condition was present before the date of enroll-
15 ment for such coverage, whether or not any
16 medical advice, diagnosis, care, or treatment
17 was recommended or received before such date.

18 “(B) TREATMENT OF GENETIC INFORMA-
19 TION.—Genetic information shall not be treated
20 as a condition described in subsection (a)(1) in
21 the absence of a diagnosis of the condition re-
22 lated to such information.

23 “(2) ENROLLMENT DATE.—The term ‘enroll-
24 ment date’ means, with respect to an individual cov-
25 ered under a group health plan or health insurance
26 coverage, the date of enrollment of the individual in

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

3 “(3) LATE ENROLLEE.—The term ‘late en-
4 rollee’ means, with respect to coverage under a
5 group health plan, a participant or beneficiary who
6 enrolls under the plan other than during—

7 “(A) the first period in which the indi-
8 vidual is eligible to enroll under the plan; or

9 “(B) a special enrollment period under
10 subsection (f).

11 “(4) WAITING PERIOD.—The term ‘waiting pe-
12 riod’ means, with respect to a group health plan and
13 an individual who is a potential participant or bene-
14 ficiary in the plan, the period that must pass with
15 respect to the individual before the individual is eli-
16 gible to be covered for benefits under the terms of
17 the plan.

18 “(c) RULES RELATING TO CREDITING PREVIOUS
19 COVERAGE.—

20 “(1) CREDITABLE COVERAGE DEFINED.—For
21 purposes of this title, the term ‘creditable coverage’
22 means, with respect to an individual, coverage of the
23 individual under any of the following:

24 “(A) A group health plan.

25 “(B) Health insurance coverage.

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

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

6 “(E) Chapter 55 of title 10, United States
7 Code.

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

10 “(G) A State health benefits risk pool.

11 “(H) A health plan offered under chapter
12 89 of title 5, United States Code.

13 “(I) A public health plan (as defined in
14 regulations).

15 “(J) A health benefit plan under section
16 5(e) of the Peace Corps Act (22 U.S.C.
17 2504(e)).

18 Such term does not include coverage consisting sole-
19 ly of coverage of excepted benefits (as defined in sec-
20 tion 2791(c)).

21 “(2) NOT COUNTING PERIODS BEFORE SIGNIFI-
22 CANT BREAKS IN COVERAGE.—

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

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

5 “(B) WAITING PERIOD NOT TREATED AS A
6 BREAK IN COVERAGE.—For purposes of sub-
7 paragraph (A) and subsection (d)(4), any pe-
8 riod that an individual is in a waiting period for
9 any coverage under a group or individual health
10 plan (or for group health insurance coverage) or
11 is in an affiliation period (as defined in sub-
12 section (g)(2)) shall not be taken into account
13 in determining the continuous period under
14 subparagraph (A).

15 “(C) TAA-ELIGIBLE INDIVIDUALS.—In the
16 case of plan years beginning before January 1,
17 2014—

18 “(i) TAA PRE-CERTIFICATION PERIOD
19 RULE.—In the case of a TAA-eligible indi-
20 vidual, the period beginning on the date
21 the individual has a TAA-related loss of
22 coverage and ending on the date that is 7
23 days after the date of the issuance by the
24 Secretary (or by any person or entity des-
25 ignated by the Secretary) of a qualified

1 health insurance costs credit eligibility cer-
2 tificate for such individual for purposes of
3 section 7527 of the Internal Revenue Code
4 of 1986 shall not be taken into account in
5 determining the continuous period under
6 subparagraph (A).

7 “(ii) DEFINITIONS.—The terms ‘TAA-
8 eligible individual’ and ‘TAA-related loss of
9 coverage’ have the meanings given such
10 terms in section 2205(b)(4).

11 “(3) METHOD OF CREDITING COVERAGE.—

12 “(A) STANDARD METHOD.—Except as oth-
13 erwise provided under subparagraph (B), for
14 purposes of applying subsection (a)(3), a group
15 health plan, and a health insurance issuer offer-
16 ing group or individual health insurance cov-
17 erage, shall count a period of creditable cov-
18 erage without regard to the specific benefits
19 covered during the period.

20 “(B) ELECTION OF ALTERNATIVE METH-
21 OD.—A group health plan, or a health insur-
22 ance issuer offering group or individual health
23 insurance, may elect to apply subsection (a)(3)
24 based on coverage of benefits within each of
25 several classes or categories of benefits specified

1 in regulations rather than as provided under
2 subparagraph (A). Such election shall be made
3 on a uniform basis for all participants and
4 beneficiaries. Under such election a group or in-
5 dividual health plan or issuer shall count a pe-
6 riod of creditable coverage with respect to any
7 class or category of benefits if any level of bene-
8 fits is covered within such class or category.

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

14 “(i) prominently state in any disclo-
15 sure statements concerning the plan, and
16 state to each enrollee at the time of enroll-
17 ment under the plan, that the plan has
18 made such election; and

19 “(ii) include in such statements a de-
20 scription of the effect of this election.

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

1 “(i) shall prominently state in any dis-
2 closure statements concerning the cov-
3 erage, and to each employer at the time of
4 the offer or sale of the coverage, that the
5 issuer has made such election; and

6 “(ii) shall include in such statements
7 a description of the effect of such election.

8 “(4) ESTABLISHMENT OF PERIOD.—Periods of
9 creditable coverage with respect to an individual
10 shall be established through presentation of certifi-
11 cations described in subsection (e) or in such other
12 manner as may be specified in regulations.

13 “(d) EXCEPTIONS.—

14 “(1) EXCLUSION NOT APPLICABLE TO CERTAIN
15 NEWBORNS.—Subject to paragraph (4), a group
16 health plan, and a health insurance issuer offering
17 group or individual health insurance coverage, may
18 not impose any preexisting condition exclusion in the
19 case of an individual who, as of the last day of the
20 30-day period beginning with the date of birth, is
21 covered under creditable coverage.

22 “(2) EXCLUSION NOT APPLICABLE TO CERTAIN
23 ADOPTED CHILDREN.—Subject to paragraph (4), a
24 group health plan, and a health insurance issuer of-
25 fering group or individual health insurance coverage,

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

9 “(3) EXCLUSION NOT APPLICABLE TO PREG-
10 NANCY.—A group health plan, and health insurance
11 issuer offering group or individual health insurance
12 coverage, may not impose any preexisting condition
13 exclusion relating to pregnancy as a preexisting con-
14 dition.

15 “(4) LOSS IF BREAK IN COVERAGE.—Para-
16 graphs (1) and (2) shall no longer apply to an indi-
17 vidual after the end of the first 63-day period during
18 all of which the individual was not covered under
19 any creditable coverage.

20 “(e) CERTIFICATIONS AND DISCLOSURE OF COV-
21 ERAGE.—

22 “(1) REQUIREMENT FOR CERTIFICATION OF
23 PERIOD OF CREDITABLE COVERAGE.—

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

1 individual health insurance coverage, shall pro-
2 vide the certification described in subparagraph
3 (B)—

4 “(i) at the time an individual ceases
5 to be covered under the plan or otherwise
6 becomes covered under a COBRA continu-
7 ation provision;

8 “(ii) in the case of an individual be-
9 coming covered under such a provision, at
10 the time the individual ceases to be covered
11 under such provision; and

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

17 The certification under clause (i) may be pro-
18 vided, to the extent practicable, at a time con-
19 sistent with notices required under any applica-
20 ble COBRA continuation provision.

21 “(B) CERTIFICATION.—The certification
22 described in this subparagraph is a written cer-
23 tification of—

24 “(i) the period of creditable coverage
25 of the individual under such plan and the

1 coverage (if any) under such COBRA con-
2 tinuation provision; and

3 “(ii) the waiting period (if any) (and
4 affiliation period, if applicable) imposed
5 with respect to the individual for any cov-
6 erage under such plan.

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

15 “(2) DISCLOSURE OF INFORMATION ON PRE-
16 VIOUS BENEFITS.—In the case of an election de-
17 scribed in subsection (c)(3)(B) by a group health
18 plan or health insurance issuer, if the plan or issuer
19 enrolls an individual for coverage under the plan and
20 the individual provides a certification of coverage of
21 the individual under paragraph (1)—

22 “(A) upon request of such plan or issuer,
23 the entity which issued the certification pro-
24 vided by the individual shall promptly disclose
25 to such requesting plan or issuer information

1 on coverage of classes and categories of health
2 benefits available under such entity’s plan or
3 coverage; and

4 “(B) such entity may charge the request-
5 ing plan or issuer for the reasonable cost of dis-
6 closing such information.

7 “(3) REGULATIONS.—The Secretary shall es-
8 tablish rules to prevent an entity’s failure to provide
9 information under paragraph (1) or (2) with respect
10 to previous coverage of an individual from adversely
11 affecting any subsequent coverage of the individual
12 under another group health plan or health insurance
13 coverage.

14 “(f) SPECIAL ENROLLMENT PERIODS.—

15 “(1) INDIVIDUALS LOSING OTHER COVERAGE.—
16 A group health plan, and a health insurance issuer
17 offering group health insurance coverage in connec-
18 tion with a group health plan, shall permit an em-
19 ployee who is eligible, but not enrolled, for coverage
20 under the terms of the plan (or a dependent of such
21 an employee if the dependent is eligible, but not en-
22 rolled, for coverage under such terms) to enroll for
23 coverage under the terms of the plan if each of the
24 following conditions is met:

1 “(A) The employee or dependent was cov-
2 ered under a group health plan or had health
3 insurance coverage at the time coverage was
4 previously offered to the employee or dependent.

5 “(B) The employee stated in writing at
6 such time that coverage under a group health
7 plan or health insurance coverage was the rea-
8 son for declining enrollment, but only if the
9 plan sponsor or issuer (if applicable) required
10 such a statement at such time and provided the
11 employee with notice of such requirement (and
12 the consequences of such requirement) at such
13 time.

14 “(C) The employee’s or dependent’s cov-
15 erage described in subparagraph (A)—

16 “(i) was under a COBRA continu-
17 ation provision and the coverage under
18 such provision was exhausted; or

19 “(ii) was not under such a provision
20 and either the coverage was terminated as
21 a result of loss of eligibility for the cov-
22 erage (including as a result of legal separa-
23 tion, divorce, death, termination of employ-
24 ment, or reduction in the number of hours

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

3 “(D) Under the terms of the plan, the em-
4 ployee requests such enrollment not later than
5 30 days after the date of exhaustion of coverage
6 described in subparagraph (C)(i) or termination
7 of coverage or employer contribution described
8 in subparagraph (C)(ii).

9 “(2) FOR DEPENDENT BENEFICIARIES.—

10 “(A) IN GENERAL.—If—

11 “(i) a group health plan makes cov-
12 erage available with respect to a dependent
13 of an individual;

14 “(ii) the individual is a participant
15 under the plan (or has met any waiting pe-
16 riod applicable to becoming a participant
17 under the plan and is eligible to be enrolled
18 under the plan but for a failure to enroll
19 during a previous enrollment period); and

20 “(iii) a person becomes such a de-
21 pendent of the individual through mar-
22 riage, birth, or adoption or placement for
23 adoption,

24 the group health plan shall provide for a de-
25 pendent special enrollment period described in

1 subparagraph (B) during which the person (or,
2 if not otherwise enrolled, the individual) may be
3 enrolled under the plan as a dependent of the
4 individual, and in the case of the birth or adop-
5 tion of a child, the spouse of the individual may
6 be enrolled as a dependent of the individual if
7 such spouse is otherwise eligible for coverage.

8 “(B) DEPENDENT SPECIAL ENROLLMENT
9 PERIOD.—A dependent special enrollment pe-
10 riod under this subparagraph shall be a period
11 of not less than 30 days and shall begin on the
12 later of—

13 “(i) the date dependent coverage is
14 made available; or

15 “(ii) the date of the marriage, birth,
16 or adoption or placement for adoption (as
17 the case may be) described in subpara-
18 graph (A)(iii).

19 “(C) NO WAITING PERIOD.—If an indi-
20 vidual seeks to enroll a dependent during the
21 first 30 days of such a dependent special enroll-
22 ment period, the coverage of the dependent
23 shall become effective—

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

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

3 “(ii) in the case of a dependent’s
4 birth, as of the date of such birth; or

5 “(iii) in the case of a dependent’s
6 adoption or placement for adoption, the
7 date of such adoption or placement for
8 adoption.

9 “(3) SPECIAL RULES FOR APPLICATION IN CASE
10 OF MEDICAID AND CHIP.—

11 “(A) IN GENERAL.—A group health plan,
12 and a health insurance issuer offering group
13 health insurance coverage in connection with a
14 group health plan, shall permit an employee
15 who is eligible, but not enrolled, for coverage
16 under the terms of the plan (or a dependent of
17 such an employee if the dependent is eligible,
18 but not enrolled, for coverage under such
19 terms) to enroll for coverage under the terms of
20 the plan if either of the following conditions is
21 met:

22 “(i) TERMINATION OF MEDICAID OR
23 CHIP COVERAGE.—The employee or de-
24 pendent is covered under a Medicaid plan
25 under title XIX of the Social Security Act

1 or under a State child health plan under
2 title XXI of such Act and coverage of the
3 employee or dependent under such a plan
4 is terminated as a result of loss of eligi-
5 bility for such coverage and the employee
6 requests coverage under the group health
7 plan (or health insurance coverage) not
8 later than 60 days after the date of termi-
9 nation of such coverage.

10 “(ii) ELIGIBILITY FOR EMPLOYMENT
11 ASSISTANCE UNDER MEDICAID OR CHIP.—
12 The employee or dependent becomes eligi-
13 ble for assistance, with respect to coverage
14 under the group health plan or health in-
15 surance coverage, under such Medicaid
16 plan or State child health plan (including
17 under any waiver or demonstration project
18 conducted under or in relation to such a
19 plan), if the employee requests coverage
20 under the group health plan or health in-
21 surance coverage not later than 60 days
22 after the date the employee or dependent is
23 determined to be eligible for such assist-
24 ance.

1 “(B) COORDINATION WITH MEDICAID AND
2 CHIP.—

3 “(i) OUTREACH TO EMPLOYEES RE-
4 GARDING AVAILABILITY OF MEDICAID AND
5 CHIP COVERAGE.—

6 “(I) IN GENERAL.—Each em-
7 ployer that maintains a group health
8 plan in a State that provides medical
9 assistance under a State Medicaid
10 plan under title XIX of the Social Se-
11 curity Act, or child health assistance
12 under a State child health plan under
13 title XXI of such Act, in the form of
14 premium assistance for the purchase
15 of coverage under a group health
16 plan, shall provide to each employee a
17 written notice informing the employee
18 of potential opportunities then cur-
19 rently available in the State in which
20 the employee resides for premium as-
21 sistance under such plans for health
22 coverage of the employee or the em-
23 ployee’s dependents. For purposes of
24 compliance with this subclause, the
25 employer may use any State-specific

1 model notice developed in accordance
2 with section 701(f)(3)(B)(i)(II) of the
3 Employee Retirement Income Security
4 Act of 1974 (29 U.S.C.
5 1181(f)(3)(B)(i)(II)).

6 “(II) OPTION TO PROVIDE CON-
7 CURRENT WITH PROVISION OF PLAN
8 MATERIALS TO EMPLOYEE.—An em-
9 ployer may provide the model notice
10 applicable to the State in which an
11 employee resides concurrent with the
12 furnishing of materials notifying the
13 employee of health plan eligibility,
14 concurrent with materials provided to
15 the employee in connection with an
16 open season or election process con-
17 ducted under the plan, or concurrent
18 with the furnishing of the summary
19 plan description as provided in section
20 104(b) of the Employee Retirement
21 Income Security Act of 1974.

22 “(ii) DISCLOSURE ABOUT GROUP
23 HEALTH PLAN BENEFITS TO STATES FOR
24 MEDICAID AND CHIP ELIGIBLE INDIVID-
25 UALS.—In the case of an enrollee in a

1 group health plan who is covered under a
2 Medicaid plan of a State under title XIX
3 of the Social Security Act or under a State
4 child health plan under title XXI of such
5 Act, the plan administrator of the group
6 health plan shall disclose to the State,
7 upon request, information about the bene-
8 fits available under the group health plan
9 in sufficient specificity, as determined
10 under regulations of the Secretary of
11 Health and Human Services in consulta-
12 tion with the Secretary that require use of
13 the model coverage coordination disclosure
14 form developed under section 311(b)(1)(C)
15 of the Children’s Health Insurance Reau-
16 thorization Act of 2009, so as to permit
17 the State to make a determination (under
18 paragraph (2)(B), (3), or (10) of section
19 2105(c) of the Social Security Act or oth-
20 erwise) concerning the cost-effectiveness of
21 the State providing medical or child health
22 assistance through premium assistance for
23 the purchase of coverage under such group
24 health plan and in order for the State to
25 provide supplemental benefits required

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

3 “(g) USE OF AFFILIATION PERIOD BY HMOs AS AL-
4 TERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

5 “(1) IN GENERAL.—A health maintenance orga-
6 nization which offers health insurance coverage in
7 connection with a group health plan and which does
8 not impose any preexisting condition exclusion al-
9 lowed under subsection (a) with respect to any par-
10 ticular coverage option may impose an affiliation pe-
11 riod for such coverage option, but only if—

12 “(A) such period is applied uniformly with-
13 out regard to any health status-related factors;
14 and

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

17 “(2) AFFILIATION PERIOD.—

18 “(A) DEFINED.—For purposes of this
19 title, the term ‘affiliation period’ means a pe-
20 riod which, under the terms of the health insur-
21 ance coverage offered by the health mainte-
22 nance organization, must expire before the
23 health insurance coverage becomes effective.
24 The organization is not required to provide
25 health care services or benefits during such pe-

1 riod and no premium shall be charged to the
2 participant or beneficiary for any coverage dur-
3 ing the period.

4 “(B) BEGINNING.—Such period shall begin
5 on the enrollment date.

6 “(C) RUNS CONCURRENTLY WITH WAITING
7 PERIODS.—An affiliation period under a plan
8 shall run concurrently with any waiting period
9 under the plan.

10 “(3) ALTERNATIVE METHODS.—A health main-
11 tenance organization described in paragraph (1) may
12 use alternative methods, from those described in
13 such paragraph, to address adverse selection as ap-
14 proved by the State insurance commissioner or offi-
15 cial or officials designated by the State to enforce
16 the requirements of this part for the State involved
17 with respect to such issuer.

18 **“SEC. 199A. EXTENSION OF DEPENDENT COVERAGE.**

19 “(a) IN GENERAL.—A group health plan and a health
20 insurance issuer offering group or individual health insur-
21 ance coverage that provides dependent coverage of chil-
22 dren shall continue to make such coverage available for
23 an adult child (who is not married) until the child turns
24 26 years of age. Nothing in this section shall require a
25 health plan or a health insurance issuer described in the

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

3 “(b) REGULATIONS.—The Secretary shall promul-
4 gate regulations to define the dependents to which cov-
5 erage shall be made available under subsection (a).

6 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
7 tion shall be construed to modify the definition of ‘depend-
8 ent’ as used in the Internal Revenue Code of 1986 with
9 respect to the tax treatment of the cost of coverage.

10 **“SEC. 199B. ANNUAL LIMITATION ON COST-SHARING.**

11 “(a) IN GENERAL.—

12 “(1) 2014.—The cost-sharing incurred under a
13 group health plan or group or individual health in-
14 surance coverage with respect to self-only coverage
15 or coverage other than self-only coverage for a plan
16 year beginning in 2014 shall not exceed the dollar
17 amounts in effect under section 223(c)(2)(A)(ii) of
18 the Internal Revenue Code of 1986 for self-only and
19 family coverage, respectively, for taxable years begin-
20 ning in 2014.

21 “(2) 2015 AND LATER.—In the case of any
22 plan year beginning in a calendar year after 2014,
23 the limitation under this paragraph shall—

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

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

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

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

11 “(b) COST-SHARING.—In this section:

12 “(1) IN GENERAL.—The term ‘cost-sharing’ in-
13 cludes—

14 “(A) deductibles, coinsurance, copayments,
15 or similar charges; and

16 “(B) any other expenditure required of an
17 insured individual which is a qualified medical
18 expense (within the meaning of section
19 223(d)(2) of the Internal Revenue Code of
20 1986) with respect to essential health benefits
21 covered under the plan.

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

1 “(c) PREMIUM ADJUSTMENT PERCENTAGE.—For
2 purposes of subsection (a)(2)(A), the premium adjustment
3 percentage for any calendar year is the percentage (if any)
4 by which the average per capita premium for health insur-
5 ance coverage in the United States for the preceding cal-
6 endar year (as estimated by the Secretary no later than
7 October 1 of such preceding calendar year) exceeds such
8 average per capita premium for 2013 (as determined by
9 the Secretary).

10 **“SEC. 199C. ENFORCEMENT OF CERTAIN HEALTH INSUR-**
11 **ANCE REQUIREMENTS.**

12 “(a) STATE ENFORCEMENT.—

13 “(1) STATE AUTHORITY.—Each State may re-
14 quire that health insurance issuers that issue, sell,
15 renew, or offer health insurance coverage in the
16 State in the individual or group market meet the re-
17 quirements of this part with respect to such issuers.

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

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

4 “(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

5 “(1) LIMITATION.—The provisions of this sub-
6 section shall apply to enforcement of a provision (or
7 provisions) described in subsection (a)(2) only—

8 “(A) as provided under such subsection;
9 and

10 “(B) with respect to individual health in-
11 surance coverage or group health plans that are
12 non-Federal governmental plans.

13 “(2) IMPOSITION OF PENALTIES.—In the cases
14 described in paragraph (1)—

15 “(A) IN GENERAL.—Subject to the suc-
16 ceeding provisions of this subsection, any non-
17 Federal governmental plan that is a group
18 health plan and any health insurance issuer
19 that fails to meet a provision of this part appli-
20 cable to such plan or issuer is subject to a civil
21 money penalty under this subsection.

22 “(B) LIABILITY FOR PENALTY.—In the
23 case of a failure by—

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

1 “(ii) a group health plan that is a
2 non-Federal governmental plan which is—

3 “(I) sponsored by 2 or more em-
4 ployers, the plan is liable for such
5 penalty; or

6 “(II) not so sponsored, the em-
7 ployer is liable for such penalty.

8 “(C) AMOUNT OF PENALTY.—

9 “(i) IN GENERAL.—The maximum
10 amount of penalty imposed under this
11 paragraph is \$100 for each day for each
12 individual with respect to which such a
13 failure occurs.

14 “(ii) CONSIDERATIONS IN IMPOSI-
15 TION.—In determining the amount of any
16 penalty to be assessed under this para-
17 graph, the Secretary shall take into ac-
18 count the previous record of compliance of
19 the entity being assessed with the applica-
20 ble provisions of this part and the gravity
21 of the violation.

22 “(iii) LIMITATIONS.—

23 “(I) PENALTY NOT TO APPLY
24 WHERE FAILURE NOT DISCOVERED
25 EXERCISING REASONABLE DILI-

1 GENCE.—No civil money penalty shall
2 be imposed under this paragraph on
3 any failure during any period for
4 which it is established to the satisfac-
5 tion of the Secretary that none of the
6 entities against whom the penalty
7 would be imposed knew, or exercising
8 reasonable diligence would have
9 known, that such failure existed.

10 “(II) PENALTY NOT TO APPLY
11 TO FAILURES CORRECTED WITHIN 30
12 DAYS.—No civil money penalty shall
13 be imposed under this paragraph on
14 any failure if such failure was due to
15 reasonable cause and not to willful ne-
16 glect, and such failure is corrected
17 during the 30-day period beginning on
18 the first day any of the entities
19 against whom the penalty would be
20 imposed knew, or exercising reason-
21 able diligence would have known, that
22 such failure existed.

23 “(D) ADMINISTRATIVE REVIEW.—

24 “(i) OPPORTUNITY FOR HEARING.—
25 The entity assessed shall be afforded an

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

10 “(ii) HEARING PROCEDURE.—If a
11 hearing is requested, the initial agency de-
12 cision shall be made by an administrative
13 law judge, and such decision shall become
14 the final order unless the Secretary modi-
15 fies or vacates the decision. Notice of in-
16 tent to modify or vacate the decision of the
17 administrative law judge shall be issued to
18 the parties within 30 days after the date of
19 the decision of the judge. A final order
20 which takes effect under this paragraph
21 shall be subject to review only as provided
22 under subparagraph (E).

23 “(E) JUDICIAL REVIEW.—

24 “(i) FILING OF ACTION FOR RE-
25 VIEW.—Any entity against whom an order

1 imposing a civil money penalty has been
2 entered after an agency hearing under this
3 paragraph may obtain review by the
4 United States district court for any district
5 in which such entity is located or the
6 United States District Court for the Dis-
7 trict of Columbia by filing a notice of ap-
8 peal in such court within 30 days from the
9 date of such order, and simultaneously
10 sending a copy of such notice by registered
11 mail to the Secretary.

12 “(ii) CERTIFICATION OF ADMINISTRA-
13 TIVE RECORD.—The Secretary shall
14 promptly certify and file in such court the
15 record upon which the penalty was im-
16 posed.

17 “(iii) STANDARD FOR REVIEW.—The
18 findings of the Secretary shall be set aside
19 only if found to be unsupported by sub-
20 stantial evidence as provided by section
21 706(2)(E) of title 5, United States Code.

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

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

3 “(F) FAILURE TO PAY ASSESSMENT; MAIN-
4 TENANCE OF ACTION.—

5 “(i) FAILURE TO PAY ASSESSMENT.—

6 If any entity fails to pay an assessment
7 after it has become a final and
8 unappealable order, or after the court has
9 entered final judgment in favor of the Sec-
10 retary, the Secretary shall refer the matter
11 to the Attorney General who shall recover
12 the amount assessed by action in the ap-
13 propriate United States district court.

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

18 “(G) PAYMENT OF PENALTIES.—Except as
19 otherwise provided, penalties collected under
20 this paragraph shall be paid to the Secretary
21 (or other officer) imposing the penalty and shall
22 be available without appropriation and until ex-
23 pended for the purpose of enforcing the provi-
24 sions with respect to which the penalty was im-
25 posed.

1 “(3) ENFORCEMENT AUTHORITY RELATING TO
2 GENETIC DISCRIMINATION.—

3 “(A) GENERAL RULE.—In the cases de-
4 scribed in paragraph (1), notwithstanding the
5 provisions of paragraph (2)(C), the succeeding
6 subparagraphs of this paragraph shall apply
7 with respect to an action under this subsection
8 by the Secretary with respect to any failure of
9 a health insurance issuer in connection with a
10 group health plan, to meet the requirements of
11 subsection (a)(1)(F), (b)(3), (c), or (d) of sec-
12 tion 196 or section 197 or 196(b)(1) with re-
13 spect to genetic information in connection with
14 the plan.

15 “(B) AMOUNT.—

16 “(i) IN GENERAL.—The amount of
17 the penalty imposed under this paragraph
18 shall be \$100 for each day in the non-
19 compliance period with respect to each par-
20 ticipant or beneficiary to whom such fail-
21 ure relates.

22 “(ii) NONCOMPLIANCE PERIOD.—For
23 purposes of this paragraph, the term ‘non-
24 compliance period’ means, with respect to
25 any failure, the period—

1 “(I) beginning on the date such
2 failure first occurs; and

3 “(II) ending on the date the fail-
4 ure is corrected.

5 “(C) MINIMUM PENALTIES WHERE FAIL-
6 URE DISCOVERED.—Notwithstanding clauses (i)
7 and (ii) of subparagraph (D):

8 “(i) IN GENERAL.—In the case of 1 or
9 more failures with respect to an indi-
10 vidual—

11 “(I) which are not corrected be-
12 fore the date on which the plan re-
13 ceives a notice from the Secretary of
14 such violation; and

15 “(II) which occurred or continued
16 during the period involved;
17 the amount of penalty imposed by subpara-
18 graph (A) by reason of such failures with
19 respect to such individual shall not be less
20 than \$2,500.

21 “(ii) HIGHER MINIMUM PENALTY
22 WHERE VIOLATIONS ARE MORE THAN DE
23 MINIMIS.—To the extent violations for
24 which any person is liable under this para-
25 graph for any year are more than de mini-

1 mis, clause (i) shall be applied by sub-
2 stituting ‘\$15,000’ for ‘\$2,500’ with re-
3 spect to such person.

4 “(D) LIMITATIONS.—

5 “(i) PENALTY NOT TO APPLY WHERE
6 FAILURE NOT DISCOVERED EXERCISING
7 REASONABLE DILIGENCE.—No penalty
8 shall be imposed by subparagraph (A) on
9 any failure during any period for which it
10 is established to the satisfaction of the
11 Secretary that the person otherwise liable
12 for such penalty did not know, and exer-
13 cising reasonable diligence would not have
14 known, that such failure existed.

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

19 “(I) such failure was due to rea-
20 sonable cause and not to willful ne-
21 glect; and

22 “(II) such failure is corrected
23 during the 30-day period beginning on
24 the first date the person otherwise lia-
25 ble for such penalty knew, or exer-

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

3 “(iii) OVERALL LIMITATION FOR UN-
4 INTENTIONAL FAILURES.—In the case of
5 failures which are due to reasonable cause
6 and not to willful neglect, the penalty im-
7 posed by subparagraph (A) for failures
8 shall not exceed the amount equal to the
9 lesser of—

10 “(I) 10 percent of the aggregate
11 amount paid or incurred by the em-
12 ployer (or predecessor employer) dur-
13 ing the preceding taxable year for
14 group health plans; or

15 “(II) \$500,000.

16 “(E) WAIVER BY SECRETARY.—In the case
17 of a failure which is due to reasonable cause
18 and not to willful neglect, the Secretary may
19 waive part or all of the penalty imposed by sub-
20 paragraph (A) to the extent that the payment
21 of such penalty would be excessive relative to
22 the failure involved.

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

24 “(1) GOVERNMENTAL PLAN.—The term ‘gov-
25 ernmental plan’ has the meaning given such term

1 under section 3(32) of the Employee Retirement In-
 2 come Security Act of 1974 and any Federal govern-
 3 mental plan.

4 “(2) FEDERAL GOVERNMENTAL PLAN.—The
 5 term “Federal governmental plan” means a govern-
 6 mental plan established or maintained for its em-
 7 ployees by the Government of the United States or
 8 by any agency or instrumentality of such Govern-
 9 ment.

10 “(3) NON-FEDERAL GOVERNMENTAL PLAN.—
 11 The term ‘non-Federal governmental plan’ means a
 12 governmental plan that is not a Federal govern-
 13 mental plan.”.

14 (b) CONFORMING AMENDMENT.—The table of con-
 15 tents under section 1(b) of the Health Insurance Port-
 16 ability and Accountability Act of 1996 (Public Law 104–
 17 191) is amended by inserting after the item relating to
 18 section 195 the following:

“Sec. 196. Guaranteed availability of coverage.

“Sec. 197. Fair health insurance premiums.

“Sec. 198. Prohibiting discrimination against individual participants and bene-
 ficiaries based on health status.

“Sec. 199. Prohibition of preexisting condition exclusions or other discrimina-
 tion based on health status.

“Sec. 199A. Extension of dependent coverage.

“Sec. 199B. Annual limitation on cost-sharing.

“Sec. 199C. Enforcement of certain health insurance requirements.”.

19 (c) ERISA AND IRC ENFORCEMENT.—

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

1 1974 (29 U.S.C. 1185 et seq.) is amended by adding
2 at the end the following new section:

3 **“SEC. 716. OTHER MARKET REFORMS.**

4 “Sections 196 and 197 of the Health Insurance Port-
5 ability and Accountability Act of 1996 shall apply to
6 health insurance issuers providing health insurance cov-
7 erage in connection with group health plans, and sections
8 198 through 199B of such Act shall apply to group health
9 plans and health insurance issuers providing health insur-
10 ance coverage in connection with group health plans, as
11 if included in this subpart, and to the extent that any pro-
12 vision of this part conflicts with a provision of such section
13 196 or 197 with respect to health insurance issuers pro-
14 viding health insurance coverage in connection with group
15 health plans or of such section 198, 199, 199A, or 199B
16 with respect to group health plans or health insurance
17 issuers providing health insurance coverage in connection
18 with group health plans, the provisions of such sections
19 196 through 199B shall apply.”.

20 (2) IRC.—Subchapter B of chapter 100 of sub-
21 title K of title 26 of the Internal Revenue Code of
22 1986 is amended by adding at the end the following
23 new section:

1 **“SEC. 9816. OTHER MARKET REFORMS.**

2 “Sections 196 and 197 of the Health Insurance Port-
3 ability and Accountability Act of 1996 shall apply to
4 health insurance issuers providing health insurance cov-
5 erage in connection with group health plans, and sections
6 198 through 199B of such Act shall apply to group health
7 plans and health insurance issuers providing health insur-
8 ance coverage in connection with group health plans, as
9 if included in this subchapter, and to the extent that any
10 provision of this chapter conflicts with a provision of such
11 section 196 or 197 with respect to health insurance issuers
12 providing health insurance coverage in connection with
13 group health plans or of such section 198, 199, 199A, or
14 199B with respect to group health plans or health insur-
15 ance issuers providing health insurance coverage in con-
16 nection with group health plans, the provisions of such
17 sections 196 through 199B shall apply.”.

18 (d) **EFFECTIVE DATE.**—The amendments made by
19 this section shall take effect on the date on which the Su-
20 preme Court of the United States issues a decision strik-
21 ing down the Patient Protection and Affordable Care Act
22 (Public Law 111–148) in its entirety.

1 **Subtitle B—Expanding Coverage**
 2 **Options**

3 **SEC. 211. RULES GOVERNING ASSOCIATION HEALTH**
 4 **PLANS.**

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

8 **“PART 8—RULES GOVERNING ASSOCIATION**
 9 **HEALTH PLANS**

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

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

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

17 “(1) is organized and maintained in good faith,
 18 with a constitution and bylaws specifically stating its
 19 purpose and providing for periodic meetings on at
 20 least an annual basis, as a bona fide trade associa-
 21 tion, a bona fide industry association (including a
 22 rural electric cooperative association or a rural tele-
 23 phone cooperative association), a bona fide profes-
 24 sional association, or a bona fide chamber of com-
 25 merce (or similar bona fide business association, in-

1 including a corporation or similar organization that
2 operates on a cooperative basis (within the meaning
3 of section 1381 of the Internal Revenue Code of
4 1986)), for substantial purposes other than that of
5 obtaining or providing medical care;

6 “(2) is established as a permanent entity which
7 receives the active support of its members and re-
8 quires for membership payment on a periodic basis
9 of dues or payments necessary to maintain eligibility
10 for membership in the sponsor; and

11 “(3) does not condition membership, such dues
12 or payments, or coverage under the plan on the
13 basis of health status-related factors with respect to
14 the employees of its members (or affiliated mem-
15 bers), or the dependents of such employees, and does
16 not condition such dues or payments on the basis of
17 group health plan participation.

18 Any sponsor consisting of an association of entities which
19 meet the requirements of paragraphs (1), (2), and (3)
20 shall be deemed to be a sponsor described in this sub-
21 section.

22 **“SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH**
23 **PLANS.**

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

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

4 “(b) STANDARDS.—Under the procedure prescribed
5 pursuant to subsection (a), in the case of an association
6 health plan that provides at least one benefit option which
7 does not consist of health insurance coverage, the applica-
8 ble authority shall certify such plan as meeting the re-
9 quirements of this part only if the applicable authority is
10 satisfied that the applicable requirements of this part are
11 met (or, upon the date on which the plan is to commence
12 operations, will be met) with respect to the plan.

13 “(c) REQUIREMENTS APPLICABLE TO CERTIFIED
14 PLANS.—An association health plan with respect to which
15 certification under this part is in effect shall meet the ap-
16 plicable requirements of this part, effective on the date
17 of certification (or, if later, on the date on which the plan
18 is to commence operations).

19 “(d) REQUIREMENTS FOR CONTINUED CERTIFI-
20 CATION.—The applicable authority may provide by regula-
21 tion for continued certification of association health plans
22 under this part.

23 “(e) CLASS CERTIFICATION FOR FULLY INSURED
24 PLANS.—The applicable authority shall establish a class
25 certification procedure for association health plans under

1 which all benefits consist of health insurance coverage.
2 Under such procedure, the applicable authority shall pro-
3 vide for the granting of certification under this part to
4 the plans in each class of such association health plans
5 upon appropriate filing under such procedure in connec-
6 tion with plans in such class and payment of the pre-
7 scribed fee under section 807(a).

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

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

15 “(2) A plan under which the sponsor does not
16 restrict membership to one or more trades and busi-
17 nesses or industries and whose eligible participating
18 employers represent a broad cross-section of trades
19 and businesses or industries.

20 “(3) A plan whose eligible participating employ-
21 ers represent one or more trades or businesses, or
22 one or more industries, consisting of any of the fol-
23 lowing: agriculture; equipment and automobile deal-
24 erships; barbering and cosmetology; certified public
25 accounting practices; child care; construction; dance,

1 theatrical and orchestra productions; disinfecting
2 and pest control; financial services; fishing; food
3 service establishments; hospitals; labor organiza-
4 tions; logging; manufacturing (metals); mining; med-
5 ical and dental practices; medical laboratories; pro-
6 fessional consulting services; sanitary services; trans-
7 portation (local and freight); warehousing; whole-
8 saling/distributing; or any other trade or business or
9 industry which has been indicated as having average
10 or above-average risk or health claims experience by
11 reason of State rate filings, denials of coverage, pro-
12 posed premium rate levels, or other means dem-
13 onstrated by such plan in accordance with regula-
14 tions.

15 **“SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND**
16 **BOARDS OF TRUSTEES.**

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

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

1 “(1) FISCAL CONTROL.—The plan is operated,
2 pursuant to a trust agreement, by a board of trust-
3 ees which has complete fiscal control over the plan
4 and which is responsible for all operations of the
5 plan.

6 “(2) RULES OF OPERATION AND FINANCIAL
7 CONTROLS.—The board of trustees has in effect
8 rules of operation and financial controls, based on a
9 3-year plan of operation, adequate to carry out the
10 terms of the plan and to meet all requirements of
11 this title applicable to the plan.

12 “(3) RULES GOVERNING RELATIONSHIP TO
13 PARTICIPATING EMPLOYERS AND TO CONTRAC-
14 TORS.—

15 “(A) BOARD MEMBERSHIP.—

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

24 “(ii) LIMITATION.—

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

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

18 “(III) TREATMENT OF PRO-
19 VIDERS OF MEDICAL CARE.—In the
20 case of a sponsor which is an associa-
21 tion whose membership consists pri-
22 marily of providers of medical care,
23 subclause (I) shall not apply in the
24 case of any service provider described

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

3 “(iii) CERTAIN PLANS EXCLUDED.—

4 Clause (i) shall not apply to an association
5 health plan which is in existence on the
6 date of the enactment of this section.

7 “(B) SOLE AUTHORITY.—The board has
8 sole authority under the plan to approve appli-
9 cations for participation in the plan and to con-
10 tract with a service provider to administer the
11 day-to-day affairs of the plan.

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

16 “(1) the requirements of subsection (a) and sec-
17 tion 801(a) shall be deemed met if such require-
18 ments would otherwise be met if the franchiser were
19 deemed to be the sponsor referred to in section
20 801(b), such network were deemed to be an associa-
21 tion described in section 801(b), and each franchisee
22 were deemed to be a member (of the association and
23 the sponsor) referred to in section 801(b); and

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

1 The Secretary may by regulation define for purposes of
2 this subsection the terms ‘franchiser’, ‘franchise network’,
3 and ‘franchisee’.

4 **“SEC. 804. PARTICIPATION AND COVERAGE REQUIRE-**
5 **MENTS.**

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

10 “(1) each participating employer must be—

11 “(A) a member of the sponsor;

12 “(B) the sponsor; or

13 “(C) an affiliated member of the sponsor

14 with respect to which the requirements of sub-
15 section (b) are met,

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

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

4 “(A) active or retired owners (including
5 self-employed individuals), officers, directors, or
6 employees of, or partners in, participating em-
7 ployers; or

8 “(B) the beneficiaries of individuals de-
9 scribed in subparagraph (A).

10 “(b) COVERAGE OF PREVIOUSLY UNINSURED EM-
11 PLOYEES.—In the case of an association health plan in
12 existence on the date of the enactment of this section, an
13 affiliated member of the sponsor of the plan may be of-
14 fered coverage under the plan as a participating employer
15 only if—

16 “(1) the affiliated member was an affiliated
17 member on the date of certification under this part;
18 or

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

1 “(c) INDIVIDUAL MARKET UNAFFECTED.—The re-
2 quirements of this subsection are met with respect to an
3 association health plan if, under the terms of the plan,
4 no participating employer may provide health insurance
5 coverage in the individual market for any employee not
6 covered under the plan which is similar to the coverage
7 contemporaneously provided to employees of the employer
8 under the plan, if such exclusion of the employee from cov-
9 erage under the plan is based on a health status-related
10 factor with respect to the employee and such employee
11 would, but for such exclusion on such basis, be eligible
12 for coverage under the plan.

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

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

1 “(2) upon request, any employer eligible to partici-
2 participate is furnished information regarding all cov-
3 erage options available under the plan; and

4 “(3) the applicable requirements of sections
5 701, 702, and 703 are met with respect to the plan.

6 **“SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN**
7 **DOCUMENTS, CONTRIBUTION RATES, AND**
8 **BENEFIT OPTIONS.**

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

12 “(1) CONTENTS OF GOVERNING INSTRU-
13 MENTS.—The instruments governing the plan in-
14 clude a written instrument, meeting the require-
15 ments of an instrument required under section
16 402(a)(1), which—

17 “(A) provides that the board of trustees
18 serves as the named fiduciary required for plans
19 under section 402(a)(1) and serves in the ca-
20 pacity of a plan administrator (referred to in
21 section 3(16)(A));

22 “(B) provides that the sponsor of the plan
23 is to serve as plan sponsor (referred to in sec-
24 tion 3(16)(B)); and

1 “(C) incorporates the requirements of sec-
2 tion 806.

3 “(2) CONTRIBUTION RATES MUST BE NON-
4 DISCRIMINATORY.—

5 “(A) The contribution rates for any par-
6 ticipating small employer do not vary on the
7 basis of any health status-related factor in rela-
8 tion to employees of such employer or their
9 beneficiaries and do not vary on the basis of the
10 type of business or industry in which such em-
11 ployer is engaged.

12 “(B) Nothing in this title or any other pro-
13 vision of law shall be construed to preclude an
14 association health plan, or a health insurance
15 issuer offering health insurance coverage in
16 connection with an association health plan,
17 from—

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

20 “(ii) varying contribution rates for
21 small employers in a State to the extent
22 that such rates could vary using the same
23 methodology employed in such State for
24 regulating premium rates in the small
25 group market with respect to health insur-

1 ance coverage offered in connection with
2 bona fide associations (within the meaning
3 of section 2791(d)(3) of the Public Health
4 Service Act),
5 subject to the requirements of section 702(b)
6 relating to contribution rates.

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

13 “(4) MARKETING REQUIREMENTS.—

14 “(A) IN GENERAL.—If a benefit option
15 which consists of health insurance coverage is
16 offered under the plan, State-licensed insurance
17 agents shall be used to distribute to small em-
18 ployers coverage which does not consist of
19 health insurance coverage in a manner com-
20 parable to the manner in which such agents are
21 used to distribute health insurance coverage.

22 “(B) STATE-LICENSED INSURANCE
23 AGENTS.—For purposes of subparagraph (A),
24 the term ‘State-licensed insurance agents’
25 means one or more agents who are licensed in

1 a State and are subject to the laws of such
2 State relating to licensure, qualification, test-
3 ing, examination, and continuing education of
4 persons authorized to offer, sell, or solicit
5 health insurance coverage in such State.

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

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

1 hibits an exclusion of a specific disease from such cov-
2 erage.

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

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

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

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

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

18 “(i) a reserve sufficient for unearned
19 contributions;

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

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

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

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

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

23 “(ii) The plan shall secure specific ex-
24 cess/stop loss insurance for the plan with
25 an attachment point which is at least equal

1 to an amount recommended by the plan's
2 qualified actuary. The applicable authority
3 may by regulation provide for adjustments
4 in the amount of such insurance in speci-
5 fied circumstances in which the plan spe-
6 cifically provides for and maintains re-
7 serves in excess of the amounts required
8 under subparagraph (A).

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

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

23 “(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS
24 RESERVES.—In the case of any association health plan de-
25 scribed in subsection (a)(2), the requirements of this sub-

1 section are met if the plan establishes and maintains sur-
2 plus in an amount at least equal to—

3 “(1) \$500,000; or

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

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

21 “(d) **ADJUSTMENTS FOR EXCESS/STOP LOSS INSUR-**
22 **ANCE.**—The applicable authority may provide for adjust-
23 ments to the levels of reserves otherwise required under
24 subsections (a) and (b) with respect to any plan or class

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

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

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

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

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

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

24 “(C) CONTINUED DUTY OF THE SEC-
25 RETARY.—The Secretary shall not cease to

1 carry out the provisions of paragraph (2) on ac-
2 count of the failure of a plan to pay any pay-
3 ment when due.

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

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

3 “(3) ASSOCIATION HEALTH PLAN FUND.—

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

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

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

23 “(1) AGGREGATE EXCESS/STOP LOSS INSUR-
24 ANCE.—The term ‘aggregate excess/stop loss insur-

1 ance’ means, in connection with an association
2 health plan, a contract—

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

9 “(B) which is guaranteed renewable; and

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

13 “(2) SPECIFIC EXCESS/STOP LOSS INSUR-
14 ANCE.—The term ‘specific 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 claims under
21 the plan in connection with a covered individual
22 in excess of an amount or amounts specified in
23 such contract in connection with such covered
24 individual;

25 “(B) which is guaranteed renewable; and

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

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

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

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

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

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

1 “(j) SOLVENCY STANDARDS WORKING GROUP.—

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

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

15 “(A) A representative of the National As-
16 sociation of Insurance Commissioners.

17 “(B) A representative of the American
18 Academy of Actuaries.

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

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

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

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

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

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

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

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

23 “(A) the sponsor; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(1) the sponsor and plan administrator;

25 “(2) each participant;

1 “(3) each participating employer; and

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

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

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

19 “(f) JURISDICTION OF COURT.—

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

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

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

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

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

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

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

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

23 “(2) the rate of such tax does not exceed the
24 rate of any tax imposed by such State on premiums
25 or contributions received by insurers or health main-

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

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

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

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

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

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

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

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

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

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

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

17 “(7) INDIVIDUAL MARKET.—

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

22 “(B) TREATMENT OF VERY SMALL
23 GROUPS.—

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

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

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

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

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

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

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

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

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

20 “(C) in the case of an association health
21 plan in existence on the date of the enactment
22 of this section, a person eligible to be a member
23 of the sponsor or one of its member associa-
24 tions.

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

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

12 “(b) RULES OF CONSTRUCTION.—

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

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

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

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

19 (b) CONFORMING AMENDMENTS TO PREEMPTION
20 RULES.—

21 (1) Section 514(b)(6) of such Act (29 U.S.C.
22 1144(b)(6)) is amended by adding at the end the
23 following new subparagraph:

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

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

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

5 (A) in subsection (b)(4), by striking “Sub-
6 section (a)” and inserting “Subsections (a) and
7 (f)”;

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

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

17 “(f)(1) Except as provided in subsection (b)(4), the
18 provisions of this title shall supersede any and all State
19 laws insofar as they may now or hereafter preclude, or
20 have the effect of precluding, a health insurance issuer
21 from offering health insurance coverage in connection with
22 an association health plan which is certified under part
23 8.

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

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

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

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

5 “(A) providing solvency standards or similar
6 standards regarding the adequacy of insurer capital,
7 surplus, reserves, or contributions, or

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

9 “(4) For additional provisions relating to association
10 health plans, see subsections (a)(2)(B) and (b) of section
11 805.

12 “(5) For purposes of this subsection, the term ‘asso-
13 ciation health plan’ has the meaning provided in section
14 801(a), and the terms ‘health insurance coverage’, ‘par-
15 ticipating employer’, and ‘health insurance issuer’ have
16 the meanings provided such terms in section 812, respec-
17 tively.”.

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

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

22 (B) in clause (ii), by inserting “and which
23 does not provide medical care (within the mean-
24 ing of section 733(a)(2)),” after “arrange-

1 ment,” and by striking “title.” and inserting
2 “title, and”; and

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

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

11 (4) Section 514(d) of such Act (29 U.S.C.
12 1144(d)) is amended—

13 (A) by striking “Nothing” and inserting
14 “(1) Except as provided in paragraph (2), noth-
15 ing”; and

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

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

23 (c) PLAN SPONSOR.—Section 3(16)(B) of such Act
24 (29 U.S.C. 102(16)(B)) is amended by adding at the end
25 the following new sentence: “Such term also includes a

1 person serving as the sponsor of an association health plan
2 under part 8.”.

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

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

14 (f) REPORT TO THE CONGRESS REGARDING CERTIFI-
15 CATION OF SELF-INSURED ASSOCIATION HEALTH
16 PLANS.—Not later than January 1, 2022, the Secretary
17 of Labor shall report to the Committee on Education and
18 Labor of the House of Representatives and the Committee
19 on Health, Education, Labor, and Pensions of the Senate
20 the effect association health plans have had, if any, on
21 reducing the number of uninsured individuals.

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

“PART 8. RULES GOVERNING ASSOCIATION HEALTH PLANS

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

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

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

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

20 “(iv) in any case in which the benefit referred
21 to in subparagraph (A) consists of medical care (as
22 defined in section 812(a)(2)), in determining, after
23 the application of clause (i), whether benefits are
24 provided to employees of two or more employers, the
25 arrangement shall be treated as having only one par-

1 participating employer if, after the application of clause
2 (i), the number of individuals who are employees and
3 former employees of any one participating employer
4 and who are covered under the arrangement is
5 greater than 75 percent of the aggregate number of
6 all individuals who are employees or former employ-
7 ees of participating employers and who are covered
8 under the arrangement.”.

9 **SEC. 213. ENFORCEMENT PROVISIONS RELATING TO ASSO-**
10 **CIATION HEALTH PLANS.**

11 (a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL
12 MISREPRESENTATIONS.—Section 501 of the Employee
13 Retirement Income Security Act of 1974 (29 U.S.C. 1131)
14 is amended by adding at the end the following new sub-
15 section:

16 “(c) Any person who willfully falsely represents, to
17 any employee, any employee’s beneficiary, any employer,
18 the Secretary, or any State, a plan or other arrangement
19 established or maintained for the purpose of offering or
20 providing any benefit described in section 3(1) to employ-
21 ees or their beneficiaries as—

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

24 “(2) having been established or maintained
25 under or pursuant to one or more collective bar-

1 gaining agreements which are reached pursuant to
2 collective bargaining described in section 8(d) of the
3 National Labor Relations Act (29 U.S.C. 158(d)) or
4 paragraph Fourth of section 2 of the Railway Labor
5 Act (45 U.S.C. 152, paragraph Fourth) or which are
6 reached pursuant to labor-management negotiations
7 under similar provisions of State public employee re-
8 lations laws; or

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

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

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

18 “(n) ASSOCIATION HEALTH PLAN CEASE AND DE-
19 SIST ORDERS.—

20 “(1) IN GENERAL.—Subject to paragraph (2),
21 upon application by the Secretary showing the oper-
22 ation, promotion, or marketing of an association
23 health plan (or similar arrangement providing bene-
24 fits consisting of medical care (as defined in section
25 733(a)(2))) that—

1 “(A) is not certified under part 8, is sub-
2 ject under section 514(b)(6) to the insurance
3 laws of any State in which the plan or arrange-
4 ment offers or provides benefits, and is not li-
5 censed, registered, or otherwise approved under
6 the insurance laws of such State; or

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

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

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

18 “(A) all benefits under it referred to in
19 paragraph (1) consist of health insurance cov-
20 erage; and

21 “(B) with respect to each State in which
22 the plan or arrangement offers or provides ben-
23 efits, the plan or arrangement is operating in
24 accordance with applicable State laws that are
25 not superseded under section 514.

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

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

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

12 “(2) RECOGNITION OF PRIMARY DOMICILE
13 STATE.—In carrying out paragraph (1), the Sec-
14 retary shall ensure that only one State will be recog-
15 nized, with respect to any particular association
16 health plan, as the State with which consultation is
17 required. In carrying out this paragraph—

18 “(A) in the case of a plan which provides
19 health insurance coverage (as defined in section
20 812(a)(3)), such State shall be the State with
21 which filing and approval of a policy type of-
22 fered by the plan was initially obtained, and

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

1 and the State in which the trust is main-
2 tained.”.

3 **SEC. 215. EFFECTIVE DATE AND TRANSITIONAL AND**
4 **OTHER RULES.**

5 (a) **EFFECTIVE DATE.**—The amendments made by
6 this Act shall take effect 1 year after the date of the enact-
7 ment of this Act. The Secretary of Labor shall first issue
8 all regulations necessary to carry out the amendments
9 made by this Act within 1 year after the date of the enact-
10 ment of this Act.

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

13 (1) **IN GENERAL.**—In any case in which, as of
14 the date of the enactment of this Act, an arrange-
15 ment is maintained in a State for the purpose of
16 providing benefits consisting of medical care for the
17 employees and beneficiaries of its participating em-
18 ployers, at least 200 participating employers make
19 contributions to such arrangement, such arrange-
20 ment has been in existence for at least 10 years, and
21 such arrangement is licensed under the laws of one
22 or more States to provide such benefits to its par-
23 ticipating employers, upon the filing with the appli-
24 cable authority (as defined in section 812(a)(5) of
25 the Employee Retirement Income Security Act of

1 1974 (as amended by this Act)) by the arrangement
2 of an application for certification of the arrangement
3 under part 8 of subtitle B of title I of such Act—

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

7 (B) the requirements of sections 801(a)
8 and 803(a) of the Employee Retirement Income
9 Security Act of 1974 shall be deemed met with
10 respect to such arrangement;

11 (C) the requirements of section 803(b) of
12 such Act shall be deemed met, if the arrange-
13 ment is operated by a board of directors
14 which—

15 (i) is elected by the participating em-
16 ployers, with each employer having one
17 vote; and

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

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

24 (E) the arrangement may be certified by
25 any applicable authority with respect to its op-

1 erations in any State only if it operates in such
2 State on the date of certification.

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

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

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

1 **SEC. 216. SHORT-TERM LIMITED DURATION INSURANCE.**

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

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

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

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

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

21 “(f) APPLICATION TO SHORT-TERM LIMITED DURA-
22 TION INSURANCE.—

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

25 “(A) a reference to ‘health insurance cov-
26 erage’ with respect to such coverage offered in

1 the individual market shall be deemed to in-
2 clude short-term limited duration insurance;
3 and

4 “(B) a reference to ‘health insurance
5 issuer’ with respect to health insurance cov-
6 erage offered in the individual market shall be
7 deemed to include an issuer of short-term lim-
8 ited duration insurance.

9 “(2) SPECIAL RULE FOR SHORT-TERM LIMITED
10 DURATION INSURANCE.—In the case of short-term
11 limited duration insurance, at the time of application
12 for enrollment in such insurance coverage, an issuer
13 of such insurance may offer renewability of such
14 coverage, and an individual may decline renewability
15 of such coverage in accordance with this section, and
16 the contract between such individual and the health
17 insurance issuer shall specify whether the individual
18 opted for renewability or no renewability.”

19 (c) APPLICABILITY.—The amendments made by sub-
20 sections (a) and (b) shall apply with respect to contracts
21 for short-term limited duration insurance that take effect
22 on or after January 1, 2021.

1 **Subtitle C—Improving Commercial**
2 **Health Insurance**

3 **SEC. 221. INVISIBLE GUARANTEED COVERAGE POOL REIN-**
4 **SURANCE PROGRAM; TAX ON EXCHANGE**
5 **PLANS.**

6 (a) ESTABLISHMENT.—Not later than January 1,
7 2021, the Secretary of Health and Human Services shall
8 establish the Invisible Guaranteed Coverage Pool Reinsur-
9 ance Program (in this section referred to as the “IGCPR
10 program”).

11 (b) STATE GRANTS.—Under the IGCPR program,
12 the Secretary shall, from amounts appropriated under
13 subsection (f) for a fiscal year, award grants to States for
14 such fiscal year, in amounts determined in accordance
15 with the allocation methodology specified under subsection
16 (d). Such grants shall be used for the purpose of estab-
17 lishing or maintaining a qualifying Invisible Guaranteed
18 Coverage Pool for the State.

19 (c) FEDERAL DEFAULT.—

20 (1) IN GENERAL.—In the case of a State that
21 does not, by a date and in a manner specified by the
22 Secretary, choose to be awarded a grant under sub-
23 section (b) for a fiscal year to operate a qualifying
24 Invisible Guaranteed Coverage Pool for the State,
25 the Secretary shall, from amounts appropriated

1 under subsection (f) for such fiscal year, use the al-
2 location determined for the State under subsection
3 (d) for participation of such State in the Federal de-
4 fault qualifying Invisible Guaranteed Coverage Pool
5 described in paragraph (2).

6 (2) FEDERAL DEFAULT QUALIFYING INVISIBLE
7 GUARANTEED COVERAGE POOL.—The Federal de-
8 fault qualifying high risk pool is, with respect to
9 each State that chooses not to be awarded a grant
10 under subsection (b) with respect to a fiscal year for
11 which funds are appropriated under subsection (f),
12 an Invisible Guaranteed Coverage Pool under which
13 health insurance issuers participating in the Ex-
14 change of such a State, with respect to designated
15 individuals who are enrolled in health insurance cov-
16 erage and are expected to experience higher than av-
17 erage health costs as determined by the insurer, cede
18 risk to the pool, without affecting the premium paid
19 by the designated individuals or their terms of cov-
20 erage. With respect to such pool—

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

24 (B) the premium amount the ceding issuer
25 shall pay to the reinsurance pool shall be 90

1 percent of the premium paid to the issuer for
2 the coverage;

3 (C) the ceding issuer shall retain the same
4 risk under the ceded policies as under any other
5 policy of the issuer with respect to the first
6 \$10,000 of benefits for each ceded policy in-
7 volved and will not retain any risk under ceded
8 policies after such first \$10,000 of benefits; and

9 (D) after a ceding issuer, with respect to
10 a ceded policy, no longer retains risk under
11 such policy pursuant to subparagraph (C), the
12 negotiated rate under such policy for items and
13 services shall be payable at the reimbursement
14 rate under the Medicare program under title
15 XVIII of the Social Security Act for such items
16 and services, or in the case of items and serv-
17 ices for which payment is available under the
18 policy but not the Medicare program, at a rate
19 determined by the Secretary.

20 (d) ALLOCATION METHODOLOGY.—Not later than
21 June 30, 2021, the Secretary shall specify an allocation
22 methodology for determining the amount of funds appro-
23 priated under subsection (f) for a fiscal year to be allo-
24 cated for each State for purposes of subsections (b) and
25 (c). Such methodology shall be based on the number of

1 residents of each State and the general health status of
2 such residents.

3 (e) QUALIFYING INVISIBLE GUARANTEED COVERAGE
4 POOL.—For purposes of this section, the term “qualifying
5 Invisible Guaranteed Coverage Pool” means, with respect
6 to a State, a method of designation under which health
7 insurance issuers identify individuals who experience high-
8 er than average health costs as determined by the State
9 and are enrolled in health insurance coverage offered in
10 the individual market, and cede the risk of spending more
11 than \$10,000 on health care services for a single indi-
12 vidual to the pool without affecting the premium paid by
13 the designated individuals or their terms of coverage. With
14 respect to such pool, the State, or an entity operating the
15 pool on behalf of the State, shall establish—

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

18 (2) the applicable attachment points or coinsur-
19 ance percentages if the ceding issuer retains any
20 portion of the risk under ceded policies, except that
21 the provisions of subparagraphs (C) and (D) of sub-
22 section (c)(2) shall apply to such high risk pool in
23 the same manner as such clauses apply to the Fed-
24 eral default high risk pool; and

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

5 (f) APPROPRIATIONS.—There is appropriated to the
 6 Secretary of Health and Human Services
 7 \$200,000,000,000 to carry out this section for the period
 8 of fiscal year 2021 through fiscal year 2029.

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

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

14 **“Subchapter C—Additional Tax on Health In-**
 15 **surance Plans Sold by Insurers Offering**
 16 **Plans on Exchanges**

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

17 **“SEC. 4401. ADDITIONAL TAX ON HEALTH INSURANCE**
 18 **PLANS SOLD BY INSURERS OFFERING PLANS**
 19 **ON EXCHANGES.**

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

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

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

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

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

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

17 **SEC. 222. EMPLOYER HEALTH INSURANCE MANDATE RE-**
18 **PEAL.**

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

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

24 (c) CONFORMING AMENDMENTS.—

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

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

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

11 (4) The table of sections for subpart D of part
12 III of subchapter A of chapter 61 of such Code is
13 amended by striking the item relating to section
14 6056.

15 (5) Section 1513 of the Patient Protection and
16 Affordable Care Act is amended by striking sub-
17 section (c).

18 (d) EFFECTIVE DATE.—

19 (1) IN GENERAL.—Except as otherwise pro-
20 vided in this subsection, the amendments made by
21 this section shall apply to months and other periods
22 beginning after December 31, 2021.

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

1 **SEC. 223. REFUNDABLE CREDITS FOR COVERAGE UNDER A**
2 **QUALIFIED HEALTH PLAN FOR INDIVIDUALS**
3 **OFFERED EMPLOYER-SPONSORED INSUR-**
4 **ANCE.**

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

7 (1) in subparagraph (B)(i), by inserting “or
8 section 5000A(f)(1)(B)”, and

9 (2) by striking subparagraph (C).

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

13 **SEC. 224. INCLUSION IN INCOME OF CERTAIN COSTS OF**
14 **EMPLOYER-PROVIDED COVERAGE UNDER**
15 **HEALTH PLANS.**

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

19 “(h) LIMITATION.—

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

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

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

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

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

5 “(B) the cost-of-living adjustment deter-
6 mined under section 1(f)(3) for such calendar
7 year, determined

8 “(i) by substituting ‘calendar year
9 2021’ for ‘calendar year 2016’ in subpara-
10 graph (A)(ii) thereof, and

11 “(ii) by substituting for the C–CPI–U
12 referred to in section 1(f)(3)(A) the
13 amount that such CPI would have been if
14 the annual percentage increase in CPI with
15 respect to each year after 2021 and before
16 2031 had been one percentage point great-
17 er.

18 “(3) TERMS RELATED TO CPI.—

19 “(A) ANNUAL PERCENTAGE INCREASE.—

20 For purposes of subparagraph (B)(ii)(II), the
21 term ‘annual percentage increase’ means the
22 percentage (if any) by which C–CPI–U for any
23 year exceeds the C–CPI–U for the prior year.

24 “(B) OTHER TERMS.—Terms used in this
25 paragraph which are also used in section

1 1(f)(3) shall have the same meanings as when
2 used in such section.”.

3 (b) **EFFECTIVE DATE.**—The amendments made by
4 this section shall apply with respect to taxable years begin-
5 ning after December 31, 2021.

6 **SEC. 225. CHANGE IN PERMISSIBLE AGE VARIATION IN**
7 **HEALTH INSURANCE PREMIUM RATES.**

8 Section 2701(a)(1)(A)(iii) of the Public Health Serv-
9 ice Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by in-
10 sserting after “(consistent with section 2707(c))” the fol-
11 lowing: “or, for plan years beginning on or after January
12 1, 2021, as the Secretary may implement through interim
13 final regulation, 5 to 1 for adults (consistent with section
14 2707(c))”.

15 **SEC. 226. PREMIUM ASSISTANCE ADJUSTMENT TO RE-**
16 **FLECT AGE.**

17 (a) **MODIFICATION OF APPLICABLE PERCENTAGE.**—
18 Section 36B(b)(3)(A) of the Internal Revenue Code of
19 1986 is amended to read as follows:

20 “(A) **APPLICABLE PERCENTAGE.**—

21 “(i) **IN GENERAL.**—The applicable
22 percentage for any taxable year shall be
23 the percentage such that the applicable
24 percentage for any taxpayer whose house-
25 hold income is within an income tier speci-

1 fied in the following table shall increase, on
 2 a sliding scale in a linear manner, from the
 3 initial percentage to the final percentage
 4 specified in such table for such income tier
 5 with respect to a taxpayer of the age in-
 6 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	3	4.3	3	4.3	3	4.3	3	4.3
150%–200%	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7	4.3	6.7
200%–250%	6.7	6.7	6.7	7.6	6.7	8.5	6.7	8.5	6.7	8.5
250%–300%	6.7	6.7	7.6	7.6	8.3	9.8	8.3	9.8	8.3	9.8
300%–400%	6.7	7	7.6	8	9.8	10	9.8	10	9.8	10
400%–600%	7	9	8	10	10	15	10	15	10	15

7 “(ii) AGE DETERMINATIONS.—

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

14 “(II) JOINT RETURNS.—In the
 15 case of a joint return, the age of the
 16 older spouse shall be taken into ac-
 17 count under clause (i).

18 “(iii) INDEXING.—In the case of any
 19 taxable year beginning after calendar year

1 2021, the initial and final percentages con-
2 tained in clause (i) shall be adjusted to re-
3 flect—

4 “(I) the excess (if any) of the
5 rate of premium growth for the period
6 beginning with calendar year 2013
7 and ending with calendar year 2021,
8 over the rate of income growth for
9 such period, and

10 “(II) in addition to any adjust-
11 ment under subclause (I), the excess
12 (if any) of the rate of premium
13 growth for calendar year 2021, over
14 the rate of growth in the consumer
15 price index for calendar year 2021.

16 “(iv) FAILSAFE.—Clause (iii)(II) shall
17 apply only if the aggregate amount of pre-
18 mium tax credits under this section and
19 cost-sharing reductions under section 1402
20 of the Patient Protection and Affordable
21 Care Act for the preceding calendar year
22 exceeds an amount equal to 0.504 percent
23 of the gross domestic product for such cal-
24 endar year.”.

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

3 (1) in subsection (c)(1)(A), by striking “400”
4 and inserting “600”; and

5 (2) in subsection (f)(2)(B)(i), by striking “400”
6 each place such reference appears and inserting
7 “600” in each such place.

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

11 **SEC. 227. PREMIUM ASSISTANCE.**

12 Notwithstanding any other provision of law, the Sec-
13 retary of the Treasury shall calculate the credit allowable
14 under section 36B of the Internal Revenue Code of 1986
15 based on the taxpayer’s prior year tax return and the Sec-
16 retary of Health and Human Services shall provide for
17 open enrollment periods that end on April 15.

18 **SEC. 228. ADDING COPPER PLANS TO EXCHANGES.**

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

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

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

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

5 (3) in subsection (d)—

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

8 “(E) COPPER LEVEL.—A plan in the cop-
9 per level shall provide a level of coverage that
10 is designed to provide benefits that are actuari-
11 ally equivalent to 50 percent of the full actu-
12 arial value of the benefits provided under the
13 plan and will have out-of-pocket limits that are
14 30 percent higher than bronze plans.”; and

15 (B) in paragraph (4)—

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

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

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

22 (b) EFFECTIVE DATE.—The amendments made by
23 this section shall apply with respect to plan years begin-
24 ning on or after January 1, 2021.

1 **SEC. 229. COPPER AND BRONZE PLANS.**

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

6 **SEC. 230. WAIVERS FOR STATE INNOVATION.**

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

10 (1) in subsection (a)(1)(C), by striking “the
11 law” and inserting “a law or has in effect a certifi-
12 cation”; and

13 (2) in subsection (b)(2)—

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

16 (B) in subparagraph (A)—

17 (i) by striking “A law” and inserting
18 the following:

19 “(i) LAWS.—A law”; and

20 (ii) by adding at the end the fol-
21 lowing:

22 “(ii) CERTIFICATIONS.—A certifi-
23 cation described in this paragraph is a doc-
24 ument, signed by the Governor of the
25 State, that certifies that such Governor
26 has the authority under existing Federal

1 and State law to take action under this
2 section, including implementation of the
3 State plan under subsection (a)(1)(B).”;

4 and

5 (C) in subparagraph (B)—

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

8 (ii) by striking “may repeal a law”
9 and all that follows through the period at
10 the end and inserting the following: “may
11 terminate the authority provided under the
12 waiver with respect to the State by—

13 “(i) repealing a law described in sub-
14 paragraph (A)(i); or

15 “(ii) terminating a certification de-
16 scribed in subparagraph (A)(ii), through a
17 certification for such termination signed by
18 the Governor of the State.”.

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

22 (1) in paragraph (1) by striking “180” and in-
23 serting “90”; and

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

25 “(3) EXPEDITED DETERMINATION.—

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

15 “(i) is submitted in response to an ur-
16 gent situation, with respect to areas in the
17 State that the Secretary determines are at
18 risk for excessive premium increases or
19 having no health plans offered in the appli-
20 cable health insurance market for the cur-
21 rent or following plan year; or

22 “(ii) is for a waiver that is the same
23 or substantially similar to a waiver that
24 the Secretary already has approved for an-
25 other State.

1 “(B) APPROVAL.—

2 “(i) URGENT SITUATIONS.—

3 “(I) PROVISIONAL APPROVAL.—A
4 waiver approved under the expedited
5 determination process under subpara-
6 graph (A)(i) shall be in effect for a
7 period of 3 years, unless the State re-
8 quests a shorter duration.

9 “(II) FULL APPROVAL.—Subject
10 to the requirements for approval oth-
11 erwise applicable under this section,
12 not later than 1 year before the expi-
13 ration of a provisional waiver period
14 described in subclause (I) with respect
15 to an application described in sub-
16 paragraph (A)(i), the Secretary shall
17 make a determination on whether to
18 extend the approval of such waiver for
19 the full term of the waiver requested
20 by the State, for a total approval pe-
21 riod not to exceed 6 years. The Sec-
22 retary may request additional infor-
23 mation as the Secretary determines
24 appropriate to make such determina-
25 tion.

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

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

14 (c) PROVIDING CERTAINTY FOR STATE-BASED RE-
15 FORMS.—Section 1332(e) of the Patient Protection and
16 Affordable Care Act (42 U.S.C. 18052(e)) is amended by
17 striking “No waiver” and all that follows through the pe-
18 riod at the end and inserting the following: “A waiver
19 under this section—

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

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

1 “(3) may not be suspended or terminated, in
2 whole or in part, by the Secretary at any time before
3 the date of expiration of the waiver period (including
4 any renewal period under paragraph (2)), unless the
5 Secretary determines that the State materially failed
6 to comply with the terms and conditions of the waiv-
7 er.”.

8 (d) ENSURING PATIENT ACCESS TO MORE FLEXIBLE
9 HEALTH PLANS.—Section 1332(b)(1)(B) of the Patient
10 Protection and Affordable Care Act (42 U.S.C.
11 18052(b)(1)(B)) is amended by striking “at least as af-
12 fordable” and inserting “of comparable affordability, in-
13 cluding for low-income individuals, individuals with serious
14 health needs, and other vulnerable populations,”.

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

18 (1) with respect to applications for waivers
19 under such section 1332 submitted after the date of
20 enactment of this Act and applications for such
21 waivers submitted prior to such date of enactment
22 and under review by the Secretary on the date of en-
23 actment, shall take effect on the date of enactment
24 of this Act; and

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

9 **SEC. 231. ENROLLMENT PERIODS.**

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

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

22 (b) HEALTH PLANS.—Subpart I of part A of title
23 XXVII of the Public Health Service Act is amended by
24 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. 232. STATE-OPERATED EXCHANGES FLEXIBILITY FOR**
 12 **OPEN ENROLLMENT PERIODS.**

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

15 (1) in paragraph (6), by striking “The Sec-
 16 retary” and inserting “Subject to paragraph (7), the
 17 Secretary”; and

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

20 “(7) FLEXIBILITY FOR ENROLLMENT PERI-
 21 ODS.—

22 “(A) STATE-OPERATED EXCHANGES OPEN
 23 ENROLLMENT PERIODS.—In the case of an Ex-
 24 change operated by a State, beginning with
 25 plan year 2021, the Exchange may provide for
 26 open enrollment periods (after the initial enroll-

1 services, as defined by the Secretary of Health and
2 Human Services.

3 (b) MEDICARE ADVANTAGE RATES APPLIED TO CER-
4 TAIN HHI HOSPITALS.—

5 (1) IN GENERAL.—Section 1866(a) of the So-
6 cial Security Act (42 U.S.C. 1395cc(a)) is amend-
7 ed—

8 (A) in paragraph (1)—

9 (i) in subparagraph (X), by striking
10 “and” at the end;

11 (ii) in subparagraph (Y), by striking
12 the period at the end and inserting “;
13 and”; and

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

16 “(Z) subject to paragraph (4), in the case
17 of a hospital located in a county whose popu-
18 lation density is above the median population
19 density for all counties in the United States
20 with respect to which there is a Herfindahl-
21 Hirschman Index (HHI) of greater than 4,000,
22 to apply the average reimbursement rate with
23 respect to individuals (regardless of whether
24 such an individual is entitled to or eligible for
25 benefits under this title, but excluding individ-

1 uals eligible for medical assistance under a
2 State plan under title XIX) furnished items and
3 services at such hospital that would be billable
4 under this title for such items and services if
5 furnished by such hospital to an individual en-
6 rolled under part C.”; and

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

9 “(4)(A) The requirement under paragraph
10 (1)(Z) shall not apply in the case of a hospital in a
11 hospital referral region if—

12 “(i) the HRR market share of such hos-
13 pital (as determined under subparagraph (B))
14 is less than 0.15; or

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

17 “(B) For purposes of subparagraph (A), the
18 HRR market share of a hospital in a hospital refer-
19 ral region is equal to—

20 “(i) the total revenue of the hospital, di-
21 vided by

22 “(ii) the total revenue of all hospital in the
23 hospital referral region.”.

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

4 (c) GRANTS FOR HOSPITAL INFRASTRUCTURE IM-
5 PROVEMENT.—

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

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

16 (3) ELIGIBILITY.—

17 (A) IN GENERAL.—An eligible State may
18 receive not more than one grant under this sub-
19 section with respect to each qualifying criterion
20 described in subparagraph (B) that is met by
21 the State.

22 (B) ELIGIBLE STATE.—For purposes of
23 this subsection, the term “eligible State” means
24 a State that meets any one or more of the fol-
25 lowing qualifying criteria:

1 (i) The State does not have in effect
2 any State certificate of need law that re-
3 quires a health care provider to provide to
4 a regulatory body a certification that the
5 community needs the services provided by
6 the health care provider.

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

9 (I) allow advanced practice pro-
10 viders (such as nurse practitioners,
11 advanced practice registered nurses,
12 clinical nurse specialists, and physi-
13 cian assistants) to evaluate patients;
14 diagnose, order, and interpret diag-
15 nostic tests; and initiate and manage
16 treatments; or

17 (II) provide that the only jus-
18 tification for limiting the scope of
19 practice of a health care provider is
20 safety to the public.

21 (iii) The State does not have in effect
22 any State laws that require managed care
23 plans to accept into the network of such
24 plan any qualified provider who is willing

1 to accept the terms and conditions of the
2 managed care plan.

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

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

17 (4) FUNDING.—There is authorized to be ap-
18 propriated to carry out this subsection
19 \$1,000,000,000 for each of the fiscal years 2019
20 through 2028. Funds appropriated under this para-
21 graph shall remain available until expended.

22 (d) CRITICAL ACCESS HOSPITAL REIMBURSEMENT
23 RATES.—

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

1 inserting “(or, for 2021, 102, plus 1 percentage
2 point for each subsequent year through 2029, and
3 110 for each subsequent year thereafter)” after
4 “101”.

5 (2) PART B.—Section 1834(g)(1) of such Act
6 (42 U.S.C. 1395m(g)(1)) is amended by inserting
7 “(or, for 2021, 102, plus 1 percentage point for each
8 subsequent year through 2029, and 110 for each
9 subsequent year thereafter)” after “101”.

10 **SEC. 302. AUTHORITY OF FEDERAL TRADE COMMISSION**
11 **OVER CERTAIN TAX-EXEMPT ORGANIZA-**
12 **TIONS.**

13 Section 4 of the Federal Trade Commission Act (15
14 U.S.C. 44) is amended, in the undesignated paragraph re-
15 lating to the definition of the term “Corporation”—

16 (1) by striking “, and any” and inserting “,
17 any”; and

18 (2) by inserting before the period at the end the
19 following: “, and any organization described in sec-
20 tion 501(c)(3) of the Internal Revenue Code of 1986
21 that is exempt from taxation under section 501(a) of
22 such Code”.

1 **SEC. 303. RESTORING THE APPLICATION OF ANTITRUST**
2 **LAWS TO THE BUSINESS OF HEALTH INSUR-**
3 **ANCE.**

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

8 “(c)(1) Nothing contained in this Act shall modify,
9 impair, or supersede the operation of any of the antitrust
10 laws with respect to the business of health insurance (in-
11 cluding the business of dental insurance and limited-scope
12 dental benefits).

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

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

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

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

23 “(D) to develop or disseminate a standard in-
24 surance policy form (including a standard addendum
25 to an insurance policy form and standard termi-
26 nology in an insurance policy form) if such contract,

1 combination, or conspiracy is not to adhere to such
2 standard form or require adherence to such standard
3 form.

4 “(3) For purposes of this subsection—

5 “(A) the term ‘antitrust laws’ has the meaning
6 given it in subsection (a) of the first section of the
7 Clayton Act (15 U.S.C. 12), except that such term
8 includes section 5 of the Federal Trade Commission
9 Act (15 U.S.C. 45) to the extent that such section
10 5 applies to unfair methods of competition;

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

14 “(i) the business of life insurance (includ-
15 ing annuities); or

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

18 “(I) any insurance or benefits defined
19 as ‘excepted benefits’ under paragraph (1),
20 subparagraph (B) or (C) of paragraph (2),
21 or paragraph (3) of section 9832(c) of the
22 Internal Revenue Code of 1986 (26 U.S.C.
23 9832(c)) whether offered separately or in
24 combination with insurance or benefits de-

1 scribed in paragraph (2)(A) of such sec-
2 tion; and

3 “(II) any other line of insurance that
4 is classified as property or casualty insur-
5 ance under State law;

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

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

15 (b) RELATED PROVISION.—For purposes of section
16 5 of the Federal Trade Commission Act (15 U.S.C. 45)
17 to the extent such section applies to unfair methods of
18 competition, section 3(e) of the McCarran-Ferguson Act
19 shall apply with respect to the business of health insurance
20 without regard to whether such business is carried on for
21 profit, notwithstanding the definition of “Corporation”
22 contained in section 4 of the Federal Trade Commission
23 Act.

1 **SEC. 304. LEVELING THE PLAYING FIELD BETWEEN PAYERS**
2 **AND PROVIDERS.**

3 (a) EXEMPTION.—It shall not be a violation of the
4 antitrust laws for one or more private health insurer
5 issuers or their designated agents to jointly negotiate
6 prices of particular hospital services with a hospital pro-
7 vider with regards to the reimbursement policies of the
8 insurers for those services.

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

10 (1) ANTITRUST LAWS.—The term “antitrust
11 laws” has the meaning given it in subsection (a) of
12 the 1st section of the Clayton Act (15 U.S.C. 12(a)),
13 except that such term includes section 5 of the Fed-
14 eral Trade Commission Act (15 U.S.C. 45) to the
15 extent such section 5 applies to unfair methods of
16 competition.

17 (2) HEALTH INSURANCE ISSUER.—The term
18 “health insurance issuer” means an insurance com-
19 pany, insurance service, or insurance organization
20 (including a health maintenance organization, as de-
21 fined in subparagraph (C)) which is licensed to en-
22 gage in the business of insurance in a State and
23 which is subject to State law which regulates insur-
24 ance (within the meaning of section 514(b)(2) of the
25 Employee Retirement Income Security Act of 1974

1 (29 U.S.C. 1144(b)(2)). Such term does not include
2 a group health plan.

3 (3) HEALTH MAINTENANCE ORGANIZATION.—

4 The term “health maintenance organization”
5 means—

6 (A) a Federally qualified health mainte-
7 nance organization (as defined in section
8 300e(a) of title 42 of the United States Code),

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

11 (C) a similar organization regulated under
12 State law for solvency in the same manner and
13 to the same extent as such a health mainte-
14 nance organization.

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

18 **SEC. 305. INCREASING TRANSPARENCY BY REMOVING GAG**
19 **CLAUSES ON PRICE AND QUALITY INFORMA-**
20 **TION.**

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

1 **“SEC. 2729B. INCREASING TRANSPARENCY BY REMOVING**
2 **GAG CLAUSES ON PRICE AND QUALITY IN-**
3 **FORMATION.**

4 “(a) INCREASING PRICE AND QUALITY TRANS-
5 PARENCY FOR PLAN SPONSORS AND GROUP AND INDI-
6 VIDUAL MARKET AND CONSUMERS.—

7 “(1) GROUP HEALTH PLANS.—A group health
8 plan or health insurance issuer offering group health
9 insurance coverage may not enter into an agreement
10 with a health care provider, network or association
11 of providers, third-party administrator, or other
12 service provider offering access to a network of pro-
13 viders that would directly or indirectly restrict a
14 group health plan or health insurance issuer from—

15 “(A) providing provider-specific cost or
16 quality of care information, through a consumer
17 engagement tool or any other means, to refer-
18 ring providers, the plan sponsor, enrollees, or
19 eligible enrollees of the plan or coverage;

20 “(B) electronically accessing de-identified
21 claims and encounter data for each enrollee in
22 the plan or coverage, upon request and con-
23 sistent with the privacy regulations promul-
24 gated pursuant to section 264(c) of the Health
25 Insurance Portability and Accountability Act,
26 the amendments to this Act made by the Ge-

1 netic Information Nondiscrimination Act of
2 2008, and the Americans with Disabilities Act
3 of 1990, with respect to the applicable health
4 plan or health insurance coverage, including, on
5 a per claim basis—

6 “(i) financial information, such as the
7 allowed amount, or any other claim-related
8 financial obligations included in the pro-
9 vider contract;

10 “(ii) provider information, including
11 name and clinical designation;

12 “(iii) service codes; or

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

16 “(C) sharing data described in subpara-
17 graph (A) or (B) with a business associate as
18 defined in section 160.103 of title 45, Code of
19 Federal Regulations (or successor regulations),
20 consistent with the privacy regulations promul-
21 gated pursuant to section 264(c) of the Health
22 Insurance Portability and Accountability Act,
23 the amendments to this Act made by the Ge-
24 netic Information Nondiscrimination Act of

1 2008, and the Americans with Disabilities Act
2 of 1990.

3 “(2) INDIVIDUAL HEALTH INSURANCE COV-
4 ERAGE.—A health insurance issuer offering indi-
5 vidual health insurance coverage may not enter into
6 an agreement with a health care provider, network
7 or association of providers, or other service provider
8 offering access to a network of providers that would
9 directly or indirectly restrict the health insurance
10 issuer from—

11 “(A) providing provider-specific price or
12 quality of care information, through a consumer
13 engagement tool or any other means, to refer-
14 ring providers, enrollees, or eligible enrollees of
15 the plan or coverage; or

16 “(B) sharing, for plan design, plan admin-
17 istration, and plan, financial, legal, and quality
18 improvement activities, data described in sub-
19 paragraph (A) with a business associate as de-
20 fined in section 160.103 of title 45, Code of
21 Federal Regulations (or successor regulations),
22 consistent with the privacy regulations promul-
23 gated pursuant to section 264(c) of the Health
24 Insurance Portability and Accountability Act,
25 the amendments to this Act made by the Ge-

1 netic Information Nondiscrimination Act of
2 2008, and the Americans with Disabilities Act
3 of 1990.

4 “(3) CLARIFICATION REGARDING PUBLIC DIS-
5 CLOSURE OF INFORMATION.—Nothing in paragraph
6 (1)(A) or (2)(A) prevents a health care provider,
7 network or association of providers, or other service
8 provider from placing reasonable restrictions on the
9 public disclosure of the information described in
10 such paragraphs (1) and (2).

11 “(4) ATTESTATION.—A group health plan or a
12 health insurance issuer offering group or individual
13 health insurance coverage shall annually submit to,
14 as applicable, the applicable authority described in
15 section 2723 or the Secretary of Labor, an attesta-
16 tion that such plan or issuer is in compliance with
17 the requirements of this subsection.

18 “(5) RULE OF CONSTRUCTION.—Nothing in
19 this section shall be construed to otherwise limit
20 group health plan, plan sponsor, or health insurance
21 issuer access to data currently permitted under the
22 privacy regulations promulgated pursuant to section
23 264(c) of the Health Insurance Portability and Ac-
24 countability Act, the amendments to this Act made
25 by the Genetic Information Nondiscrimination Act of

1 2008, and the Americans with Disabilities Act of
2 1990.”.

3 **SEC. 306. BANNING ANTICOMPETITIVE TERMS IN FACILITY**
4 **AND INSURANCE CONTRACTS THAT LIMIT AC-**
5 **CESS TO HIGHER QUALITY, LOWER COST**
6 **CARE.**

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

10 “(b) PROTECTING HEALTH PLANS NETWORK DE-
11 SIGN FLEXIBILITY.—

12 “(1) IN GENERAL.—A group health plan or a
13 health insurance issuer offering group or individual
14 health insurance coverage shall not enter into an
15 agreement with a provider, network or association of
16 providers, or other service provider offering access to
17 a network of service providers if such agreement, di-
18 rectly or indirectly—

19 “(A) restricts the group health plan or
20 health insurance issuer from—

21 “(i) directing or steering enrollees to
22 other health care providers; or

23 “(ii) offering incentives to encourage
24 enrollees to utilize specific health care pro-
25 viders;

1 “(B) requires the group health plan or
2 health insurance issuer to enter into any addi-
3 tional contract with an affiliate of the provider,
4 such as an affiliate of the provider, as a condi-
5 tion of entering into a contract with such pro-
6 vider;

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

11 “(D) restricts other group health plans or
12 health insurance issuers not party to the con-
13 tract from paying a lower rate for items or
14 services than the contracting plan or issuer
15 pays for such items or services.

16 “(2) ADDITIONAL REQUIREMENT FOR SELF-IN-
17 SURED PLANS.—A self-insured group health plan
18 shall not enter into an agreement with a provider,
19 network or association of providers, third-party ad-
20 ministrator, or other service provider offering access
21 to a network of providers if such agreement directly
22 or indirectly requires the group health plan to cer-
23 tify, attest, or otherwise confirm in writing that the
24 group health plan is bound by restrictive contracting
25 terms between the service provider and a third-party

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

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

8 “(A) a health maintenance organization
9 (as defined in section 2791(b)(3)), if such
10 health maintenance organization operates pri-
11 marily through exclusive contracts with multi-
12 specialty physician groups, nor to any arrange-
13 ment between such a health maintenance orga-
14 nization and its affiliates; or

15 “(B) a value-based network arrangement,
16 such as an exclusive provider network, account-
17 able care organization, center of excellence, a
18 provider sponsored health insurance issuer that
19 operates primarily through aligned multi-spe-
20 cialty physician group practices or integrated
21 health systems, or such other similar network
22 arrangements as determined by the Secretary
23 through rulemaking.

24 “(4) ATTESTATION.—A group health plan or
25 health insurance issuer offering group or individual

1 health insurance coverage shall annually submit to,
2 as applicable, the applicable authority described in
3 section 2723 or the Secretary of Labor, an attesta-
4 tion that such plan or issuer is in compliance with
5 the requirements of this subsection.

6 “(c) MAINTENANCE OF EXISTING HIPAA, GINA,
7 AND ADA PROTECTIONS.—Nothing in this section shall
8 modify, reduce, or eliminate the existing privacy protec-
9 tions and standards provided by reason of State and Fed-
10 eral law, including the requirements of parts 160 and 164
11 of title 45, Code of Federal Regulations (or any successor
12 regulations).

13 “(d) REGULATIONS.—The Secretary, not later than
14 1 year after the date of enactment of the Fair Care Act
15 of 2020, shall promulgate regulations to carry out this sec-
16 tion.

17 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
18 tion shall be construed to limit network design or cost or
19 quality initiatives by a group health plan or health insur-
20 ance issuer, including accountable care organizations, ex-
21 clusive provider organizations, networks that tier providers
22 by cost or quality or steer enrollees to centers of excel-
23 lence, or other pay-for-performance programs.

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

1 compliance with the antitrust laws, as defined in sub-
2 section (a) of the first section of the Clayton Act (15
3 U.S.C. 12(a)).”.

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

13 **SEC. 307. REPEALING ELIGIBILITY OF CERTAIN ACOS.**

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

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

19 **SEC. 308. REPEAL OF HEALTH CARE REFORM PROVISIONS**
20 **LIMITING MEDICARE EXCEPTION TO THE**
21 **PROHIBITION ON CERTAIN PHYSICIAN RE-**
22 **FERRALS FOR HOSPITALS.**

23 Sections 6001 and 10601 of the Patient Protection
24 and Affordable Care Act (Public Law 111–148; 124 Stat.
25 684, 1005) and section 1106 of the Health Care and Edu-

1 cation Reconciliation Act of 2010 (Public Law 111–152;
2 124 Stat. 1049) are repealed and the provisions of law
3 amended by such sections are restored as if such sections
4 had never been enacted.

5 **SEC. 309. ALTERNATIVE PAYMENT MODEL FOR CERTAIN**
6 **SHOPPABLE PROCEDURES.**

7 (a) IN GENERAL.—A group health plan and a health
8 insurance issuer offering group or individual health insur-
9 ance coverage (as such terms are defined in section 2791
10 of the Public Health Service Act (42 U.S.C. 300gg–91))
11 may elect, with respect to a plan year, to provide a set
12 payment amount to an enrollee under such plan or cov-
13 erage for certain shoppable procedures (as defined in sub-
14 section (b)) in accordance with the provisions of this sec-
15 tion in lieu of otherwise providing coverage for such a pro-
16 cedure under such plan or coverage, but only if the en-
17 rollee so agrees to such set payment amount.

18 (b) DEFINITION.—For purposes of this section, the
19 term “shoppable procedure” means a procedure specified
20 by the Secretary of Health and Human Services (in this
21 section referred to as the “Secretary”) with respect to
22 which individuals may be expected to compare prices for
23 such procedure of health care providers and facilities, in-
24 cluding primary and preventive services, prenatal care and

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

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

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

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

13 (3) not be less than the median negotiated rate
14 for all group health plans and health insurance cov-
15 erage offered in such area for such procedure;

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

19 (5) represent the entirety of the payment obli-
20 gation of such plan or such issuer with respect to
21 such procedure; and

22 (6) may be retained by such enrollee to the ex-
23 tent that the amount of such payment exceeds the
24 amount charged by such provider or facility for such
25 procedure.

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

9 (e) EHB WAIVER AUTHORITY.—The Secretary may
10 waive such provisions of section 1302(b) of the Patient
11 Protection and Affordable Care Act (42 U.S.C. 18022(b))
12 with respect to a group health plan, health insurance
13 issuer offering group or individual health insurance cov-
14 erage, and a plan year as the Secretary determines nec-
15 essary to allow for the provision of set payment amounts
16 described in subsection (a).

17 **Subtitle B—Price Transparency**

18 **SEC. 321. PRICE TRANSPARENCY.**

19 Section 1866 of the Social Security Act (42 U.S.C.
20 1395cc), as amended by section 301, is further amended—

21 (1) in subsection (a)(1)—

22 (A) in subparagraph (Y), by striking
23 “and” at the end;

24 (B) in subparagraph (Z), by striking the
25 period at the end and inserting “; and”; and

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

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

5 (2) by adding at the end the following new sub-
6 section:

7 “(l) REQUIREMENT RELATING TO PUBLISHING CER-
8 TAIN HOSPITAL PRICES.—

9 “(1) IN GENERAL.—For purposes of subsection
10 (a)(1)(AA), the requirement described in this sub-
11 section is, with respect to a hospital and year (begin-
12 ning with 2021), for the hospital to publicly post,
13 through the system established under paragraph (3),
14 for each common shoppable service included in the
15 list published under paragraph (2) for such year, the
16 volume-weighted average price charged by the hos-
17 pital to—

18 “(A) individuals enrolled during such year
19 in group health plans or health insurance cov-
20 erage offered in the individual or group market
21 (as such terms are defined in section 2791 of
22 the Public Health Service Act); and

23 “(B) individuals who are not enrolled in
24 any health insurance coverage or health benefits
25 plan and individuals who are enrolled in such

1 coverage or plan but such coverage or plan does
2 not provide benefits for the service.

3 “(2) COMMON SHOPPABLE SERVICES.—For
4 purposes of subsection (a)(1)(AA) and this sub-
5 section, the Secretary shall, for 2021 and each sub-
6 sequent year, publish a list of the 100 common
7 shoppable services that are the most highly utilized
8 in a hospital-based setting.

9 “(3) STANDARDIZED DIGITAL REPORTING SYS-
10 TEM.—Not later than January 1, 2021, the Sec-
11 retary shall establish a standardized digital system
12 for purposes of paragraph (1).”.

13 **SEC. 322. PRICE TRANSPARENCY REQUIREMENTS.**

14 (a) HOSPITALS.—Section 2718(e) of the Public
15 Health Service Act (42 U.S.C. 300gg–18(e)) is amend-
16 ed—

17 (1) by striking “Each hospital” and inserting
18 the following:

19 “(1) IN GENERAL.—Each hospital”;

20 (2) by inserting “, in a machine-readable for-
21 mat, via open application program interfaces
22 (APIs)” after “a list”;

23 (3) by inserting “, along with such additional
24 information as the Secretary may require with re-
25 spect to such charges for purposes of promoting

1 public awareness of hospital pricing in advance of
2 receiving a hospital item or service” before the pe-
3 riod; and

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

5 “(2) DEFINITION OF STANDARD CHARGES.—

6 Notwithstanding any other provision of law, for pur-
7 poses of paragraph (1), the term ‘standard charges’
8 means the rates hospitals, including providers or en-
9 tities that contract with or practice at a hospital,
10 charge for all items and services at a minimum,
11 chargemaster rates, rates that hospitals negotiate
12 with third party payers across all plans, including
13 those related to a patient’s specific plan, discounted
14 cash prices, and other rates determined by the Sec-
15 retary.

16 “(3) ENFORCEMENT.—In addition to any other

17 enforcement actions or penalties that may apply
18 under subsection (b)(3) or another provision of law,
19 a hospital that fails to provide the information re-
20 quired by this subsection and has not completed a
21 corrective action plan to comply with the require-
22 ments of such subsection shall be subject to a civil
23 monetary penalty of an amount not to exceed \$300
24 per day that the violation is ongoing as determined
25 by the Secretary. Such penalty shall be imposed and

1 collected in the same manner as civil money pen-
2 alties under subsection (a) of section 1128A of the
3 Social Security Act are imposed and collected.”.

4 (b) TRANSPARENCY IN COVERAGE.—Section
5 1311(e)(3) of the Patient Protection and Affordable Care
6 Act (42 U.S.C. 18031(e)(3)) is amended—

7 (1) in subparagraph (A)—

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

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

16 (C) by inserting after clause (viii), the fol-
17 lowing:

18 “(ix) Information on the specific nego-
19 tiated payment rates between the plan and
20 health care providers for all items and
21 services covered under the plan.”;

22 (2) in subparagraph (B)—

23 (A) in the heading, by striking “USE” and
24 inserting “DELIVERY METHODS AND USE”;

1 (B) by inserting “, as applicable,” after
2 “English proficiency”; and

3 (C) by inserting after the second sentence,
4 the following: “The Secretary shall establish
5 standards for electronic delivery and access to
6 such information by individuals, free of charge,
7 in machine readable format, through an Inter-
8 net website and via open APIs.”;

9 (3) in subparagraph (C)—

10 (A) in the first sentence, by inserting “or
11 out-of-network provider” after “item or service
12 by a participating provider”;

13 (B) in the second sentence, by striking
14 “through an Internet website” and inserting
15 “free of charge, in machine readable format,
16 through an Internet website, and via open
17 APIs, in accordance with standards established
18 by the Secretary,”; and

19 (C) by adding at the end the following:
20 “Such information shall include specific nego-
21 tiated rates that allow for comparison between
22 providers and across plans, and related to a pa-
23 tient’s specific plan, including after an enrollee
24 has exceeded their deductible responsibility.”;
25 and

1 (4) in subparagraph (D) by striking “subpara-
2 graph (A)” and inserting “subparagraphs (A), (B),
3 and (C)”.

4 **SEC. 323. DESIGNATION OF NONGOVERNMENTAL, NON-**
5 **PROFIT TRANSPARENCY ORGANIZATIONS TO**
6 **LOWER AMERICANS’ HEALTH CARE COSTS.**

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

11 **“SEC. 2796. DESIGNATION OF A NONGOVERNMENTAL, NON-**
12 **PROFIT TRANSPARENCY ORGANIZATION TO**
13 **LOWER AMERICANS’ HEALTH CARE COSTS.**

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

23 “(b) REQUIREMENTS.—

24 “(1) IN GENERAL.—The database established
25 under subsection (a) shall—

1 “(A) improve transparency by using de-
2 identified health care data to—

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

5 “(ii) assist providers and hospitals, as
6 they work with patients, to make informed
7 choices about care;

8 “(iii) enable providers, hospitals, and
9 communities to improve services and out-
10 comes for patients by benchmarking their
11 performance against that of other pro-
12 viders, hospitals, and communities;

13 “(iv) enable purchasers, including em-
14 ployers, employee organizations, and health
15 plans, to develop value-based purchasing
16 models, improve quality, and reduce the
17 cost of health care and insurance coverage
18 for enrollees;

19 “(v) enable employers and employee
20 organizations to evaluate network design
21 and construction, and the cost of care for
22 enrollees;

23 “(vi) facilitate State-led initiatives to
24 lower health care costs and improve qual-
25 ity; and

1 “(vii) promote competition based on
2 quality and cost;

3 “(B) collect medical claims, prescription
4 drug claims, and remittance data consistent
5 with the protections and requirements of sub-
6 section (d);

7 “(C) be established in such a manner that
8 allows the data collected pursuant to subpara-
9 graph (B) to be shared with any State all-payer
10 claims database or regional database operated
11 with authorization from States, at cost, using a
12 standardized format, if such State or regional
13 database also submits claims data to the data-
14 base established under this section; and

15 “(D) be available to—

16 “(i) the Director of the Congressional
17 Budget Office, the Comptroller General of
18 the United States, the Executive Director
19 of the Medicare Payment Advisory Com-
20 mission, and the Executive Director of the
21 Medicaid and CHIP Payment Advisory
22 Commission, upon request, subject to the
23 privacy and security requirements of au-
24 thorized users under subsection (e)(2); and

1 “(ii) authorized users, including em-
2 ployers, employee organizations, providers,
3 group health plans, health insurance
4 issuers, researchers, and policymakers,
5 subject to subsection (e).

6 “(2) PRIVACY AND SECURITY; BREACH NOTIFI-
7 CATIONS.—

8 “(A) REGULATIONS.—

9 “(i) IN GENERAL.—The Secretary
10 shall issue regulations prescribing the ex-
11 tent to which, and the manner in which,
12 the following rules (and any successors of
13 such rules) shall apply to the activities
14 under this section of an entity receiving a
15 contract under subsection (a):

16 “(I) The Privacy Rule under part
17 160 and subparts A and E of part
18 164 of title 45, Code of Federal Regu-
19 lations (or any successor regulations).

20 “(II) The Security Rule under
21 part 160 and subparts A and C of
22 part 164 of such title 45 (or any suc-
23 cessor regulations).

24 “(III) The Breach Notification
25 Rule under part 160 and subparts A

1 and D of part 164 of such title 45 (or
2 any successor regulations).

3 “(ii) SUPPLEMENTAL REGULA-
4 TIONS.—In order to ensure data privacy
5 and security and the notification of
6 breaches, the Secretary may issue such
7 supplemental regulations on the subjects of
8 the rules listed under clause (i) as the Sec-
9 retary determines appropriate to address
10 differences between the activities described
11 by this section and the activities covered by
12 such rules.

13 “(B) ENFORCEMENT.—Section 1176 of
14 Social Security Act shall apply with respect to
15 a violation of this paragraph in the same man-
16 ner such section 1176 applies to a violation of
17 part C of title XI of the Social Security Act,
18 and the Secretary may include in the regula-
19 tions promulgated under this section provisions
20 to apply such section to this paragraph.

21 “(C) PROCEDURE.—

22 “(i) TIMING.—The Secretary shall
23 issue the initial set of regulations under
24 this paragraph not later than 1 year after

1 the date of enactment of the Fair Care Act
2 of 2020.

3 “(ii) AUTHORITY TO USE INTERIM
4 FINAL PROCEDURES.—The Secretary may
5 make such initial set of regulations effec-
6 tive and final immediately upon issuance,
7 on an interim basis, and provide for a pe-
8 riod of public comment on such initial set
9 of regulations after the date of publication.

10 “(D) REQUIREMENTS OF ENTITY.—An en-
11 tity receiving the contract under this section
12 shall—

13 “(i) not disclose to the public any in-
14 dividually identifiable health information or
15 proprietary financial information;

16 “(ii) strictly limit staff access to the
17 data to staff with appropriate training,
18 clearance, and background checks and re-
19 quire regular privacy and security training;

20 “(iii) maintain effective security
21 standards for transferring data or making
22 data available to authorized users;

23 “(iv) develop a process for providing
24 access to data to authorized users, in a se-

1 cure manner that maintains privacy and
2 confidentiality of data; and

3 “(v) adhere to current best security
4 practices with respect to the management
5 and use of such data for health services re-
6 search, in accordance with applicable Fed-
7 eral privacy law.

8 “(3) CONSULTATION.—

9 “(A) ADVISORY COMMITTEE.—Not later
10 than 180 days after the date of enactment of
11 the Fair Care Act of 2020, the Secretary shall
12 convene an Advisory Committee (referred to in
13 this section as the ‘Committee’), consisting of
14 13 members, to advise the Secretary, a con-
15 tracting entity, and Congress on the establish-
16 ment, operations, and use of the database es-
17 tablished under this section.

18 “(B) MEMBERSHIP.—

19 “(i) APPOINTMENT.—In accordance
20 with clause (ii), the Secretary, in consulta-
21 tion with the Secretary of Labor and the
22 Comptroller General of the United States
23 shall, not later than 180 days after the
24 date of enactment of the Fair Care Act of
25 2020, appoint members to the Committee

1 who have distinguished themselves in the
2 fields of health services research, health ec-
3 onomics, health informatics, or the govern-
4 ance of State all-payer claims databases, or
5 who represent organizations likely to sub-
6 mit data to or use the database, including
7 patients, employers, or employee organiza-
8 tions that sponsor group health plans,
9 health care providers, health insurance
10 issuers, or third-party administrators of
11 group health plans. Such members shall
12 serve 3-year terms on a staggered basis.
13 Vacancies on the Committee shall be filled
14 by appointment consistent with this sub-
15 section not later than 3 months after the
16 vacancy arises.

17 “(ii) COMPOSITION.—In accordance
18 with clause (i)—

19 “(I) the Secretary, in consulta-
20 tion with the Secretary of Labor, shall
21 appoint to the Committee—

22 “(aa) 1 member selected by
23 the Secretary, in coordination
24 with the Secretary of Labor, to

1 serve as the chair of the Com-
2 mittee;

3 “(bb) the Assistant Sec-
4 retary for Planning and Evalua-
5 tion of the Department of Health
6 and Human Services, or a des-
7 ignee of such Assistant Sec-
8 retary;

9 “(cc) 1 representative of the
10 Centers for Medicare & Medicaid
11 Services;

12 “(dd) 1 representative of the
13 Agency for Health Research and
14 Quality;

15 “(ee) 1 representative of the
16 Office for Civil Rights of the De-
17 partment of Health and Human
18 Services with expertise in data
19 privacy and security;

20 “(ff) 1 representative of the
21 National Center for Health Sta-
22 tistics; and

23 “(gg) 1 representative of the
24 Employee Benefits and Security

1 Administration of the Depart-
2 ment of Labor; and

3 “(II) the Comptroller General of
4 the United States shall appoint to the
5 Committee—

6 “(aa) 1 representative of an
7 employer that sponsors a group
8 health plan;

9 “(bb) 1 representative of an
10 employee organization that spon-
11 sors a group health plan;

12 “(cc) 1 academic researcher
13 with expertise in health econom-
14 ics or health services research;

15 “(dd) 1 consumer advocate;
16 and

17 “(ee) 2 additional members.

18 “(C) DUTIES.—The Committee shall—

19 “(i) advise the Secretary on the man-
20 agement of the contract under subsection
21 (a);

22 “(ii) assist and advise the entities re-
23 ceiving the contract under subsection (a) in
24 establishing—

1 “(I) the scope and format of the
2 data to be submitted under subsection
3 (d);

4 “(II) best practices with respect
5 to de-identification of data, as appro-
6 priate;

7 “(III) the appropriate uses of
8 data by authorized users, including
9 developing standards for the approval
10 of requests by organizations to access
11 and use the data; and

12 “(IV) the appropriate formats
13 and methods for making reports and
14 analyses based on the database to the
15 public;

16 “(iii) conduct an annual review of
17 whether data was used according to the
18 appropriate uses as described in clause
19 (ii)(II), and advise the designated entities
20 on using the data for authorized purposes;

21 “(iv) report, as appropriate, to the
22 Secretary and Congress on the operation of
23 the database and opportunities to better
24 achieve the objectives of this section;

1 “(v) establish additional restrictions
2 on researchers who receive compensation
3 from entities described in subsection
4 (e)(2)(B)(ii), in order to protect propri-
5 etary financial information; and

6 “(vi) establish objectives for research
7 and public reporting.

8 “(4) STATE REQUIREMENTS.—A State may re-
9 quire health insurance issuers and other payers to
10 submit claims data to the database established
11 under this section, provided that such data is sub-
12 mitted to the entities awarded contracts under this
13 section in a form and manner established by the
14 Secretary, and pursuant to subsection (d)(4)(B).

15 “(5) SANCTIONS.—The Secretary shall take ap-
16 propriate action to sanction users who attempt to re-
17 identify data accessed pursuant to paragraph
18 (1)(D).

19 “(c) CONTRACT REQUIREMENTS.—

20 “(1) COMPETITIVE PROCEDURES.—The Sec-
21 retary shall enter into the contract under subsection
22 (a) using full and open competition procedures pur-
23 suant to chapter 33 of title 41, United States Code.

1 “(2) ELIGIBLE ENTITIES.—To be eligible to
2 enter into a contract described in subsection (a), an
3 entity shall—

4 “(A) be a private nonprofit entity governed
5 by a board that includes representatives of the
6 academic research community and individuals
7 with expertise in employer-sponsored insurance,
8 research using health care claims data and ac-
9 tuarial analysis;

10 “(B) conduct its business in an open and
11 transparent manner that provides the oppor-
12 tunity for public comment on its activities; and

13 “(C) agree to comply with any require-
14 ments imposed under the rulemaking described
15 in subsection (d)(4)(A).

16 “(3) CONSIDERATIONS.—In awarding a con-
17 tract under subsection (a), the Secretary shall con-
18 sider an entity’s experience in—

19 “(A) health care claims data collection, ag-
20 gregation, quality assurance, analysis, and secu-
21 rity;

22 “(B) supporting academic research on
23 health costs, spending, and utilization for and
24 by privately insured patients;

1 “(C) working with large health insurance
2 issuers and third-party administrators to as-
3 semble a national claims database;

4 “(D) effectively collaborating with and en-
5 gaging stakeholders to develop reports;

6 “(E) meeting budgets and timelines, in-
7 cluding in connection with report generation;
8 and

9 “(F) facilitating the creation of, or sup-
10 porting, State all-payer claims databases.

11 “(4) CONTRACT TERM.—A contract awarded
12 under this section shall be for a period of 5 years,
13 and may be renewed after a subsequent competitive
14 bidding process under this section.

15 “(5) TRANSITION OF CONTRACT.—If the Sec-
16 retary, following a competitive process at the end of
17 the contract period, selects a new entity to maintain
18 the database, all data shall be transferred to the new
19 entity according to a schedule and process to be de-
20 termined by the Secretary. Upon termination of a
21 contract, no entity may keep data held by the data-
22 base or disclose such data to any entity other than
23 the entity so designated by the Secretary. The Sec-
24 retary shall include enforcement terms in any con-
25 tract with an organization chosen under this section,

1 to ensure the timely transfer of all data, and any as-
2 sociated code or algorithms, to a new entity in the
3 event of contract termination.

4 “(d) RECEIVING HEALTH INFORMATION.—

5 “(1) REQUIREMENTS.—

6 “(A) IN GENERAL.—The Secretary of
7 Labor shall ensure that the applicable self-in-
8 sured group health plan, through its third-party
9 administrator, pharmacy benefit manager, or
10 other entity designated by the group health
11 plan, as applicable, electronically submits all
12 claims data with respect to the plan, pursuant
13 to subparagraph (B).

14 “(B) SCOPE OF INFORMATION AND FOR-
15 MAT OF SUBMISSION.—An entity awarded the
16 contract under subsection (a), in consultation
17 with the Committee described in subsection
18 (b)(3), and pursuant to the privacy and security
19 requirements of subsection (b)(2), shall—

20 “(i) specify the data elements required
21 to be submitted under subparagraph (A),
22 which shall include all data related to
23 transactions described in subparagraphs
24 (A) and (E) of section 1173(a)(2) of the
25 Social Security Act, including all data ele-

1 ments normally present in such trans-
2 actions when adjudicated, and enrollment
3 information;

4 “(ii) specify the form and manner for
5 such submissions, and the historical period
6 to be included in the initial submission;
7 and

8 “(iii) offer an automated submission
9 option to minimize administrative burdens
10 for entities required to submit data.

11 “(C) DE-IDENTIFICATION OF DATA.—An
12 entity awarded the contract under subsection
13 (a) shall—

14 “(i) establish a process under which
15 data is de-identified consistent with the de-
16 identification requirements under section
17 164.514 of title 45, Code of Federal Regu-
18 lations (or any successor regulations),
19 while retaining the ability to link data lon-
20 gitudinally for the purposes of research on
21 cost and quality, and the ability to com-
22 plete risk adjustment and geographic anal-
23 ysis;

24 “(ii) ensure that any third-party sub-
25 contractors who perform the de-identifica-

1 tion process described in clause (i) retain
2 only the minimum necessary information
3 to perform such a process, and adhere to
4 effective security and encryption practices
5 in data storage and transmission;

6 “(iii) store claims and other data col-
7 lected under this subsection only in de-
8 identified form, in accordance with section
9 164.514 of title 45, Code of Federal Regu-
10 lations (or any successor regulations); and

11 “(iv) ensure that individually identifi-
12 able data is encrypted, in accordance with
13 guidance issued by the Secretary under
14 section 13402(h)(2) of the HITECH Act.

15 “(2) APPLICABLE SELF-INSURED GROUP
16 HEALTH PLAN.—For purposes of paragraph (1), a
17 self-insured group health plan is an applicable self-
18 insured group health plan if such plan is self-admin-
19 istered, or is administered by a third-party plan ad-
20 ministrator that meets 1 or both of the following cri-
21 teria:

22 “(A) Administers health, medical, or phar-
23 macy benefits for more than 50,000 enrollees.

24 “(B) Is one of the 5 largest administrators
25 or issuers of self-insured group health plans in

1 a State in which such administrator operates,
2 as measured by the aggregate number of enroll-
3 ees in plans administered by such administrator
4 in such State, as determined by the Secretary.

5 “(3) THIRD-PARTY ADMINISTRATORS.—In the
6 case of a third-party administrator that is required
7 under this subsection to submit claims data with re-
8 spect to an applicable self-insured group health plan,
9 such administrator shall submit claims data with re-
10 spect to all self-insured group health plans that the
11 administrator administers, including such plans that
12 are not applicable self-insured group health plans, as
13 described in paragraph (2).

14 “(4) RECEIVING OTHER INFORMATION.—

15 “(A) MEDICARE DATA.—The Secretary,
16 through rulemaking, shall ensure that the data
17 made available to such entity is available to
18 qualified entities under section 1874(e) of the
19 Social Security Act is made available to each
20 entity awarded a contract under subsection (a).

21 “(B) STATE DATA.—An entity awarded a
22 contract under subsection (a) shall collect data
23 from State all payer claims databases that seek
24 access to the database established under this
25 section.

1 “(5) AVAILABILITY OF DATA.—An entity re-
2 quired to submit data under this subsection may not
3 place any restrictions on the use of such data by au-
4 thorized users.

5 “(e) USES OF INFORMATION.—

6 “(1) IN GENERAL.—An entity awarded a con-
7 tract under subsection (a) shall make the database
8 available to users who are authorized under this sub-
9 section, at cost, and reports and analyses based on
10 the data available to the public with no charge.

11 “(2) AUTHORIZATION OF USERS.—

12 “(A) IN GENERAL.—An entity may request
13 authorization by an entity awarded a contract
14 under subsection (a) for access to the database
15 in accordance with this paragraph.

16 “(B) APPLICATION.—An entity desiring
17 authorization under this paragraph shall submit
18 to an entity awarded a contract an application
19 for such access, which shall include—

20 “(i) in the case of an entity requesting
21 access for research purposes—

22 “(I) a description of the uses and
23 methodologies for evaluating health
24 system performance using such data;
25 and

1 “(II) documentation of approval
2 of the research by an institutional re-
3 view board, if applicable for a par-
4 ticular plan of research; or

5 “(ii) in the case of an entity such as
6 an employer, health insurance issuer,
7 third-party administrator, or health care
8 provider, requesting access for the purpose
9 of quality improvement or cost-contain-
10 ment, a description of the intended uses
11 for such data.

12 “(C) REQUIREMENTS.—

13 “(i) RESEARCH.—Upon approval of
14 an application for research purposes under
15 subparagraph (B)(i), the authorized user
16 shall enter into a data use and confiden-
17 tiality agreement with an entity awarded a
18 contract under subsection (a), which shall
19 include a prohibition on attempts to re-
20 identify and disclose individually identifi-
21 able health information and proprietary fi-
22 nancial information.

23 “(ii) QUALITY IMPROVEMENT AND
24 COST-CONTAINMENT.—In consultation with
25 the Committee described in subsection

1 (b)(3), the Secretary shall, through rule-
2 making, establish the form and manner in
3 which authorized users described in sub-
4 paragraph (B)(ii) may access data. Data
5 provided to such authorized users shall be
6 provided in a form and manner such that
7 users may not obtain individually identifi-
8 able price information with respect to di-
9 rect competitors. Upon approval, such au-
10 thorized user shall enter into a data use
11 and confidentiality agreement with the en-
12 tity.

13 “(iii) CUSTOMIZED REPORTS.—Em-
14 ployers and employer organizations may
15 request customized reports from an entity
16 awarded a contract under subsection (a),
17 at cost, subject to the requirements of this
18 section with respect to privacy, security,
19 and proprietary financial information.

20 “(iv) NON-CUSTOMIZED REPORTS.—
21 An entity awarded a contract under sub-
22 section (a), in consultation with the Com-
23 mittee, shall make available to all author-
24 ized users aggregate data sets, free of
25 charge.

1 “(f) FUNDING.—

2 “(1) INITIAL FUNDING.—There are authorized
3 to be appropriated, and there are appropriated, out
4 of monies in the Treasury not otherwise appro-
5 priated, \$20,000,000 for fiscal year 2020, for the
6 implementation of the initial contract and establish-
7 ment of the database under this section.

8 “(2) ONGOING FUNDING.—There are author-
9 ized to be appropriated \$15,000,000 for each of fis-
10 cal years 2021 through 2025, for purposes of car-
11 rying out this section (other than the grant program
12 under subsection (h)).

13 “(g) ANNUAL REPORT.—

14 “(1) SUBMISSION.—On each of the dates de-
15 scribed in paragraph (2), an entity receiving a con-
16 tract under subsection (a) shall submit to Congress,
17 the Secretary of Health and Human Services, and
18 the Secretary of Labor and publish online for access
19 by the general public, a report containing a descrip-
20 tion of—

21 “(A) trends in the price, utilization, and
22 total spending on health care services, including
23 a geographic analysis of differences in such
24 trends;

25 “(B) limitations in the data set;

1 “(C) progress towards the objectives of
2 this section; and

3 “(D) the performance by the entity of the
4 duties required under such contract.

5 “(2) DATES DESCRIBED.—The reports de-
6 scribed in paragraph (1) shall be submitted—

7 “(A) not later than 3 years after the date
8 of enactment of the Fair Care Act of 2020;

9 “(B) the later of 1 year after the date that
10 is 3 years after such date of enactment or
11 March 1 of the year after the date that is 3
12 years after such date of enactment; and

13 “(C) March 1 of each year thereafter.

14 “(3) PUBLIC REPORTS AND RESEARCH.—An
15 entity receiving a contract under subsection (a)
16 shall, in coordination with authorized users, make
17 analyses and research available to the public on an
18 ongoing basis to promote the objectives of this sec-
19 tion.

20 “(h) GRANTS TO STATES.—

21 “(1) IN GENERAL.—The Secretary, in consulta-
22 tion with the Secretary of Labor, may award grants
23 to States for the purpose of establishing and main-
24 taining State all-payer claims databases that im-

1 prove transparency of data in order to meet the
2 goals of subsection (a)(1).

3 “(2) REQUIREMENT.—To be eligible to receive
4 the funding under paragraph (1), a State shall sub-
5 mit data to the database as described in subsection
6 (b)(1)(C), using the format described in subsection
7 (d)(1).

8 “(3) FUNDING.—There is authorized to be ap-
9 propriated \$100,000,000 for the period of fiscal
10 years 2020 through 2029 for the purpose of award-
11 ing grants to States under this subsection.

12 “(i) EXEMPTION FROM PUBLIC DISCLOSURE.—

13 “(1) IN GENERAL.—Claims data provided to
14 the database, and the database itself shall not be
15 considered public records and shall be exempt from
16 public disclosure requirements.

17 “(2) RESTRICTIONS ON USES FOR CERTAIN
18 PROCEEDINGS.—Data disclosed to authorized users
19 shall not be subject to discovery or admission as
20 public information, or evidence in judicial or admin-
21 istrative proceedings without consent of the affected
22 parties.

23 “(j) DEFINITIONS.—

24 “(1) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
25 FORMATION.—The term ‘individually identifiable

1 health information' has the meaning given such term
2 in section 1171(6) of the Social Security Act.

3 “(2) PROPRIETARY FINANCIAL INFORMATION.—

4 The term ‘proprietary financial information’ means
5 data that would disclose the terms of a specific con-
6 tract between an individual health care provider or
7 facility and a specific group health plan, Medicaid
8 managed care organization or other managed care
9 entity, or health insurance issuer offering group or
10 individual coverage.

11 “(k) RULE OF CONSTRUCTION.—Nothing in this sec-
12 tion shall be construed to affect or modify enforcement
13 of the privacy, security, or breach notification rules pro-
14 mulgated under section 264(c) of the Health Insurance
15 Portability and Accountability Act of 1996 (or successor
16 regulations).”.

17 (b) GAO REPORT.—

18 (1) IN GENERAL.—The Comptroller General of
19 the United States shall conduct a study on—

20 (A) the performance of the entity awarded
21 a contract under section 2795(a) of the Public
22 Health Service Act, as added by subsection (a),
23 under such contract;

24 (B) the privacy and security of the infor-
25 mation reported to the entity; and

1 (C) the costs incurred by such entity in
2 performing such duties.

3 (2) REPORTS.—Not later than 2 years after the
4 effective date of the first contract entered into under
5 section 2795(a) of the Public Health Service Act, as
6 added by subsection (a), and again not later than 4
7 years after such effective date, the Comptroller Gen-
8 eral of the United States shall submit to Congress
9 a report containing the results of the study con-
10 ducted under paragraph (1), together with rec-
11 ommendations for such legislation and administra-
12 tive action as the Comptroller General determines
13 appropriate.

14 **SEC. 324. PROTECTING PATIENTS AND IMPROVING THE AC-**
15 **CURACY OF PROVIDER DIRECTORY INFOR-**
16 **MATION.**

17 (a) IN GENERAL.—Subpart II of part A of title
18 XXVII of the Public Health Service Act (42 U.S.C.
19 300gg–11 et seq.), as amended by the preceding sections,
20 is further amended by adding at the end the following:

21 **“SEC. 2729C. PROTECTING PATIENTS AND IMPROVING THE**
22 **ACCURACY OF PROVIDER DIRECTORY INFOR-**
23 **MATION.**

24 “(a) NETWORK STATUS OF PROVIDERS.—

1 “(1) IN GENERAL.—Beginning on the date that
2 is one year after the date of enactment of this sec-
3 tion, a group health plan or a health insurance
4 issuer offering group or individual health insurance
5 coverage shall—

6 “(A) establish business processes to ensure
7 that all enrollees in such plan or coverage re-
8 ceive proof of a health care provider’s network
9 status, based on what a plan or issuer knows or
10 could reasonably know—

11 “(i) through a written electronic com-
12 munication from the plan or issuer to the
13 enrollee, as soon as practicable and not
14 later than 1 business day after a telephone
15 inquiry is made by such enrollee for such
16 information;

17 “(ii) through an oral confirmation,
18 documented by such issuer or coverage,
19 and kept in the enrollee’s file for a min-
20 imum of 2 years; and

21 “(iii) in real-time through an online
22 health care provider directory search tool
23 maintained by the plan or issuer; and

24 “(B) include in any print directory a dis-
25 closure that the information included in the di-

1 rectory is accurate as of the date of the last
2 data update and that enrollees or prospective
3 enrollees should consult the group health plan
4 or issuer’s electronic provider directory on its
5 website or call a specified customer service tele-
6 phone number to obtain the most current pro-
7 vider directory information.

8 “(2) GROUP HEALTH PLAN AND HEALTH IN-
9 SURANCE ISSUER BUSINESS PROCESSES.—Beginning
10 on the date that is one year after the date of enact-
11 ment of the Fair Care Act of 2020, a group health
12 plan or a health insurance issuer offering group or
13 individual health insurance coverage shall establish
14 business processes to—

15 “(A) verify and update, at least once every
16 90 days, the provider directory information for
17 all providers included in the online health care
18 provider directory search tool described in para-
19 graph (1)(A)(iii); and

20 “(B) remove any provider from such online
21 directory search tool if such provider has not
22 verified the directory information within the
23 previous 6 months or the plan or issuer has
24 been unable to verify the provider’s network
25 participation.

1 “(b) COST-SHARING LIMITATIONS.—

2 “(1) IN GENERAL.—A group health plan or a
3 health insurance issuer offering group or individual
4 health insurance coverage shall not apply, and shall
5 ensure that no provider applies cost-sharing to an
6 enrollee for treatment or services provided by a
7 health care provider in excess of the normal cost-
8 sharing applied for in-network care (including any
9 balance bill issued by the health care provider in-
10 volved), if such enrollee, or health care provider re-
11 ferring such enrollee, demonstrates (based on the
12 electronic, written information described in sub-
13 section (a)(1)(A)(i), the oral confirmation described
14 in subsection (a)(1)(A)(ii), or a copy of the online
15 provider directory described in subsection
16 (a)(1)(A)(iii) on the date the enrollee attempted to
17 obtain the provider’s network status) that the en-
18 rollee relied on the information described in sub-
19 section (a)(1), if the provider’s network status or di-
20 rectory information on such directory was incorrect
21 at the time the treatment or services involved was
22 provided.

23 “(2) REFUNDS TO ENROLLEES.—If a health
24 care provider submits a bill to an enrollee in viola-
25 tion of paragraph (1), and the enrollee pays such

1 bill, the provider shall reimburse the enrollee for the
2 full amount paid by the enrollee in excess of the in-
3 network cost-sharing amount for the treatment or
4 services involved, plus interest, at an interest rate
5 determined by the Secretary.

6 “(c) PROVIDER BUSINESS PROCESSES.—A health
7 care provider shall have in place business processes to en-
8 sure the timely provision of provider directory information
9 to a group health plan or a health insurance issuer offer-
10 ing group or individual health insurance coverage to sup-
11 port compliance by such plans or issuers with subsection
12 (a)(1). Such providers shall submit provider directory in-
13 formation to a plan or issuers, at a minimum—

14 “(1) when the provider begins a network agree-
15 ment with a plan or with an issuer with respect to
16 certain coverage;

17 “(2) when the provider terminates a network
18 agreement with a plan or with an issuer with respect
19 to certain coverage;

20 “(3) when there are material changes to the
21 content of provider directory information described
22 in subsection (a)(1); and

23 “(4) every 90 days throughout the duration of
24 the network agreement with a plan or issuer.

25 “(d) ENFORCEMENT.—

1 “(1) IN GENERAL.—Subject to paragraph (2), a
2 health care provider that violates a requirement
3 under subsection (c) or takes actions that prevent a
4 group health plan or health insurance issuer from
5 complying with subsection (a)(1) or (b) shall be sub-
6 ject to a civil monetary penalty of not more than
7 \$10,000 for each act constituting such violation.

8 “(2) SAFE HARBOR.—The Secretary may waive
9 the penalty described under paragraph (1) with re-
10 spect to a health care provider that unknowingly vio-
11 lates subsection (b)(1) with respect to an enrollee if
12 such provider rescinds the bill involved and, if appli-
13 cable, reimburses the enrollee within 30 days of the
14 date on which the provider billed the enrollee in vio-
15 lation of such subsection.

16 “(3) PROCEDURE.—The provisions of section
17 1128A of the Social Security Act, other than sub-
18 sections (a) and (b) and the first sentence of sub-
19 section (c)(1) of such section, shall apply to civil
20 money penalties under this subsection in the same
21 manner as such provisions apply to a penalty or pro-
22 ceeding under section 1128A of the Social Security
23 Act.

24 “(e) SAVINGS CLAUSE.—Nothing in this section shall
25 prohibit a provider from requiring in the terms of a con-

1 tract, or contract termination, with a group health plan
2 or health insurance issuer—

3 “(1) that the plan or issuer remove, at the time
4 of termination of such contract, the provider from a
5 directory of the plan or issuer described in sub-
6 section (a)(1); or

7 “(2) that the plan or issuer bear financial re-
8 sponsibility, including under subsection (b), for pro-
9 viding inaccurate network status information to an
10 enrollee.

11 “(f) DEFINITION.—For purposes of this section, the
12 term ‘provider directory information’ includes the names,
13 addresses, specialty, and telephone numbers of individual
14 health care providers, and the names, addresses, and tele-
15 phone numbers of each medical group, clinic, or facility
16 contracted to participate in any of the networks of the
17 group health plan or health insurance coverage involved.

18 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to preempt any provision of State
20 law relating to health care provider directories or network
21 adequacy.”.

22 (b) EFFECTIVE DATE.—Section 2729C of the Public
23 Health Service Act, as added by subsection (a), shall take
24 effect with respect to plan years beginning on or after the

1 date that is 18 months after the date of enactment of this
2 Act.

3 **SEC. 325. ENSURING ENROLLEE ACCESS TO COST-SHARING**
4 **INFORMATION.**

5 (a) IN GENERAL.—Subpart II of part A of title
6 XXVII of the Public Health Service Act (42 U.S.C.
7 300gg–11 et seq.), as amended by the preceding sections,
8 is further amended by adding at the end the following:

9 **“SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.**

10 “(a) PROVIDER DISCLOSURES.—A provider that is
11 in-network with respect to a group health plan or a health
12 insurance issuer offering group or individual health insur-
13 ance coverage shall provide to an enrollee in the plan or
14 coverage who submits a request for the information de-
15 scribed in paragraph (1) or (2), together with accurate
16 and complete information about the enrollee’s coverage
17 under the applicable plan or coverage—

18 “(1) as soon as practicable and not later than
19 2 business days after the enrollee requests such in-
20 formation, a good faith estimate of the expected en-
21 rollee cost-sharing for the provision of a particular
22 health care service (including any service that is rea-
23 sonably expected to be provided in conjunction with
24 such specific service); and

1 “(2) as soon as practicable and not later than
2 2 business days after an enrollee requests such in-
3 formation, the contact information for any ancillary
4 providers for a scheduled health care service.

5 “(b) INSURER DISCLOSURES.—A group health plan
6 or a health insurance issuer offering group or individual
7 health insurance coverage shall provide an enrollee in the
8 plan or coverage with a good faith estimate of the enroll-
9 ee’s cost-sharing (including deductibles, copayments, and
10 coinsurance) for which the enrollee would be responsible
11 for paying with respect to a specific health care service
12 (including any service that is reasonably expected to be
13 provided in conjunction with such specific service), as soon
14 as practicable and not later than 2 business days after
15 a request for such information by an enrollee.

16 “(c) ENFORCEMENT.—

17 “(1) IN GENERAL.—Subject to paragraph (2), a
18 health care provider that violates a requirement
19 under subsection (a) shall be subject to a civil mone-
20 tary penalty of not more than \$10,000 for each act
21 constituting such violation.

22 “(2) PROCEDURE.—The provisions of section
23 1128A of the Social Security Act, other than sub-
24 sections (a) and (b) and the first sentence of sub-
25 section (c)(1) of such section, shall apply to civil

1 money penalties under this subsection in the same
2 manner as such provisions apply to a penalty or pro-
3 ceeding under section 1128A of the Social Security
4 Act.”.

5 (b) EFFECTIVE DATE.—Section 2729G of the Public
6 Health Service Act, as added by subsection (a), shall apply
7 with respect to plan years beginning on or after the date
8 that is 18 months after the date of enactment of this Act.

9 **SEC. 326. ACCESS OF INDIVIDUALS TO PROTECTED HEALTH**
10 **INFORMATION.**

11 The provisions of section 164.524 of title 45, Code
12 of Federal Regulations, as in effect on the day before the
13 date of the enactment of this Act, shall have the force and
14 effect of law.

15 **SEC. 327. TIMELY BILLS FOR PATIENTS.**

16 (a) IN GENERAL.—

17 (1) AMENDMENT.—Part P of title III of the
18 Public Health Service Act (42 U.S.C. 280g et seq.)
19 is amended by adding at the end the following:

20 **“SEC. 399V-7. TIMELY BILLS FOR PATIENTS.**

21 **“(a) IN GENERAL.—**The Secretary shall require—

22 **“(1) health care facilities, or in the case of**
23 **practitioners providing services outside of such a fa-**
24 **cility, practitioners, to provide to patients a list of**
25 **services rendered during the visit to such facility or**

1 practitioner, and, in the case of a facility, the name
2 of the provider for each such service, upon discharge
3 or end of the visit or by postal or electronic commu-
4 nication as soon as practicable and not later than 5
5 calendar days after discharge or date of visit; and

6 “(2) health care facilities and practitioners to
7 furnish all adjudicated bills to the patient as soon as
8 practicable, but not later than 45 calendar days
9 after discharge or date of visit.

10 “(b) PAYMENT AFTER BILLING.—No patient may be
11 required to pay a bill for health care services any earlier
12 than 35 days after the postmark date of a bill for such
13 services.

14 “(c) EFFECT OF VIOLATION.—

15 “(1) NOTIFICATION AND REFUND REQUIRE-
16 MENTS.—

17 “(A) PROVIDER LISTS.—If a facility or
18 practitioner fails to provide a patient a list as
19 required under subsection (a)(1), such facility
20 or practitioner shall report such failure to the
21 Secretary.

22 “(B) BILLING.—If a facility or practitioner
23 bills a patient after the 45-calendar-day period
24 described in subsection (a)(2), such facility or
25 practitioner shall—

1 “(i) report such bill to the Secretary;

2 and

3 “(ii) refund the patient for the full
4 amount paid in response to such bill with
5 interest, at a rate determined by the Sec-
6 retary.

7 “(2) CIVIL MONETARY PENALTIES.—

8 “(A) IN GENERAL.—The Secretary may
9 impose civil monetary penalties of up to
10 \$10,000 a day on any facility or practitioner
11 that—

12 “(i) fails to provide a list required
13 under subsection (a)(1) more than 10
14 times, beginning on the date of such tenth
15 failure;

16 “(ii) submits more than 10 bills out-
17 side of the period described in subsection
18 (a)(2), beginning on the date on which
19 such facility or practitioner sends the tenth
20 such bill;

21 “(iii) fails to report to the Secretary
22 any failure to provide lists as required
23 under paragraph (1)(A), beginning on the
24 date that is 45 calendar days after dis-
25 charge or visit; or

1 “(iv) fails to send any bill as required
2 under subsection (a)(2), beginning on the
3 date that is 45 calendar days after the
4 date of discharge or visit, as applicable.

5 “(B) PROCEDURE.—The provisions of sec-
6 tion 1128A of the Social Security Act, other
7 than subsections (a) and (b) and the first sen-
8 tence of subsection (c)(1) of such section, shall
9 apply to civil money penalties under this sub-
10 section in the same manner as such provisions
11 apply to a penalty or proceeding under section
12 1128A of the Social Security Act.

13 “(3) SAFE HARBOR.—The Secretary may ex-
14 empt a practitioner or facility from the penalties
15 under paragraph (2)(A) or extend the period of time
16 specified under subsection (a)(2) for compliance with
17 such subsection if a practitioner or facility—

18 “(A) makes a good-faith attempt to send a
19 bill within 30 days but is unable to do so be-
20 cause of an incorrect address; or

21 “(B) experiences extenuating cir-
22 cumstances (as defined by the Secretary), such
23 as a hurricane or cyberattack, that may reason-
24 ably delay delivery of a timely bill.”.

1 (2) RULEMAKING.—Not later than 1 year after
2 the date of enactment of this Act, the Secretary
3 shall promulgate final regulations to define the term
4 “extenuating circumstance” for purposes of section
5 399V–7(c)(3)(B) of the Public Health Service Act,
6 as added by paragraph (1).

7 (b) GROUP HEALTH PLAN AND HEALTH INSURANCE
8 ISSUER REQUIREMENTS.—Subpart II of part A of title
9 XXVII of the Public Health Service Act (42 U.S.C.
10 300gg–11), as amended by the preceding sections, is fur-
11 ther amended by adding at the end the following:

12 **“SEC. 2729D. TIMELY BILLS FOR PATIENTS.**

13 “(a) IN GENERAL.—A group health plan or health
14 insurance issuer offering group or individual health insur-
15 ance coverage shall have in place business practices with
16 respect to in-network facilities and practitioners to ensure
17 that claims are adjudicated in order to facilitate facility
18 and practitioner compliance with the requirements under
19 section 399V–7(a).

20 “(b) CLARIFICATION.—Nothing in subsection (a) pro-
21 hibits a provider and a group health plan or health insur-
22 ance issuer from establishing in a contract the timeline
23 for submission by either party to the other party of billing
24 information, adjudication, sending of remittance informa-
25 tion, or any other coordination required between the pro-

1 vider and the plan or issuer necessary for meeting the
2 deadline described in section 399V-7(a)(2).”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 subsections (a) and (b) shall take effect 6 months after
5 the date of enactment of this Act.

6 **SEC. 328. ADVISORY GROUP ON REDUCING BURDEN OF**
7 **HOSPITAL ADMINISTRATIVE REQUIREMENTS.**

8 (a) IN GENERAL.—Not later than January 1, 2021,
9 the Secretary of Health and Human Services shall convene
10 an advisory group to provide, in accordance with this sec-
11 tion, recommendations on ways the Federal Government
12 could reduce the burden of administrative requirements on
13 hospitals.

14 (b) RECOMMENDATIONS.—Not later than January 1,
15 2022, the advisory board convened under this section
16 shall—

17 (1) submit to the Secretary of Health and
18 Human Services recommendations described under
19 subsection (a) for executive action and any rec-
20 ommendations for State actions for potential consid-
21 eration in making grants under section 2(c) to
22 States; and

23 (2) submit to Congress recommendations de-
24 scribed under subsection (a) for legislative proposals.

1 (c) MEMBERSHIP.—The advisory board under this
2 section shall consist of the following members:

3 (1) Three representatives of companies that
4 have—

5 (A) geographically distributed workforces;

6 (B) at least 10,000 employees; and

7 (C) no more than 10 percent of such em-
8 ployees in any single State.

9 (2) Three representatives of health insurance
10 issuers and health plans, consisting of—

11 (A) one representative of for-profit health
12 insurance issuers and health plans with at least
13 20,000,000 enrollees in the employer-sponsored
14 market;

15 (B) one representative of non-profit health
16 insurance issuers and health plans operating in
17 at least 5 States; and

18 (C) one representative of non-profit health
19 insurance issuers and health plans operating in
20 a rural State (as defined by the Census Bu-
21 reau).

22 (3) Seven public policy experts in the field of
23 hospital consolidation.

1 **SEC. 329. 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. 330. 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, 2021, 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 **SEC. 331. EMPLOYER BENEFITS REPORTS.**

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

8 (1) The amount the sponsor of such group
9 health plan expended with respect to such individual
10 under such plan for such plan year (or, in the case
11 of a health insurance issuer offering group health in-
12 surance coverage, the amount the employer of such
13 individual contributed for such coverage for such in-
14 dividual for such plan year).

15 (2) The amount the sponsor of such group
16 health plan expended with respect to such individual
17 under such plan for each previous plan year (or, in
18 the case of a health insurance issuer offering group
19 health insurance coverage, the amount the employer
20 of such individual contributed for such coverage for
21 such individual for each previous plan year), if appli-
22 cable.

23 (b) LIMITATION.—Subsection (a) shall not apply to
24 a group health plan, or a health insurance issuer offering
25 group health insurance coverage, for a plan year if, for

1 such plan year, the number of individuals enrolled under
2 such plan or such coverage was less than 100.

3 (c) PENALTY.—In the case that the Secretary of
4 Health and Human Services determines that a group
5 health plan or a health insurance issuer offering group
6 health insurance failed to provide the notice required
7 under subsection (a), the Secretary may impose a civil
8 monetary penalty on the sponsor of such plan or such
9 issuer, as applicable, in an amount not to exceed \$100
10 per individual enrolled in such plan or such coverage per
11 day that such sponsor or issuer failed to provide such noti-
12 fication to such individual.

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

18 **SEC. 332. GROUP HEALTH PLAN REPORTING REQUIRE-**
19 **MENTS.**

20 Part C of title XXVII of the Public Health Service
21 Act (42 U.S.C. 300gg–91 et seq.), as amended by the pre-
22 ceding sections, is further amended by adding at the end
23 the following:

1 **“SEC. 2797. GROUP HEALTH PLAN REPORTING.**

2 “(a) IN GENERAL.—A group health plan or health
3 insurance issuer offering group or individual health insur-
4 ance coverage shall submit to the Secretary, not later than
5 March 1 of each year, the following information with re-
6 spect to the health plan in the previous plan year:

7 “(1) The beginning and end dates of the plan
8 year.

9 “(2) The number of enrollees.

10 “(3) Each State in which the plan is offered.

11 “(4) The 50 brand prescription drugs most fre-
12 quently dispensed by pharmacies for claims paid by
13 the issuer, and the total number of paid claims for
14 each such drug.

15 “(5) The 50 most costly prescription drugs with
16 respect to the plan by total annual spending, and the
17 annual amount spent by the plan for each such
18 drug.

19 “(6) The 50 prescription drugs with the great-
20 est increase in plan expenditures over the plan year
21 preceding the plan year that is the subject of the re-
22 port, and, for each such drug, the change in
23 amounts expended by the plan in each such plan
24 year.

25 “(7) Total spending on health care services by
26 such group health plan, broken down by—

- 1 “(A) the type of costs, including—
- 2 “(i) hospital costs;
- 3 “(ii) health care provider and clinical
- 4 service costs;
- 5 “(iii) costs for prescription drugs; and
- 6 “(iv) other medical costs; and
- 7 “(B) spending on prescription drugs by—
- 8 “(i) the health plan; and
- 9 “(ii) the enrollees.
- 10 “(8) The average monthly premium—
- 11 “(A) paid by employers on behalf of enroll-
- 12 ees; and
- 13 “(B) paid by enrollees.
- 14 “(9) Any impact on premiums by rebates, fees,
- 15 and any other remuneration paid by drug manufac-
- 16 turers to the plan or its administrators or service
- 17 providers, with respect to prescription drugs pre-
- 18 scribed to enrollees in the plan, including—
- 19 “(A) the amounts so paid for each thera-
- 20 peutic class of drugs; and
- 21 “(B) the amounts so paid for each of the
- 22 25 drugs that yielded the highest amount of re-
- 23 bates and other remuneration under the plan
- 24 from drug manufacturers during the plan year.

1 “(10) Any reduction in premiums and out-of-
2 pocket costs associated with rebates, fees, or other
3 remuneration described in paragraph (9).

4 “(b) REPORT.—Not later than 18 months after the
5 date on which the first report is required under subsection
6 (a) and biannually thereafter, the Secretary, acting
7 through the Assistant Secretary of Planning and Evalua-
8 tion and in coordination with the Inspector General of the
9 Department of Health and Human Services, shall make
10 available on the internet website of the Department of
11 Health and Human Services a report on prescription drug
12 reimbursements under group health plans, prescription
13 drug pricing trends, and the role of prescription drug costs
14 in contributing to premium increases or decreases under
15 such plans, aggregated in such a way as no drug or plan
16 specific information will be made public.

17 “(c) PRIVACY PROTECTIONS.—No confidential or
18 trade secret information submitted to the Secretary under
19 subsection (a) shall be included in the report under sub-
20 section (b).”.

1 **SEC. 333. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**
2 **ON PROFIT- AND REVENUE-SHARING IN**
3 **HEALTH CARE.**

4 (a) STUDY.—Not later than 1 year after the date of
5 enactment of this Act, the Comptroller General of the
6 United States shall conduct a study to—

7 (1) describe what is known about profit- and
8 revenue-sharing relationships in the commercial
9 health care markets, including those relationships
10 that—

11 (A) involve one or more—

12 (i) physician groups that practice
13 within a hospital included in the profit- or
14 revenue-sharing relationship, or refer pa-
15 tients to such hospital;

16 (ii) laboratory, radiology, or pharmacy
17 services that are delivered to privately in-
18 sured patients of such hospital;

19 (iii) surgical services;

20 (iv) hospitals or group purchasing or-
21 ganizations; or

22 (v) rehabilitation or physical therapy
23 facilities or services; and

24 (B) include revenue- or profit-sharing
25 whether through a joint venture, management

1 or professional services agreement, or other
2 form of gain-sharing contract;

3 (2) describe Federal oversight of such relation-
4 ships, including authorities of the Department of
5 Health and Human Services and the Federal Trade
6 Commission to review such relationships and their
7 potential to increase costs for patients, and identify
8 limitations in such oversight; and

9 (3) as appropriate, make recommendations to
10 improve Federal oversight of such relationships.

11 (b) REPORT.—Not later than 1 year after the date
12 of enactment of this Act, the Comptroller General of the
13 United States shall prepare and submit a report on the
14 study conducted under subsection (a) to the Committee
15 on Health, Education, Labor, and Pensions of the Senate
16 and the Committee on Education and Labor and Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives.

1 **Subtitle C—Prescription Drug**
2 **Competition and Innovation**

3 **SEC. 341. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
4 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
5 **UCTS.**

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

9 **“SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
10 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
11 **UCTS.**

12 “(a) ESTABLISHMENT OF PROGRAM.—The Secretary
13 shall establish a program to expedite the development of,
14 and provide priority review under section 505(j) for, ge-
15 neric complex drug products.

16 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
17 generic complex drug product may request that the Sec-
18 retary designate such product for expedited development
19 and priority review under this section.

20 “(c) DESIGNATION PROCESS.—

21 “(1) IN GENERAL.—Not later than 60 calendar
22 days after the receipt of a request under subsection
23 (c), the Secretary shall determine whether the prod-
24 uct that is the subject of the request meets the cri-
25 teria under subsection (e) to be considered a generic

1 complex drug product. If the Secretary determines
2 that the product meets the criteria, the Secretary
3 shall designate the product for expedited develop-
4 ment and priority review.

5 “(2) REVIEW.—Review of a request under sub-
6 section (b) shall be undertaken by a team that is
7 composed of experienced staff and senior managers
8 of the Food and Drug Administration.

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

14 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
15 VIEW GUIDANCE.—

16 “(1) CONTENT.—Not later than December 31,
17 2021, the Secretary shall issue guidance on the im-
18 plementation of this section. Such guidance shall—

19 “(A) set forth the process by which a per-
20 son may seek a designation under subsection
21 (c);

22 “(B) provide a template for requests under
23 subsection (b);

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

4 “(D) identify the criteria and processes the
5 Secretary will use to expedite the development
6 and review of products designated under this
7 section.

8 “(2) PROCESS.—Prior to finalizing the guid-
9 ance under paragraph (1), the Secretary shall seek
10 public comment on a draft version of that guidance.

11 “(e) GENERIC COMPLEX DRUG PRODUCT DE-
12 FINED.—In this section, the term ‘generic complex drug
13 product’ means a product that represents a complex ther-
14 apy that consists of or includes a drug for approval under
15 section 505(j) and that—

16 “(1)(A) contains complex active ingredients
17 (such as peptides, polymeric compounds, complex
18 mixtures of active ingredients, and naturally sourced
19 ingredients);

20 “(B) is composed of complex formulations (such
21 as liposomes or colloids);

22 “(C) requires a complex route of delivery (such
23 as locally acting drugs such as dermatological prod-
24 ucts and complex ophthalmological products and otic

1 dosage forms that are formulated as suspensions,
2 emulsions, or gels); or

3 “(D) involves a complex dosage form (such as
4 transdermals, metered dose inhalers, or extended re-
5 lease injectables);

6 “(2) presents as a complex drug-device com-
7 bination product (such as auto injectors or metered
8 dose inhalers); or

9 “(3) is a product that would benefit from early
10 scientific engagement due to complexity or uncer-
11 tainty concerning the approval pathway under sec-
12 tion 505(j).”.

13 **SEC. 342. PREVENTING BLOCKING OF GENERIC DRUGS.**

14 (a) IN GENERAL.—Section 505(j)(5)(B)(iv)(I) of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355(j)(5)(B)(iv)(I)) is amended—

17 (1) by striking “180 days after the date” and
18 inserting “180 days after the earlier of the fol-
19 lowing:

20 “(aa) The date”; and

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

22 “(bb) The date on which all of the fol-
23 lowing conditions are first met, provided
24 no application submitted by any first appli-
25 cant is approved on or before such date:

1 “(AA) An application for the
2 drug submitted by an applicant other
3 than a first applicant has received
4 tentative approval and could receive
5 approval, if no first applicant were eli-
6 gible for 180-day exclusivity under
7 this clause, and such applicant has
8 not entered into an agreement that
9 would prevent commercial marketing
10 upon approval and has submitted a
11 notification to the Secretary docu-
12 menting that it has not entered into
13 an agreement that would prevent com-
14 mercial marketing.

15 “(BB) Thirty-three months have
16 passed since the date of submission of
17 an application for the drug by one
18 first applicant, if there is only one
19 first applicant, or, in the case of more
20 than one first applicant, 33 months
21 have passed since the date of submis-
22 sion of all such applications.

23 “(CC) Approval of an application
24 for the drug submitted by at least one

1 first applicant would not be precluded
2 under clause (iii).”.

3 (b) INFORMATION.—Not later than 60 days of the
4 date of enactment of this Act, the Secretary of Health and
5 Human Services (referred to in this subsection as the
6 “Secretary”) shall publish, as appropriate and available,
7 information sufficient to allow applicants to assess wheth-
8 er the conditions described in subitems (AA) through (CC)
9 of section 505(j)(5)(B)(iv)(I)(bb) of the Federal Food,
10 Drug, and Cosmetic Act (as amended by subsection (a))
11 have been or will be satisfied for all applications where
12 the exclusivity period under (iv)(I) of section 505(j)(5)(B)
13 of the Federal Food, Drug, and Cosmetic Act (as so
14 amended) has not expired, and shall provide updates to
15 reflect the most recent information available to the Sec-
16 retary.

17 **SEC. 343. ENSURING TIMELY ACCESS TO GENERICS.**

18 Section 505(q) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355(q)) is amended—

20 (1) in paragraph (1)—

21 (A) in subparagraph (A)(i), by inserting “,
22 10.31,” after “10.30”;

23 (B) in subparagraph (E)—

24 (i) by striking “application and” and
25 inserting “application or”;

1 (ii) by striking “If the Secretary” and
2 inserting the following:

3 “(i) IN GENERAL.—If the Secretary”;
4 and

5 (iii) by striking the second sentence
6 and inserting the following:

7 “(ii) PRIMARY PURPOSE OF DELAY-
8 ING.—

9 “(I) IN GENERAL.—In deter-
10 mining whether a petition was sub-
11 mitted with the primary purpose of
12 delaying an application, the Secretary
13 may consider the following factors:

14 “(aa) Whether the petition
15 was submitted in accordance with
16 paragraph (2)(B), based on when
17 the petitioner knew or reasonably
18 should have known the relevant
19 information relied upon to form
20 the basis of such petition.

21 “(bb) Whether the petitioner
22 has submitted multiple or serial
23 petitions or supplements to peti-
24 tions raising issues that reason-
25 ably could have been known to

1 the petitioner at the time of sub-
2 mission of the earlier petition or
3 petitions.

4 “(cc) Whether the petition
5 was submitted close in time to a
6 known, first date upon which an
7 application under subsection
8 (b)(2) or (j) of this section or
9 section 351(k) of the Public
10 Health Service Act could be ap-
11 proved.

12 “(dd) Whether the petition
13 was submitted without relevant
14 data or information in support of
15 the scientific positions forming
16 the basis of such petition.

17 “(ee) Whether the petition
18 raises the same or substantially
19 similar issues as a prior petition
20 to which the Secretary has re-
21 sponded substantively already, in-
22 cluding if the subsequent submis-
23 sion follows such response from
24 the Secretary closely in time.

1 “(ff) Whether the petition
2 requests changing the applicable
3 standards that other applicants
4 are required to meet, including
5 requesting testing, data, or label-
6 ing standards that are more on-
7 erous or rigorous than the stand-
8 ards the Secretary has deter-
9 mined to be applicable to the list-
10 ed drug, reference product, or pe-
11 titioner’s version of the same
12 drug.

13 “(gg) The petitioner’s record
14 of submitting petitions to the
15 Food and Drug Administration
16 that have been determined by the
17 Secretary to have been submitted
18 with the primary purpose of
19 delay.

20 “(hh) Other relevant and
21 appropriate factors, which the
22 Secretary shall describe in guid-
23 ance.

24 “(II) GUIDANCE.—The Secretary
25 may issue or update guidance, as ap-

1 appropriate, to describe factors the Sec-
2 retary considers in accordance with
3 subclause (II).”;

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

5 “(iii) REFERRAL TO THE FEDERAL
6 TRADE COMMISSION.—The Secretary shall
7 establish procedures for referring to the
8 Federal Trade Commission any petition or
9 supplement to a petition that the Secretary
10 determines was submitted with the primary
11 purpose of delaying approval of an applica-
12 tion. Such procedures shall include notifi-
13 cation to the petitioner by the Secretary.”;

14 (D) by striking subparagraph (F);

15 (E) by redesignating subparagraphs (G)
16 through (I) as subparagraphs (F) through (H),
17 respectively; and

18 (F) in subparagraph (H), as so redesign-
19 ated, by striking “submission of this petition”
20 and inserting “submission of this document”;

21 (2) in paragraph (2)—

22 (A) by redesignating subparagraphs (A)
23 through (C) as subparagraphs (C) through (E),
24 respectively;

1 (B) by inserting before subparagraph (C),
2 as so redesignated, the following:

3 “(A) IN GENERAL.—A person shall submit
4 a petition to the Secretary under paragraph (1)
5 before filing a civil action in which the person
6 seeks to set aside, delay, rescind, withdraw, or
7 prevent submission, review, or approval of an
8 application submitted under subsection (b)(2)
9 or (j) of this section or section 351(k) of the
10 Public Health Service Act. Such petition and
11 any supplement to such a petition shall describe
12 all information and arguments that form the
13 basis of the relief requested in any civil action
14 described in the previous sentence.

15 “(B) TIMELY SUBMISSION OF CITIZEN PE-
16 TITION.—A petition and any supplement to a
17 petition shall be submitted within 60 days after
18 the person knew, or reasonably should have
19 known, the information that forms the basis of
20 the request made in the petition or supple-
21 ment.”;

22 (C) in subparagraph (C), as so redesign-
23 ated—

24 (i) in the heading, by striking “WITH-
25 IN 150 DAYS”;

1 (ii) in clause (i), by striking “during
2 the 150-day period referred to in para-
3 graph (1)(F),”; and

4 (iii) by amending clause (ii) to read as
5 follows:

6 “(ii) on or after the date that is 151
7 days after the date of submission of the
8 petition, the Secretary approves or has ap-
9 proved the application that is the subject
10 of the petition without having made such a
11 final decision.”;

12 (D) by amending subparagraph (D), as so
13 redesignated, to read as follows:

14 “(D) DISMISSAL OF CERTAIN CIVIL AC-
15 TIONS.—

16 “(i) PETITION.—If a person files a
17 civil action against the Secretary in which
18 a person seeks to set aside, delay, rescind,
19 withdraw, or prevent submission, review, or
20 approval of an application submitted under
21 subsection (b)(2) or (j) of this section or
22 section 351(k) of the Public Health Service
23 Act without complying with the require-
24 ments of subparagraph (A), the court shall

1 dismiss without prejudice the action for
2 failure to exhaust administrative remedies.

3 “(ii) TIMELINESS.—If a person files a
4 civil action against the Secretary in which
5 a person seeks to set aside, delay, rescind,
6 withdraw, or prevent submission, review, or
7 approval of an application submitted under
8 subsection (b)(2) or (j) of this section or
9 section 351(k) of the Public Health Service
10 Act without complying with the require-
11 ments of subparagraph (B), the court shall
12 dismiss with prejudice the action for fail-
13 ure to timely file a petition.

14 “(iii) FINAL RESPONSE.—If a civil ac-
15 tion is filed against the Secretary with re-
16 spect to any issue raised in a petition time-
17 ly filed under paragraph (1) in which the
18 petitioner requests that the Secretary take
19 any form of action that could, if taken, set
20 aside, delay, rescind, withdraw, or prevent
21 submission, review, or approval of an appli-
22 cation submitted under subsection (b)(2)
23 or (j) of this section or section 351(k) of
24 the Public Health Service Act before the
25 Secretary has taken final agency action on

1 the petition within the meaning of sub-
2 paragraph (C), the court shall dismiss
3 without prejudice the action for failure to
4 exhaust administrative remedies.”; and

5 (E) in clause (iii) of subparagraph (E), as
6 so redesignated, by striking “as defined under
7 subparagraph (2)(A)” and inserting “within the
8 meaning of subparagraph (C)”;

9 (3) in paragraph (4)—

10 (A) by striking “EXCEPTIONS” and all that
11 follows through “This subsection does” and in-
12 serting “EXCEPTIONS.—This subsection does”;

13 (B) by striking subparagraph (B); and

14 (C) by redesignating clauses (i) and (ii) as
15 subparagraphs (A) and (B), respectively, and
16 adjusting the margins accordingly.

17 **SEC. 344. PREEMPTION OF STATE BARRIERS TO THE SUB-**
18 **STITUTION OF BIOSIMILAR PRODUCTS.**

19 No State, or any political subdivision thereof, may,
20 under any circumstances, prohibit a pharmacy or phar-
21 macist from dispensing, in place of a biological reference
22 product, any biosimilar that the Food and Drug Adminis-
23 tration has designated as an interchangeable product for
24 that biological reference product.

1 **SEC. 345. INCREASING PHARMACEUTICAL OPTIONS TO**
2 **TREAT AN UNMET MEDICAL NEED.**

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

6 “(4) UNMET MEDICAL NEED.—For purposes of
7 paragraph (1), a drug shall be deemed to address an
8 unmet medical need for a disease or condition if
9 fewer than 3 available drugs exist for the treatment
10 of such disease or condition.”.

11 **SEC. 346. PROVISIONAL APPROVAL OF NEW HUMAN DRUGS.**

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

15 **“SEC. 524B. PROVISIONAL APPROVAL OF NEW HUMAN**
16 **DRUGS.**

17 “(a) PRIORITY REVIEW AND EVALUATION OF APPLI-
18 CATIONS.—

19 “(1) IN GENERAL.—The Secretary shall estab-
20 lish a priority review system to evaluate applications
21 submitted under this pathway for provisional ap-
22 proval within 90 days of receipt of a completed ap-
23 plication.

24 “(2) REVIEW OF APPLICATIONS DURING
25 EPIDEMICS AND PANDEMICS.—In the case of an epi-
26 demic or pandemic, including with respect to

1 COVID–19, the Secretary shall accept and review
2 various portions of an application submitted under
3 the pathway under this section for provisional ap-
4 proval on a rolling basis, and the review of any part
5 of an application so submitted shall be completed
6 not later than 3 weeks after submission.

7 “(3) OTHER DESIGNATIONS.—If a drug sub-
8 mitted for review under the pathway under this sec-
9 tion is eligible for a special designation by the Sec-
10 retary under this Act, including as a drug for a rare
11 disease or condition under section 526, all benefits
12 of such other designation shall be available for use
13 under provisional approval, including any tax credits
14 and waiving of fees under chapter VII.

15 “(b) ELIGIBILITY.—A drug may be eligible for provi-
16 sional approval under this section if the Secretary deter-
17 mines that the drug is intended for the treatment, preven-
18 tion, or medical diagnosis of—

19 “(1) a serious or life-threatening disease or con-
20 dition for which there is a reasonable likelihood that
21 premature death will occur without early medical
22 intervention for an individual contracting or being
23 diagnosed with such disease or condition;

24 “(2) a disease or condition that poses a threat
25 of epidemic or pandemic; or

1 “(3) a disease or condition associated with mor-
2 bidity that has a substantial impact on day-to-day
3 functioning.

4 “(c) STANDARD OF REVIEW FOR APPROVAL.—

5 “(1) REQUIREMENTS.—An application for pro-
6 visional approval under this section may be approved
7 only if the Secretary determines that—

8 “(A) there is substantial evidence of safety
9 for the drug, such that there is evidence con-
10 sisting of adequate and well-controlled inves-
11 tigations, including clinical investigations, by
12 experts qualified by scientific training and expe-
13 rience to evaluate the safety of the drug in-
14 volved, on the basis of which it could fairly and
15 responsibly be concluded that the drug will have
16 the effect it purports or is represented to have
17 under the conditions of use prescribed, rec-
18 ommended, or suggested in the labeling or pro-
19 posed labeling; and

20 “(B) there is relevant early evidence based
21 on adequate and well-controlled investigations,
22 including early-stage clinical investigations, to
23 establish that—

24 “(i) the drug provides a positive
25 therapeutic outcome; and

1 “(ii) the outcome of the drug is con-
2 sistent with or greater than currently mar-
3 keted on-label therapies, with equal or
4 fewer side effects, if there are currently
5 marketed on-label therapies.

6 “(2) PROTOCOLS.—The Secretary shall promul-
7 gate rules that establish the appropriate protocols
8 for a sponsor of an application for provisional ap-
9 proval under this section and the Commissioner to
10 follow to enable rolling, real-time, mid-trial submis-
11 sion while preserving the integrity of the ongoing
12 trial and without penalizing the sponsor for making
13 use of this pathway.

14 “(3) REAL WORLD EVIDENCE.—The Secretary
15 shall allow the use of real world evidence (as defined
16 in section 505F(b)), including real world data used
17 to generate real world evidence, to support an appli-
18 cation for provisional approval under this section,
19 and to fulfill the follow-up requirements and support
20 applications for full approval as described under sec-
21 tion 505 or section 351 of the Public Health Service
22 Act, as applicable.

23 “(4) USE OF SCIENTIFICALLY SUBSTANTIATED
24 SURROGATES.—

1 “(A) IN GENERAL.—The sponsor of an ap-
2 plication for provisional approval under this sec-
3 tion may use scientifically substantiated surro-
4 gates to support such application.

5 “(B) DEFINITION.—In subparagraph (A),
6 the term ‘scientifically substantiated surrogates’
7 means surrogate endpoints to predict clinical
8 benefit other than such endpoints previously
9 validated by the Secretary, based on—

10 “(i) epidemiologic, therapeutic, patho-
11 physiologic, or other evidence; or

12 “(ii) an effect on a clinical endpoint
13 other than survival or irreversible mor-
14 bidity of interest.

15 “(d) TRANSPARENCY AND PATIENT MONITORING
16 REQUIREMENTS.—

17 “(1) REGISTRIES.—

18 “(A) IN GENERAL.—The sponsor of a drug
19 provisionally approved under this section shall
20 require that all patients who use such drug par-
21 ticipate in an observational registry and consent
22 to the sponsor’s collection, and submission to
23 the registry, of data related to the patient’s use
24 of such drug until such drug receives full ap-
25 proval under section 505 or section 351 of the

1 Public Health Service Act, or the provisional
2 approval is rescinded.

3 “(B) REQUIREMENTS FOR REGISTRIES.—
4 An observational registry described in subpara-
5 graph (A) may be run by a third party, such as
6 a government, for profit, or non-profit organiza-
7 tion, and shall track all patients who use the
8 provisionally approved drug.

9 “(C) ACCESSIBILITY.—An observational
10 registry described in subparagraph (A) shall be
11 easily accessible for—

12 “(i) all patients who are participating
13 in any registry related to a provisionally
14 approved drug that allows for easy, unre-
15 stricted (or transparent) access for such
16 patients to their patient data and related
17 information regarding their usage of the
18 provisionally approved drug; and

19 “(ii) approved researchers and med-
20 ical professionals who may access data
21 maintained in the registry, which access
22 shall be for public health research and only
23 in a de-identified, aggregated manner.

1 “(2) FUNDING.—An observational registry
2 under this subsection shall be maintained, as appli-
3 cable—

4 “(A) by the sponsor of the drug provision-
5 ally approved under this section that is the sub-
6 ject of the registry;

7 “(B) by a third party, such as a govern-
8 ment, for profit, or nonprofit organization; or

9 “(C) the Federal Government, in the case
10 of any drug so approved that is intended to
11 treat a disease or condition associated with an
12 epidemic or pandemic.

13 “(3) SPONSOR REQUIREMENTS.—

14 “(A) IN GENERAL.—For any drug applica-
15 tion provisionally approved under this section,
16 the Secretary shall notify the sponsor of the
17 exact data such sponsor is required to submit
18 to an observational registry.

19 “(B) ANNUAL REVIEW OF THE REGISTRY;
20 PENALTIES.—The Secretary shall conduct an
21 annual review of observational registries estab-
22 lished under this subsection. If, at such an an-
23 nual review, less than 90 percent of patients are
24 participating in an observational registry with
25 respect to a drug approved under this section,

1 the Secretary shall issue to the sponsor of such
2 drug a civil monetary penalty of not more than
3 \$100,000. If a violation of this section is not
4 corrected within the 30-day period following no-
5 tification, the sponsor shall, in addition to any
6 penalty under this subparagraph be subject to
7 a civil monetary penalty of not more than
8 \$10,000 for each day of the violation after such
9 period until the violation is corrected. If appli-
10 cation patient participation in an observational
11 registry is not at or above 90 percent within 6
12 months of issuance of such penalty, the provi-
13 sional approval shall be withdrawn.

14 “(4) ANNUAL REPORT TO CONGRESS.—The
15 Secretary shall submit an annual report to Congress
16 on all drugs granted provisional approval under this
17 section. Such report shall include—

18 “(A) the number of patients treated with
19 each such drug, and the number of patients
20 tracked in an observational registry with re-
21 spect to each such drug;

22 “(B) a discussion of the minimum amount
23 of data required in the registries, including pa-
24 tient treatments and uses, length of use, side
25 effects encountered, relevant biomarkers or sci-

1 entifically substantiated surrogates, scan re-
2 sults, cause of death and how long the patient
3 lived, and adverse drug effects;

4 “(C) a list of all such drugs for which an
5 application for full approval under section 505
6 of this Act or section 351 of the Public Health
7 Service Act, or an application for an extension
8 of provisional approval under this section, has
9 been submitted; and

10 “(D) a list of all applications denied provi-
11 sional approval under this section, together with
12 an explanation for the decisions to deny each
13 such application.

14 “(e) WITHDRAWAL OF PROVISIONAL APPROVAL.—

15 “(1) IN GENERAL.—The Secretary shall with-
16 draw provisional approval under this section if there
17 are a significant number of patients who experience
18 serious adverse effects, compared to the other cur-
19 rently marketed on-label therapies that are available
20 for the applicable disease or condition.

21 “(2) EFFECT OF WITHDRAWAL.—If a provi-
22 sional approval is withdrawn under this subsection,
23 the sponsor may not make the drug available to any
24 new patients, but may be allowed to continue to
25 make such drug available to patients who started

1 taking the drug prior to the date of withdrawal, for
2 as long a period as dictated by patient need, as de-
3 termined by the Secretary.

4 “(f) TRANSPARENCY.—Any scientific, medical, aca-
5 demic, or health care journal publishing an article explain-
6 ing, releasing, conveying or announcing research findings
7 which were funded by the Department of Health and
8 Human Services shall be prohibited from publishing such
9 research unless—

10 “(1) such article conveying research findings is
11 made publicly available on the journal’s internet
12 website without a paywall or charge not later than
13 3 months after the date on which such article was
14 first provided to subscribers of such journal (or first
15 made available for purchase); and

16 “(2) the article’s author or researcher or au-
17 thor’s institution (or, in the case of multiple authors,
18 researchers, or institutions, all such authors, re-
19 searchers, or institutions) received less than 30 per-
20 cent of funding for such research from the Depart-
21 ment of Health and Human Services throughout the
22 period of time the research was conducted.

23 “(g) INFORMED CONSENT.—Prior to receiving a drug
24 provisionally approved under this section, the sponsor of
25 the drug shall receive from each patient, or the patient’s

1 representative, informed consent, through a signed in-
2 formed consent form, acknowledging that such patient un-
3 derstands that the drug did not undergo the usual process
4 for full approval of a drug by the Food and Drug Adminis-
5 tration, and that such patient is willing to accept the risks
6 involved in taking such drug.

7 “(h) POSTMARKET CONTROLS AND LABELING.—

8 “(1) FDA ANNUAL REVIEW OF REGISTRY
9 DATA.—The Secretary shall annually review the data
10 made available through the observational registries
11 under subsection (d) and make a determination re-
12 garding whether the side effect profile of any drug
13 approved under this pathway does not support the
14 benefit provided, or the data shows the benefit is
15 less than the benefits offered through other, fully
16 approved drugs.

17 “(2) LABELING.—The sponsor of the provision-
18 ally approved drug shall ensure that all labeling and
19 promotional materials for the drug bear the state-
20 ment ‘provisionally approved by the FDA pending a
21 full demonstration of effectiveness under application
22 number _____’ (specifying the application
23 number assigned by the Secretary in place of the
24 blank). All promotional, educational and marketing
25 materials for provisionally approved products shall

1 be reviewed and approved by the Secretary before
2 such materials are distributed.

3 “(3) RESCISSION OF PROVISIONAL AP-
4 PROVAL.—If the Secretary determines that the side
5 effect profile of any drug included in such observa-
6 tional registries does not support the benefit pro-
7 vided by such drug, or that the data shows that the
8 benefit is less than the benefits offered through
9 other, fully approved drugs, the Secretary shall re-
10 scind such provisional approval.

11 “(i) DURATION OF PROVISIONAL APPROVAL; RE-
12 QUIREMENT TO BRING DRUG TO MARKET.—

13 “(1) DURATION; RENEWALS.—The period of
14 provisional approval for a drug approved under this
15 section is effective for a 2-year period. The sponsor
16 may request renewal for provisional approval status
17 for up to 3 subsequent 2-year periods by the Sec-
18 retary. Provisional approval status with respect to a
19 drug shall not exceed a total of 6 years from the ini-
20 tial date the sponsor was awarded provisional ap-
21 proval status.

22 “(2) MARKETING REQUIREMENT.—If any drug
23 that receives provisional approval status under this
24 section is not brought to market within 180 days of
25 the approval, such approval shall be rescinded.

1 “(j) LIMITATION ON LIABILITY.—With respect to any
2 claim under State law alleging that a drug sold or other-
3 wise made available pursuant to a grant of provisional ap-
4 proval under this section is unsafe or ineffective, no liabil-
5 ity in a cause of action shall lie against a sponsor or manu-
6 facturer, unless the relevant conduct constitutes reckless
7 or willful misconduct, gross negligence, or an intentional
8 tort under any applicable State law.

9 “(k) APPLYING FOR FULL APPROVAL.—

10 “(1) IN GENERAL.—Except as provided under
11 paragraph (2), the sponsor of a drug granted provi-
12 sional approval pursuant to this section may, at any
13 point, submit an application for full approval of such
14 drug under section 505 of this Act or section 351
15 of the Public Health Service Act, as applicable.

16 “(2) EFFECT OF RECESSION ON APPROVAL AND
17 AUTOMATIC APPROVAL.—

18 “(A) IN GENERAL.—The sponsor of a drug
19 granted provisional approval pursuant to this
20 section that has been rescinded under sub-
21 section (h)(3), may submit an application for
22 full approval of such drug under section 505 of
23 this Act or section 351 of the Public Health
24 Service Act at any time.

1 “(B) AUTOMATIC APPROVAL.—Such full
2 approval may be awarded at any time for any
3 drug granted provisional approval pursuant to
4 this section if the sponsor of the drug estab-
5 lishes a 15 percent improvement in an impor-
6 tant endpoint, including surrogate endpoints
7 not validated by the Food and Drug Adminis-
8 tration, compared to a standard drug.

9 “(3) REAL-TIME EPIDEMIC AND PANDEMIC VAC-
10 CINE APPROVAL.—

11 “(A) IN GENERAL.—In the case of a vac-
12 cine developed in response to an epidemic or
13 pandemic, including COVID–19, the Secretary
14 shall share data information regarding the ap-
15 proval of the vaccine with the Advisory Com-
16 mittee on Immunization Practices of the Cen-
17 ters for Disease Control and Prevention as the
18 review nears completion.

19 “(B) EVALUATION.—Any vaccine that has
20 been approved by the Secretary for an epidemic
21 or pandemic-related disease, including COVID–
22 19, shall be evaluated by the Advisory Com-
23 mittee on Immunization Practices of the Cen-
24 ters for Disease Control and Prevention not
25 later than 1 week after the date of submission

1 to the Advisory Committee by the Secretary of
2 the vaccine.

3 “(l) PATIENT ADVOCATE GENERAL.—Not later than
4 6 months after the date of enactment of the Promising
5 Pathway Act, the Secretary shall establish within the Of-
6 fice of the Commissioner, the position of Patient Advocate
7 General, who shall provide assistance to patients and their
8 families who use drugs under evaluation in this pathway
9 or drugs reviewed or approved under section 505 or sec-
10 tion 351 of the Public Health Service Act. Such assistance
11 shall include providing bi-informational communication
12 about maintaining patient health, delivery of proper in-
13 formed consent, participating in clinical investigations,
14 completing required documentation in order to participate
15 in the applicable programs, and providing other informa-
16 tion.”.

17 (b) CONFORMING AMENDMENT.—Section 505(a) of
18 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
19 355(a)) is amended by inserting “, or there is in effect
20 a provisional approval under section 524B with respect to
21 such drug” before the period.

22 (c) REIMBURSEMENT.—

23 (1) PRIVATE HEALTH INSURERS.—Section
24 2719A of the Public Health Service Act (42 U.S.C.

1 300gg–19a) is amended by adding at the end the
2 following:

3 “(e) TREATMENT OF CERTAIN DRUGS.—A group
4 health plan or health insurance issuer of group or indi-
5 vidual health insurance coverage shall not deny coverage
6 of any drug provisionally approved under section 524B of
7 the Federal Food, Drug, and Cosmetic Act on the basis
8 of such drug being experimental. In determining coverage
9 under the applicable plan or coverage, a group health plan
10 or health insurance issuer shall treat a drug provisionally
11 approved under such section in the same manner as such
12 plan or coverage would treat a drug approved under sec-
13 tion 505 of the Federal Food, Drug, and Cosmetic Act
14 or section 351 of this Act. Nothing in this subsection shall
15 be construed to require a group health plan or health in-
16 surance issuer to cover any specific drug provisionally ap-
17 proved under such section 524B.”.

18 (2) FEDERAL HEALTH CARE PROGRAMS.—The
19 requirement under subsection (e) of section 2719A
20 of the Public Health Service Act (as added by para-
21 graph (1)) shall apply with respect to coverage de-
22 terminations under a Federal health care program
23 (as defined in section 1128B(f) of the Social Secu-
24 rity Act (42 U.S.C. 1320a–7b(f))) in the same man-

1 ner such requirement applies under such subsection
2 (e).

3 (3) CONFORMING AMENDMENT.—Section
4 1927(k)(2)(A)(i) of the Social Security Act (42
5 U.S.C. 1396r–8(k)(2)(A)(i)) is amended—

6 (A) by striking “or which” and inserting “,
7 which”; and

8 (B) by inserting “, or which is provision-
9 ally approved under section 524B of such Act”
10 before the semicolon.

11 **SEC. 347. CONSOLIDATING EXCLUSIVITY PERIODS FOR**
12 **DRUGS TREATING RARE DISEASES AND CON-**
13 **DITIONS.**

14 (a) IN GENERAL.—Subsection (a) of section 527 of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 360cc) is amended to read as follows:

17 “(a) EXCLUSIVITY.—

18 “(1) IN GENERAL.—Except as provided in sub-
19 section (b), if the Secretary approves an application
20 filed pursuant to section 505, or issues a license
21 under section 351 of the Public Health Service Act,
22 for a drug designated under section 526 for a rare
23 disease or condition, the Secretary may not approve
24 an application filed pursuant to section 505, or issue
25 a license under section 351 of the Public Health

1 Service Act, for the same drug for the same disease
2 or condition for a person who is not the holder of
3 such approved application or of such license until
4 the expiration of the exclusivity period described in
5 paragraph (2).

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

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

14 “(B) in the case of a drug that has pre-
15 viously received a period of exclusivity under
16 paragraph (1), a single 3-year period of exclu-
17 sivity with respect to any subsequent designa-
18 tion of such drug under such section for any
19 other rare disease or condition.

20 “(3) LIMITATION.—In the case of a drug that
21 has received two periods of exclusivity pursuant to
22 paragraph (1), no additional exclusivity period under
23 this section is available with respect to such drug,
24 regardless of whether such drug has been designated
25 under section 526 for a rare disease or condition

1 that is distinct from the rare disease or condition for
2 which such exclusivity periods were granted.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) Section 505(j)(5)(B)(iv)(II)(dd)(AA) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 360cc) is amended by striking “7-year period” and
7 inserting “exclusivity period”.

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

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

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

22 (5) Section 527(b) of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 360cc) is amended by
24 striking “the 7-year period” and inserting “any ex-
25 clusivity period”.

1 (6) Section 351(m)(2)(B) of the Public Health
2 Service Act (42 U.S.C. 262) is amended by striking
3 “rather than 7 years” and inserting “or 3 years and
4 6 months, rather than 7 years or 3 years, respec-
5 tively”.

6 (7) Section 351(m)(3)(B) of the Public Health
7 Service Act (42 U.S.C. 262) is amended by striking
8 “rather than 7 years” and inserting “or 3 years and
9 6 months, rather than 7 years or 3 years, respec-
10 tively”.

11 **SEC. 348. EXCLUSIVITY PERIOD FOR BRAND NAME BIO-**
12 **LOGICAL PRODUCTS.**

13 (a) **IN GENERAL.**—Section 351(k)(7)(A) of the Pub-
14 lic Health Service Act (42 U.S.C. 262(k)(7)(A)) is amend-
15 ed by striking “12 years” and inserting “5 years”.

16 (b) **CONFORMING CHANGES.**—Paragraphs (2)(A) and
17 (3)(A) of section 351(m) of the Public Health Service Act
18 (42 U.S.C. 262(m)) is amended by striking “12 years”
19 each place it appears and inserting “5 years”.

20 (c) **APPLICABILITY.**—This Act and the amendments
21 made by this Act apply only with respect to a biological
22 product for which the reference product (as such term is
23 used in section 351 of the Public Health Service Act (42
24 U.S.C. 262)) is licensed under subsection (a) of such sec-
25 tion on or after the date of enactment of this Act.

1 **SEC. 349. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.**

2 Section 351(k)(7) of the Public Health Service Act
3 (42 U.S.C. 262(k)(7)) is amended by adding at the end
4 the following:

5 “(D) DEEMED LICENSES.—

6 “(i) NO ADDITIONAL EXCLUSIVITY
7 THROUGH DEEMING.—An approved appli-
8 cation that is deemed to be a license for a
9 biological product under this section pursu-
10 ant to section 7002(e)(4) of the Biologics
11 Price Competition and Innovation Act of
12 2009 shall not be treated as having been
13 first licensed under subsection (a) for pur-
14 poses of subparagraphs (A) and (B).

15 “(ii) APPLICATION OF LIMITATIONS
16 ON EXCLUSIVITY.—Subparagraph (C) shall
17 apply with respect to a reference product
18 referred to in such subparagraph that was
19 the subject of an approved application that
20 was deemed to be a license pursuant to
21 section 7002(e)(4) of the Biologics Price
22 Competition and Innovation Act of 2009.

23 “(iii) APPLICABILITY.—The exclu-
24 sivity periods described in section 527, sec-
25 tion 505A(b)(1)(A)(ii), and section
26 505A(c)(1)(A)(ii) of the Federal Food,

1 Drug, and Cosmetic Act shall continue to
2 apply to a biological product after an ap-
3 proved application for the biological prod-
4 uct is deemed to be a license for the bio-
5 logical product under subsection (a) pursu-
6 ant to section 7002(e)(4) of the Biologics
7 Price Competition and Innovation Act of
8 2009.”.

9 **SEC. 350. STREAMLINING THE TRANSITION OF BIOLOGICAL**
10 **PRODUCTS.**

11 Section 7002(e)(4) of the Biologics Price Competition
12 and Innovation Act of 2009 (Public Law 111–148) is
13 amended by adding at the end the following: “With respect
14 to an application for a biological product submitted under
15 section 505(b) of the Federal Food, Drug, and Cosmetic
16 Act (21 U.S.C. 355(b)) with a filing date that is not later
17 than September 23, 2019, and that does not receive final
18 approval on or before March 23, 2020, such application
19 shall be deemed to be withdrawn and the Secretary shall
20 refund the fee paid under section 736(a)(1)(B) of the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C.
22 379h(a)(1)(B)). Notwithstanding any such withdrawal of
23 the drug application, the Secretary shall consider any pre-
24 viously conducted scientific review and accelerate review
25 of any such subsequent application with respect to such

1 biological product under section 351 of the Public Health
2 Service Act (42 U.S.C. 262). The Secretary shall provide
3 additional assistance to the sponsor or manufacturer of
4 such application.”.

5 **SEC. 351. REGULATION OF MANUFACTURER-SPONSORED**
6 **COPAY CONTRIBUTIONS.**

7 Notwithstanding any other provision of law, the Sec-
8 retary of Health and Human Services may establish a
9 mechanism to regulate drug manufacturers’ financial con-
10 tributions to patient out-of-pocket costs, such as drug co-
11 pays.

12 **SEC. 352. ANTITRUST EXEMPTION FOR PRIVATE HEALTH**
13 **INSURER ISSUERS TO NEGOTIATE WHOLE-**
14 **SALE ACQUISITION PRICES OF PRESCRIP-**
15 **TION DRUGS PURCHASED FROM DRUG MANU-**
16 **FACTURERS.**

17 (a) EXEMPTION.—It shall not be a violation of the
18 antitrust laws for one or more private health insurer
19 issuers or their designated agents to jointly negotiate
20 wholesale acquisition prices of a prescription drug with a
21 manufacturer of a prescription drug with regards to the
22 reimbursement policies of the insurers of the manufactur-
23 er’s drugs so long as no one single wholesale acquisition
24 price is jointly determined between the insurance issuers
25 or their designated agents.

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

2 (1) ANTITRUST LAWS.—The term “antitrust
3 laws” has the meaning given it in subsection (a) of
4 the 1st section of the Clayton Act (15 U.S.C. 12(a)),
5 except that such term includes section 5 of the Fed-
6 eral Trade Commission Act (15 U.S.C. 45) to the
7 extent such section 5 applies to unfair methods of
8 competition.

9 (2) HEALTH INSURANCE ISSUER.—The term
10 “health insurance issuer” means an insurance com-
11 pany, insurance service, or insurance organization
12 (including a health maintenance organization, as de-
13 fined in subparagraph (C)) which is licensed to en-
14 gage in the business of insurance in a State and
15 which is subject to State law which regulates insur-
16 ance (within the meaning of section 514(b)(2) of the
17 Employee Retirement Income Security Act of 1974
18 (29 U.S.C. 1144(b)(2))). Such term does not include
19 a group health plan.

20 (3) HEALTH MAINTENANCE ORGANIZATION.—
21 The term “health maintenance organization”
22 means—

23 (A) a Federally qualified health mainte-
24 nance organization (as defined in section
25 300e(a) of title 42 of the United States Code),

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

3 (C) a similar organization regulated under
4 State law for solvency in the same manner and
5 to the same extent as such a health mainte-
6 nance organization.

7 (4) MANUFACTURER.—The term “manufac-
8 turer” means anyone who is engaged in manufac-
9 turing, preparing, propagating, compounding, proc-
10 essing, packaging, repackaging, or labeling of a pre-
11 scription drug.

12 (5) PRESCRIPTION DRUG.—The term “prescrip-
13 tion drug” means any human drug required by Fed-
14 eral law or regulation to be dispensed only by a pre-
15 scription, including finished dosage forms and active
16 ingredients subject to section 503(b) of the Federal
17 Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

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

21 **SEC. 353. BIOLOGICAL PRODUCT INNOVATION.**

22 Section 351(j) of the Public Health Service Act (42
23 U.S.C. 262(j)) is amended—

24 (1) by striking “except that a product” and in-
25 serting “except that—

1 “(1) a product”;

2 (2) by striking “Act.” and inserting “Act; and”;

3 and

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

5 “(2) no requirement under such Act regarding
6 an official compendium (as defined in section 201(j)
7 of such Act), or other reference in such Act to an
8 official compendium (as so defined), shall apply with
9 respect to a biological product subject to regulation
10 under this section.”.

11 **SEC. 354. CLARIFYING THE MEANING OF NEW CHEMICAL**

12 **ENTITY.**

13 (a) IN GENERAL.—Chapter V of the Federal Food,
14 Drug, and Cosmetic Act is amended—

15 (1) in section 505 (21 U.S.C. 355)—

16 (A) in subsection (c)(3)(E), by striking
17 “active ingredient (including any ester or salt of
18 the active ingredient)” each place it appears
19 and inserting “active moiety (as defined by the
20 Secretary in section 314.3 of title 21, Code of
21 Federal Regulations (or any successor regula-
22 tions))”;

23 (B) in subsection (j)(5)(F), by striking
24 “active ingredient (including any ester or salt of
25 the active ingredient)” each place it appears

1 and inserting “active moiety (as defined by the
2 Secretary in section 314.3 of title 21, Code of
3 Federal Regulations (or any successor regula-
4 tions))”;

5 (C) in subsection (l)(2)(A)—

6 (i) by amending clause (i) to read as
7 follows:

8 “(i) not later than 30 days after the date
9 of approval of such applications—

10 “(I) for a drug, no active moiety (as
11 defined by the Secretary in section 314.3
12 of title 21, Code of Federal Regulations (or
13 any successor regulations)) of which has
14 been approved in any other application
15 under this section; or

16 “(II) for a biological product, no ac-
17 tive ingredient of which has been approved
18 in any other application under section 351
19 of the Public Health Service Act; and”;
20 and

21 (ii) in clause (ii), by inserting “or bio-
22 logical product” before the period;

23 (D) by amending subsection (s) to read as
24 follows:

1 “(s) REFERRAL TO ADVISORY COMMITTEE.—The
2 Secretary shall—

3 “(1) refer a drug or biological product to a
4 Food and Drug Administration advisory committee
5 for review at a meeting of such advisory committee
6 prior to the approval of such drug or biological if it
7 is—

8 “(A) a drug, no active moiety (as defined
9 by the Secretary in section 314.3 of title 21,
10 Code of Federal Regulations (or any successor
11 regulations)) of which has been approved in any
12 other application under this section; or

13 “(B) a biological product, no active ingre-
14 dient of which has been approved in any other
15 application under section 351 of the Public
16 Health Service Act; or

17 “(2) if the Secretary does not refer a drug or
18 biological product described in paragraph (1) to a
19 Food and Drug Administration advisory committee
20 prior to such approval, provide in the action letter
21 on the application for the drug or biological product
22 a summary of the reasons why the Secretary did not
23 refer the drug or biological product to an advisory
24 committee prior to approval.”; and

1 (E) in subsection (u)(1), in the matter pre-
2 ceding subparagraph (A)—

3 (i) by striking “active ingredient (in-
4 cluding any ester or salt of the active in-
5 gredient)” and inserting “active moiety (as
6 defined by the Secretary in section 314.3
7 of title 21, Code of Federal Regulations (or
8 any successor regulations))”; and

9 (ii) by striking “same active ingre-
10 dient” and inserting “same active moiety”;

11 (2) in section 512(c)(2)(F) (21 U.S.C.
12 360b(c)(2)(F)), by striking “active ingredient (in-
13 cluding any ester or salt of the active ingredient)”
14 each place it appears and inserting “active moiety
15 (as defined by the Secretary in section 314.3 of title
16 21, Code of Federal Regulations (or any successor
17 regulations))”;

18 (3) in section 524(a)(4) (21 U.S.C.
19 360n(a)(4)), by amending subparagraph (C) to read
20 as follows:

21 “(C) is for—

22 “(i) a human drug, no active moiety
23 (as defined by the Secretary in section
24 314.3 of title 21, Code of Federal Regula-
25 tions (or any successor regulations)) of

1 which has been approved in any other ap-
2 plication under section 505(b)(1); or

3 “(ii) a biological product, no active in-
4 gredient of which has been approved in any
5 other application under section 351 of the
6 Public Health Service Act.”;

7 (4) in section 529(a)(4) (21 U.S.C.
8 360ff(a)(4)), by striking subparagraphs (A) and (B)
9 and inserting the following:

10 “(A) is for a drug or biological product
11 that is for the prevention or treatment of a rare
12 pediatric disease;

13 “(B)(i) is for such a drug—

14 “(I) that contains no active moiety (as
15 defined by the Secretary in section 314.3
16 of title 21, Code of Federal Regulations (or
17 any successor regulations)) that has been
18 previously approved in any other applica-
19 tion under subsection (b)(1), (b)(2), or (j)
20 of section 505; and

21 “(II) that is the subject of an applica-
22 tion submitted under section 505(b)(1); or

23 “(ii) or is for such a biological product—

24 “(I) that contains no active ingredient
25 that has been previously approved in any

1 other application under section 351(a) or
2 351(k) of the Public Health Service Act;
3 and

4 “(II) that is the subject of an applica-
5 tion submitted under section 351(a) of the
6 Public Health Service Act;”; and

7 (5) in section 565A(a)(4) (21 U.S.C. 360bbb-
8 4a(a)(4)), by amending subparagraph (D) to read as
9 follows:

10 “(D) is for—

11 “(i) a human drug, no active moiety
12 (as defined by the Secretary in section
13 314.3 of title 21, Code of Federal Regula-
14 tions (or any successor regulations)) of
15 which has been approved in any other ap-
16 plication under section 505(b)(1); or

17 “(ii) a biological product, no active in-
18 gredient of which has been approved in any
19 other application under section 351 of the
20 Public Health Service Act.”.

21 (b) TECHNICAL CORRECTIONS.—Chapter V of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
23 et seq.) is amended—

24 (1) in section 505 (21 U.S.C. 355)—

1 (A) in subsection (c)(3)(E), by repealing
2 clause (i); and

3 (B) in subsection (j)(5)(F), by repealing
4 clause (i); and

5 (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.
6 355a(c)(1)(A)(i)), by striking “(c)(3)(D)” and in-
7 serting “(c)(3)(E)”.

8 **SEC. 355. PROMPT APPROVAL OF DRUGS RELATED TO**
9 **SAFETY INFORMATION.**

10 Section 505 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 355) is amended by adding at the end the
12 following:

13 “(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY
14 INFORMATION IS ADDED TO LABELING.—

15 “(1) GENERAL RULE.—A drug for which an ap-
16 plication has been submitted or approved under sub-
17 section (b)(2) or (j) shall not be considered ineligible
18 for approval under this section or misbranded under
19 section 502 on the basis that the labeling of the
20 drug omits safety information, including contra-
21 indications, warnings, precautions, dosing, adminis-
22 tration, or other information pertaining to safety,
23 when the omitted safety information is protected by
24 exclusivity under clause (iii) or (iv) of subsection
25 (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),

1 or section 527(a), or by an extension of such exclu-
2 sivity under section 505A or 505E.

3 “(2) LABELING.—Notwithstanding clauses (iii)
4 and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)
5 of subsection (c)(3)(E), or section 527, the Sec-
6 retary shall require that the labeling of a drug ap-
7 proved pursuant to an application submitted under
8 subsection (b)(2) or (j) that omits safety information
9 described in paragraph (1) include a statement of
10 any appropriate safety information that the Sec-
11 retary considers necessary to assure safe use.

12 “(3) AVAILABILITY AND SCOPE OF EXCLU-
13 SIVITY.—This subsection does not affect—

14 “(A) the availability or scope of exclusivity
15 or an extension of exclusivity described in sub-
16 paragraph (A) or (B) of section 505A(o)(3);

17 “(B) the question of the eligibility for ap-
18 proval under this section of any application de-
19 scribed in subsection (b)(2) or (j) that omits
20 any other aspect of labeling protected by exclu-
21 sivity under—

22 “(i) clause (iii) or (iv) of subsection
23 (j)(5)(F);

24 “(ii) clause (iii) or (iv) of subsection
25 (c)(3)(E); or

1 “(iii) section 527(a); or

2 “(C) except as expressly provided in para-
3 graphs (1) and (2), the operation of this section
4 or section 527.”.

5 **SEC. 356. CONDITIONS OF USE FOR BIOSIMILAR BIOLOGI-
6 CAL PRODUCTS.**

7 Section 351(k)(2)(A)(iii) of the Public Health Service
8 Act (42 U.S.C. 262(k)(2)(A)(iii)) is amended—

9 (1) in subclause (I), by striking “; and” and in-
10 serting a semicolon;

11 (2) in subclause (II), by striking the period and
12 inserting “; and”; and

13 (3) by adding at the end the following:

14 “(III) may include information to
15 show that the conditions of use pre-
16 scribed, recommended, or suggested in
17 the labeling proposed for the biological
18 product have been previously approved
19 for the reference product.”.

20 **SEC. 357. EDUCATION ON BIOLOGICAL PRODUCTS.**

21 Subpart 1 of part F of title III of the Public Health
22 Service Act (42 U.S.C. 262 et seq.) is amended by adding
23 at the end the following:

24 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

25 “(a) INTERNET WEBSITE.—

1 “(1) IN GENERAL.—The Secretary may main-
2 tain and operate an internet website to provide edu-
3 cational materials for health care providers, patients,
4 and caregivers, regarding the meaning of the terms,
5 and the standards for review and licensing of, bio-
6 logical products, including biosimilar biological prod-
7 ucts and interchangeable biosimilar biological prod-
8 ucts.

9 “(2) CONTENT.—Educational materials pro-
10 vided under paragraph (1) may include—

11 “(A) explanations of key statutory and
12 regulatory terms, including ‘biosimilar’ and
13 ‘interchangeable’, and clarification regarding
14 the use of interchangeable biosimilar biological
15 products;

16 “(B) information related to development
17 programs for biological products, including bio-
18 similar biological products and interchangeable
19 biosimilar biological products and relevant clin-
20 ical considerations for prescribers, which may
21 include, as appropriate and applicable, informa-
22 tion related to the comparability of such biologi-
23 cal products;

24 “(C) an explanation of the process for re-
25 porting adverse events for biological products,

1 including biosimilar biological products and
2 interchangeable biosimilar biological products;
3 and

4 “(D) an explanation of the relationship be-
5 tween biosimilar biological products and inter-
6 changeable biosimilar biological products li-
7 censed under section 351(k) and reference
8 products (as defined in section 351(i)), includ-
9 ing the standards for review and licensing of
10 each such type of biological product.

11 “(3) FORMAT.—The educational materials pro-
12 vided under paragraph (1) may be—

13 “(A) in formats such as webinars, con-
14 tinuing medical education modules, videos, fact
15 sheets, infographics, stakeholder toolkits, or
16 other formats as appropriate and applicable;
17 and

18 “(B) tailored for the unique needs of
19 health care providers, patients, caregivers, and
20 other audiences, as the Secretary determines
21 appropriate.

22 “(4) OTHER INFORMATION.—In addition to the
23 information described in paragraph (2), the Sec-
24 retary shall continue to publish the following infor-
25 mation:

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 II
21 (of chapter 5) 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. 359. 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 D—Prescription Drug and**
20 **Pharmacy Benefit Manager**
21 **Transparency**

22 **SEC. 361. PATENT DISCLOSURE REQUIREMENTS.**

23 (a) IN GENERAL.—Section 351 of the Public Health
24 Service Act (42 U.S.C. 262) is amended by adding at the
25 end the following:

1 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
2 TO PATENTS.—

3 “(1) APPROVED APPLICATION HOLDER LISTING
4 REQUIREMENTS.—

5 “(A) IN GENERAL.—Beginning on the date
6 of enactment of this subsection, within 30 days
7 of approval of an application under subsection
8 (a) or (k), the holder of such approved applica-
9 tion shall submit to the Secretary a list of each
10 patent required to be disclosed (as described in
11 paragraph (3)).

12 “(B) PREVIOUSLY APPROVED OR LI-
13 CENSED BIOLOGICAL PRODUCTS.—

14 “(i) PRODUCTS APPROVED UNDER
15 SECTION 351 OF THE PHSA.—Not later
16 than 30 days after the date of enactment
17 of the Fair Care Act of 2020, the holder
18 of a biological product license that was ap-
19 proved under subsection (a) or (k) before
20 the date of enactment of such Act shall
21 submit to the Secretary a list of each pat-
22 ent required to be disclosed (as described
23 in paragraph (3)).

24 “(ii) PRODUCTS APPROVED UNDER
25 SECTION 505 OF THE FFDCA.—Not later

1 than 30 days after March 23, 2021, the
2 holder of an approved application for a bio-
3 logical product under section 505 of the
4 Federal Food, Drug, and Cosmetic Act
5 that is deemed to be a license for the bio-
6 logical product under this section on
7 March 23, 2021, shall submit a list of each
8 patent required to be disclosed (as de-
9 scribed in paragraph (3)).

10 “(C) UPDATES.—The holder of a biological
11 product license approved under subsection (a)
12 or (k) shall submit to the Secretary a list that
13 includes—

14 “(i) any patent first required to be
15 disclosed (as described in paragraph (3))
16 after the submission under subparagraph
17 (A) or (B), as applicable, within 30 days of
18 the earlier of—

19 “(I) the date of issuance of such
20 patent by the United States Patent
21 and Trademark Office; or

22 “(II) the date of approval of a
23 supplemental application for the bio-
24 logical product; and

1 “(ii) any patent, or any claim with re-
2 spect to a patent, included on the list pur-
3 suant to this paragraph with respect to the
4 biological product subsequently determined
5 to be invalid or unenforceable, within 30
6 days of a determination of patent inva-
7 lidity.

8 “(2) PUBLICATION OF INFORMATION.—

9 “(A) IN GENERAL.—Within 1 year of the
10 date of enactment of the Fair Care Act of
11 2020, the Secretary shall publish and make
12 available to the public a single, easily search-
13 able, list that includes—

14 “(i) the official and proprietary name
15 of each biological product licensed under
16 subsection (a) or (k), and of each biological
17 product application approved under section
18 505 of the Federal Food, Drug, and Cos-
19 metic Act and deemed to be a license for
20 the biological product under this section on
21 March 23, 2021;

22 “(ii) with respect to each biological
23 product described in clause (i), each patent
24 submitted in accordance with paragraph
25 (1);

1 “(iii) the date of licensure and appli-
2 cation number for each such biological
3 product;

4 “(iv) the marketing status, dosage
5 form, route of administration, strength,
6 and, if applicable, reference product, for
7 each such biological product;

8 “(v) the licensure status for each such
9 biological product, including whether the li-
10 cense at the time of listing is approved,
11 withdrawn, or revoked;

12 “(vi) any period of any exclusivity
13 under subsection (k)(7)(A) or subsection
14 (k)(7)(B) of this section or section 527 of
15 the Federal Food, Drug, and Cosmetic
16 Act, and any extension of such period in
17 accordance with subsection (m) of this sec-
18 tion with respect to each such biological
19 product, and the date on which such exclu-
20 sivity expires;

21 “(vii) information regarding any de-
22 termination related to biosimilarity or
23 interchangeability for each such biological
24 product; and

1 “(viii) information regarding approved
2 indications for each such biological prod-
3 uct, in such manner as the Secretary de-
4 termines appropriate.

5 “(B) UPDATES.—Every 30 days after the
6 publication of the first list under subparagraph
7 (A), the Secretary shall revise the list to in-
8 clude—

9 “(i)(I) each biological product licensed
10 under subsection (a) or (k) during the 30-
11 day period; and

12 “(II) with respect to each biological
13 product described in subclause (I), the in-
14 formation described in clauses (i) through
15 (viii) of subparagraph (A); and

16 “(ii) any updates to information pre-
17 viously published in accordance with sub-
18 paragraph (A).

19 “(3) PATENTS REQUIRED TO BE DISCLOSED.—
20 In this section, a ‘patent required to be disclosed’ is
21 any patent for which the holder of a biological prod-
22 uct license approved under subsection (a) or (k), or
23 a biological product application approved under sec-
24 tion 505 of the Federal Food, Drug, and Cosmetic
25 Act and deemed to be a license for a biological prod-

1 uct under this section on March 23, 2021, believes
2 a claim of patent infringement could reasonably be
3 asserted by the holder, or by a patent owner that
4 has granted an exclusive license to the holder with
5 respect to the biological product that is the subject
6 of such license, if a person not licensed by the holder
7 engaged in the making, using, offering to sell, sell-
8 ing, or importing into the United States of the bio-
9 logical product that is the subject of such license.”.

10 (b) DISCLOSURE OF PATENTS.—Section
11 351(l)(3)(A)(i) of the Public Health Service Act (42
12 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
13 in the list provided by the reference product sponsor under
14 subsection (o)(1)” after “a list of patents”.

15 (c) RESTRICTION ON CLAIMS OF PATENT INFRINGE-
16 MENT.—Section 271(e) of title 35, United States Code,
17 is amended by adding at the end the following:

18 “(7) The owner of a patent that should have
19 been included in the list described in section
20 351(o)(1) of the Public Health Service Act (42
21 U.S.C. 262(o)(1)), including any updates required
22 under subparagraph (C) of that section, but was not
23 timely included in such list, may not bring an action
24 under this section for infringement of the patent.”.

1 (d) REGULATIONS.—The Secretary of Health and
2 Human Services may promulgate regulations to carry out
3 subsection (o) of section 351 of the Public Health Service
4 Act (42 U.S.C. 262), as added by subsection (a).

5 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
6 including an amendment made by this Act, shall be con-
7 strued to require or allow the Secretary of Health and
8 Human Services to delay the licensing of a biological prod-
9 uct under section 351 of the Public Health Service Act
10 (42 U.S.C. 262).

11 **SEC. 362. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.**

12 (a) IN GENERAL.—Section 351 of the Public Health
13 Service Act (42 U.S.C. 262) is amended by adding at the
14 end the following:

15 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
16 TO PATENTS.—

17 “(1) APPROVED APPLICATION HOLDER LISTING
18 REQUIREMENTS.—

19 “(A) IN GENERAL.—Beginning on the date
20 of enactment of the Fair Care Act of 2020,
21 within 60 days of approval of an application
22 under subsection (a) or (k), the holder of such
23 approved application shall submit to the Sec-
24 retary a list of each patent required to be dis-
25 closed (as described in paragraph (3)).

1 “(B) PREVIOUSLY APPROVED OR LI-
2 CENSED BIOLOGICAL PRODUCTS.—

3 “(i) PRODUCTS LICENSED UNDER
4 SECTION 351 OF THE PHSA.—Not later
5 than 30 days after the date of enactment
6 of the Fair Care Act of 2020, the holder
7 of a biological product license that was ap-
8 proved under subsection (a) or (k) before
9 the date of enactment of such Act shall
10 submit to the Secretary a list of each pat-
11 ent required to be disclosed (as described
12 in paragraph (3)).

13 “(ii) PRODUCTS APPROVED UNDER
14 SECTION 505 OF THE FFDCA.—Not later
15 than 30 days after March 23, 2020, the
16 holder of an approved application for a bio-
17 logical product under section 505 of the
18 Federal Food, Drug, and Cosmetic Act
19 that is deemed to be a license for the bio-
20 logical product under this section on
21 March 23, 2020, shall submit to the Sec-
22 retary a list of each patent required to be
23 disclosed (as described in paragraph (3)).

24 “(C) UPDATES.—The holder of a biological
25 product license that is the subject of an applica-

1 tion under subsection (a) or (k) shall submit to
2 the Secretary a list that includes—

3 “(i) any patent not previously re-
4 quired to be disclosed (as described in
5 paragraph (3)) under subparagraph (A) or
6 (B), as applicable, within 30 days of the
7 earlier of—

8 “(I) the date of issuance of such
9 patent by the United States Patent
10 and Trademark Office; or

11 “(II) the date of approval of a
12 supplemental application for the bio-
13 logical product; and

14 “(ii) any patent, or any claim with re-
15 spect to a patent, included on the list pur-
16 suant to this paragraph, that the Patent
17 Trial and Appeal Board of the United
18 States Patent and Trademark Office deter-
19 mines in a written decision to cancel as
20 unpatentable, within 30 days of such deci-
21 sion.

22 “(2) PUBLICATION OF INFORMATION.—

23 “(A) IN GENERAL.—Within 1 year of the
24 date of enactment of the Fair Care Act of
25 2020, the Secretary shall publish and make

1 available to the public a single, easily searchable
2 list that includes—

3 “(i) the official and proprietary name
4 of each biological product licensed, or
5 deemed to be licensed, under subsection (a)
6 or (k);

7 “(ii) with respect to each biological
8 product described in clause (i), each patent
9 submitted in accordance with paragraph
10 (1);

11 “(iii) the date of licensure and appli-
12 cation number for each such biological
13 product;

14 “(iv) the marketing status, dosage
15 form, route of administration, strength,
16 and, if applicable, reference product, for
17 each such biological product;

18 “(v) the licensure status for each such
19 biological product, including whether the li-
20 cense at the time of listing is approved,
21 withdrawn, or revoked;

22 “(vi) with respect to each such bio-
23 logical product, any period of exclusivity
24 under paragraph (6), (7)(A), or (7)(B) of
25 subsection (k) of this section or section

1 527 of the Federal Food, Drug, and Cos-
2 metic Act, and any extension of such pe-
3 riod in accordance with subsection (m) of
4 this section, for which the Secretary has
5 determined such biological product to be
6 eligible, and the date on which such exclu-
7 sivity expires;

8 “(vii) any determination of biosimi-
9 larity or interchangeability for each such
10 biological product; and

11 “(viii) information regarding approved
12 indications for each such biological prod-
13 uct, in such manner as the Secretary de-
14 termines appropriate.

15 “(B) UPDATES.—Every 30 days after the
16 publication of the first list under subparagraph
17 (A), the Secretary shall revise the list to in-
18 clude—

19 “(i)(I) each biological product licensed
20 under subsection (a) or (k) during the 30-
21 day period; and

22 “(II) with respect to each biological
23 product described in subclause (I), the in-
24 formation described in clauses (i) through
25 (viii) of subparagraph (A); and

1 “(ii) any updates to information pre-
2 viously published in accordance with sub-
3 paragraph (A).

4 “(C) NONCOMPLIANCE.—Beginning 18
5 months after the date of enactment of the Fair
6 Care Act of 2020, the Secretary, in consultation
7 with the Director of the United States Patent
8 and Trademark Office, shall publish and make
9 available to the public a list of any holders of
10 biological product licenses, and the cor-
11 responding biological product or products, that
12 failed to submit information as required under
13 paragraph (1), including any updates required
14 under paragraph (1)(C), in such manner and
15 format as the Secretary determines appropriate.
16 If information required under paragraph (1) is
17 submitted following publication of such list, the
18 Secretary shall remove such holders of such bio-
19 logical product licenses from the public list in a
20 reasonable period of time.

21 “(3) PATENTS REQUIRED TO BE DISCLOSED.—
22 In this section, a ‘patent required to be disclosed’ is
23 any patent for which the holder of a biological prod-
24 uct license approved under subsection (a) or (k), or
25 a biological product application approved under sec-

1 tion 505 of the Federal Food, Drug, and Cosmetic
2 Act and deemed to be a license for a biological prod-
3 uct under this section on March 23, 2020, believes
4 a claim of patent infringement could reasonably be
5 asserted by the holder, or by a patent owner that
6 has granted an exclusive license to the holder with
7 respect to the biological product that is the subject
8 of such license, if a person not licensed by the owner
9 engaged in the making, using, offering to sell, sell-
10 ing, or importing into the United States of the bio-
11 logical product that is the subject of such license.”.

12 (b) DISCLOSURE OF PATENTS.—Section
13 351(l)(3)(A)(i) of the Public Health Service Act (42
14 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
15 in the list provided by the reference product sponsor under
16 subsection (o)(1)” after “a list of patents”.

17 (c) REVIEW AND REPORT ON NONCOMPLIANCE.—
18 Not later than 30 months after the date of enactment of
19 this Act, the Secretary shall—

20 (1) solicit public comments regarding appro-
21 priate remedies, in addition to the publication of the
22 list under subsection (o)(2)(C) of section 351 of the
23 Public Health Service Act (42 U.S.C. 262), as added
24 by subsection (a), with respect to holders of biologi-
25 cal product licenses who fail to timely submit infor-

1 mation as required under subsection (o)(1) of such
2 section 351, including any updates required under
3 subparagraph (C) of such subsection (o)(1); and

4 (2) submit to Congress an evaluation of com-
5 ments received under paragraph (1) and the rec-
6 ommendations of the Secretary concerning appro-
7 priate remedies.

8 (d) REGULATIONS.—The Secretary of Health and
9 Human Services may promulgate regulations to carry out
10 subsection (o) of section 351 of the Public Health Service
11 Act (42 U.S.C. 262), as added by subsection (a).

12 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
13 including an amendment made by this Act, shall be con-
14 strued to require or allow the Secretary of Health and
15 Human Services to delay the licensing of a biological prod-
16 uct under section 351 of the Public Health Service Act
17 (42 U.S.C. 262).

18 **SEC. 363. ORANGE BOOK MODERNIZATION.**

19 (a) SUBMISSION OF PATENT INFORMATION FOR
20 BRAND NAME DRUGS.—

21 (1) IN GENERAL.—Paragraph (1) of section
22 505(b) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 355(b)) is amended to read as follows:

24 “(b)(1)(A) Any person may file with the Secretary
25 an application with respect to any drug subject to the pro-

1 visions of subsection (a). Such persons shall submit to the
2 Secretary as part of the application—

3 “(i) full reports of investigations which have
4 been made to show whether or not such drug is safe
5 for use and whether such drug is effective in use;

6 “(ii) a full list of the articles used as compo-
7 nents of such drug;

8 “(iii) a full statement of the composition of
9 such drug;

10 “(iv) a full description of the methods used in,
11 and the facilities and controls used for, the manufac-
12 ture, processing, and packing of such drug;

13 “(v) such samples of such drug and of the arti-
14 cles used as components thereof as the Secretary
15 may require;

16 “(vi) specimens of the labeling proposed to be
17 used for such drug;

18 “(vii) any assessments required under section
19 505B; and

20 “(viii) the patent number and expiration date,
21 of each patent for which a claim of patent infringe-
22 ment could reasonably be asserted if a person not li-
23 censed by the owner engaged in the manufacture,
24 use, or sale of the drug, and that—

1 “(I) claims the drug for which the appli-
2 cant submitted the application and is a drug
3 substance patent or a drug product patent; or

4 “(II) claims the method of using the drug
5 for which approval is sought or has been grant-
6 ed in the application.

7 “(B) If an application is filed under this subsection
8 for a drug, and a patent of the type described in subpara-
9 graph (A)(viii) that claims such drug or a method of using
10 such drug is issued after the filing date, the applicant shall
11 amend the application to include such patent informa-
12 tion.”.

13 (2) GUIDANCE.—The Secretary of Health and
14 Human Services shall, in consultation with the Di-
15 rector of the National Institutes of Health and with
16 representatives of the drug manufacturing industry,
17 review and develop guidance, as appropriate, on the
18 inclusion of women and minorities in clinical trials
19 required under subsection (b)(1)(A)(i) of section 505
20 of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355), as amended by paragraph (1).

22 (b) CONFORMING CHANGES TO REQUIREMENTS FOR
23 SUBSEQUENT SUBMISSION OF PATENT INFORMATION.—
24 Section 505(c)(2) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 355(c)(2)) is amended—

1 (1) by inserting before the first sentence the
2 following: “Not later than 30 days after the date of
3 approval of an application under subsection (b), the
4 holder of the approved application shall file with the
5 Secretary the patent number and the expiration date
6 of any patent described in subclause (I) or (II) of
7 subsection (b)(1)(A)(viii), except that a patent that
8 is identified as claiming a method of using such
9 drug shall be filed only if the patent claims a meth-
10 od of use approved in the application. The holder of
11 the approved application shall file with the Secretary
12 the patent number and the expiration date of any
13 patent described in subclause (I) or (II) of sub-
14 section (b)(1)(A)(viii) that is issued after the date of
15 approval of the application, not later than 30 days
16 after the date of issuance of the patent, except that
17 a patent that claims a method of using such drug
18 shall be filed only if approval for such use has been
19 granted in the application.”;

20 (2) by inserting after “the patent number and
21 the expiration date of any patent which” the fol-
22 lowing: “fulfills the criteria in subsection (b) and”;

23 (3) by inserting after the third sentence (as
24 amended by paragraph (1)) the following: “Patent
25 information that is not the type of patent informa-

1 tion required by subsection (b)(1)(A)(viii) shall not
2 be submitted under this paragraph.”; and

3 (4) by inserting after “could not file patent in-
4 formation under subsection (b) because no patent”
5 the following: “of the type required to be submitted
6 in subsection (b)(1)(A)(viii)”.

7 (c) LISTING OF EXCLUSIVITIES.—Subparagraph (A)
8 of section 505(j)(7) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 355(j)(7)) is amended by adding at
10 the end the following:

11 “(iv) For each drug included on the list, the Sec-
12 retary shall specify any exclusivity period that is applica-
13 ble, for which the Secretary has determined the expiration
14 date, and for which such period has not yet expired
15 under—

16 “(I) clause (ii), (iii), or (iv) of subsection
17 (c)(3)(E) of this section;

18 “(II) clause (iv) or (v) of paragraph (5)(B) of
19 this subsection;

20 “(III) clause (ii), (iii), or (iv) of paragraph
21 (5)(F) of this subsection;

22 “(IV) section 505A;

23 “(V) section 505E;

24 “(VI) section 527(a); or

25 “(VII) subsection (u)”.

1 (d) ORANGE BOOK UPDATES WITH RESPECT TO IN-
2 VALIDATED PATENTS.—

3 (1) IN GENERAL.—

4 (A) AMENDMENTS.—Section 505(j)(7)(A)
5 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 355(j)(7)(A)), as amended by sub-
7 section (c), is further amended by adding at the
8 end the following:

9 “(v) In the case of a listed drug for which the
10 list under clause (i) includes a patent for such drug,
11 and where the Under Secretary of Commerce for In-
12 tellectual Property and Director of the United States
13 Patent and Trademark Office have cancelled any
14 claim of the patent pursuant to a decision by the
15 Patent Trial and Appeal Board in an inter partes
16 review conducted under chapter 31 of title 35,
17 United States Code, or a post-grant review con-
18 ducted under chapter 32 of that title, and from
19 which no appeal has been taken, or can be taken,
20 the holder of the applicable approved application
21 shall notify the Secretary, in writing, within 14 days
22 of such cancellation, and, if the patent has been
23 deemed wholly inoperative or invalid, or if a patent
24 claim has been cancelled, the revisions required
25 under clause (iii) shall include striking the patent or

1 information regarding such patent claim from the
2 list with respect to such drug, as applicable, except
3 that the Secretary shall not remove a patent from
4 the list before the expiration of any 180-day exclu-
5 sivity period under paragraph (5)(B)(iv) that relies
6 on a certification described in paragraph
7 (2)(A)(vii)(IV) with respect to such patent.”.

8 (B) APPLICATION.—The amendment made
9 by subparagraph (A) shall not apply with re-
10 spect to any determination with respect to a
11 patent or patent claim that is made prior to the
12 date of enactment of this Act.

13 (2) NO EFFECT ON FIRST APPLICANT EXCLU-
14 SIVITY PERIOD.—Section 505(j)(5)(B)(iv)(I), as
15 amended by the preceding sections, is amended by
16 adding at the end the following: “This subclause
17 shall apply even if a patent is stricken from the list
18 under paragraph (7)(A), pursuant to paragraph
19 (7)(A)(v), provided that, at the time that the first
20 applicant submitted an application under this sub-
21 section containing a certification described in para-
22 graph (2)(A)(vii)(IV), the patent that was the sub-
23 ject of such certification was included in such list
24 with respect to the listed drug.”.

1 **SEC. 364. MODERNIZING THE LABELING OF CERTAIN GE-**
2 **NERIC DRUGS.**

3 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 351 et seq.) is amended by inserting after
5 section 503C the following:

6 **“SEC. 503D. PROCESS TO UPDATE LABELING FOR CERTAIN**
7 **DRUGS.**

8 “(a) DEFINITIONS.—For purposes of this section:

9 “(1) The term ‘covered drug’ means a drug ap-
10 proved under section 505(c)—

11 “(A) for which there are no unexpired pat-
12 ents included in the list under section 505(j)(7)
13 and no unexpired period of exclusivity;

14 “(B) for which the approval of the applica-
15 tion has been withdrawn for reasons other than
16 safety or effectiveness; and

17 “(C) for which, with respect to the label-
18 ing—

19 “(i) new scientific evidence is available
20 regarding the conditions of use of the
21 drug;

22 “(ii) there is a relevant accepted use
23 in clinical practice that is not reflected in
24 the approved labeling; or

1 “(iii) the labeling of such drug does
2 not reflect current legal and regulatory re-
3 quirements.

4 “(2) The term ‘period of exclusivity’, with re-
5 spect to a drug approved under section 505(c),
6 means any period of exclusivity under clause (ii),
7 (iii), or (iv) of section 505(c)(3)(E), clause (ii), (iii),
8 or (iv) of section 505(j)(5)(F), or section 505A,
9 505E, or 527.

10 “(3) The term ‘generic version’ means a drug
11 approved under section 505(j) whose reference drug
12 is a covered drug.

13 “(4) The term ‘relevant accepted use’ means a
14 use for a drug in clinical practice that is supported
15 by scientific evidence that appears to the Secretary
16 to meet the standards for approval under section
17 505.

18 “(5) The term ‘selected drug’ means a covered
19 drug for which the Secretary has determined
20 through the process under subsection (c) that the la-
21 beling should be changed.

22 “(b) IDENTIFICATION OF COVERED DRUGS.—The
23 Secretary may identify covered drugs for which labeling
24 updates would provide a public health benefit. To assist

1 in identifying covered drugs, the Secretary may do one or
2 both of the following:

3 “(1) Enter into cooperative agreements or con-
4 tracts with public or private entities to review the
5 available scientific evidence concerning such drugs.

6 “(2) Seek public input concerning such drugs,
7 including input on whether there is a relevant ac-
8 cepted use in clinical practice that is not reflected in
9 the approved labeling of such drugs or whether new
10 scientific evidence is available regarding the condi-
11 tions of use for such drug, by—

12 “(A) holding one or more public meetings;

13 “(B) opening a public docket for the sub-
14 mission of public comments; or

15 “(C) other means, as the Secretary deter-
16 mines appropriate.

17 “(c) SELECTION OF DRUGS FOR UPDATING.—If the
18 Secretary determines, with respect to a covered drug, that
19 the available scientific evidence meets the standards under
20 section 505 for adding or modifying information to the
21 labeling or providing supplemental information to the la-
22 beling regarding the use of the covered drug, the Secretary
23 may initiate the process under subsection (d).

24 “(d) INITIATION OF THE PROCESS OF UPDATING.—
25 If the Secretary determines that labeling changes are ap-

1 appropriate for a selected drug pursuant to subsection (c),
2 the Secretary shall provide notice to the holders of ap-
3 proved applications for a generic version of such drug
4 that—

5 “(1) summarizes the findings supporting the
6 determination of the Secretary that the available sci-
7 entific evidence meets the standards under section
8 505 for adding or modifying information or pro-
9 viding supplemental information to the labeling of
10 the covered drug pursuant to subsection (c);

11 “(2) provides a clear statement regarding the
12 additional, modified, or supplemental information for
13 such labeling, according to the determination by the
14 Secretary (including, as applicable, modifications to
15 add the relevant accepted use to the labeling of the
16 drug as an additional indication for the drug); and

17 “(3) states whether the statement under para-
18 graph (2) applies to the selected drug as a class of
19 covered drugs or only to a specific drug product.

20 “(e) RESPONSE TO NOTIFICATION.—Within 30 days
21 of receipt of notification provided by the Secretary pursu-
22 ant to subsection (d), the holder of an approved applica-
23 tion for a generic version of the selected drug shall—

24 “(1) agree to change the approved labeling to
25 reflect the additional, modified, or supplemental in-

1 formation the Secretary has determined to be appro-
2 priate; or

3 “(2) notify the Secretary that the holder of the
4 approved application does not believe that the re-
5 quested labeling changes are warranted and submit
6 a statement detailing the reasons why such changes
7 are not warranted.

8 “(f) REVIEW OF APPLICATION HOLDER’S RE-
9 SPONSE.—

10 “(1) IN GENERAL.—Upon receipt of the appli-
11 cation holder’s response, the Secretary shall prompt-
12 ly review each statement received under subsection
13 (e)(2) and determine which labeling changes pursu-
14 ant to the Secretary’s notice under subsection (d)
15 are appropriate, if any. If the Secretary disagrees
16 with the reasons why such labeling changes are not
17 warranted, the Secretary shall provide opportunity
18 for discussions with the application holders to reach
19 agreement on whether the labeling for the covered
20 drug should be updated to reflect current scientific
21 evidence, and if so, the content of such labeling
22 changes.

23 “(2) CHANGES TO LABELING.—After consid-
24 ering all responses from the holder of an approved
25 application under paragraph (1) or (2) of subsection

1 (e), and any discussion under paragraph (1), the
2 Secretary may order such holder to make the label-
3 ing changes the Secretary determines are appro-
4 priate. Such holder of an approved application
5 shall—

6 “(A) update its paper labeling for the drug
7 at the next printing of that labeling;

8 “(B) update any electronic labeling for the
9 drug within 30 days; and

10 “(C) submit the revised labeling through
11 the form, ‘Supplement—Changes Being Ef-
12 fected’.

13 “(g) VIOLATION.—If the holder of an approved appli-
14 cation for the generic version of the selected drug does
15 not comply with the requirements of subsection (f)(2),
16 such generic version of the selected drug shall be deemed
17 to be misbranded under section 502.

18 “(h) LIMITATIONS; GENERIC DRUGS.—

19 “(1) IN GENERAL.—With respect to any label-
20 ing change required under this section, the generic
21 version shall be deemed to have the same conditions
22 of use and the same labeling as a reference drug for
23 purposes of clauses (i) and (v) of section
24 505(j)(2)(A). Any labeling change so required shall
25 not have any legal effect for the applicant that is

1 different than the legal effect that would have re-
2 sulted if a supplemental application had been sub-
3 mitted and approved to conform the labeling of the
4 generic version to a change in the labeling of the ref-
5 erence drug.

6 “(2) SUPPLEMENTAL APPLICATIONS.—Changes
7 to labeling made in accordance with this paragraph
8 shall not be eligible for an exclusivity period under
9 this Act.

10 “(i) DRUG PRODUCT CLASSES.—In the case of a se-
11 lected drug for which the labeling changes ordered by the
12 Secretary under subsection (d)(2) are required for a class
13 of covered drugs, such labeling changes shall be made for
14 generic versions of such drug in that class.

15 “(j) RULES OF CONSTRUCTION.—

16 “(1) APPROVAL STANDARDS.—This section
17 shall not be construed as altering the applicability of
18 the standards for approval of an application under
19 section 505. No order shall be issued under this sub-
20 section unless the evidence supporting the changed
21 labeling meets the standards for approval applicable
22 to any change to labeling under section 505.

23 “(2) REMOVAL OF INFORMATION.—Nothing in
24 this section shall be construed to give the Secretary
25 additional authority to remove approved indications

1 for drugs, other than the authority described in this
2 section.

3 “(k) REPORTS.—Not later than 4 years after the
4 date of the enactment of the Fair Care Act of 2020 and
5 every 4 years thereafter, the Secretary shall prepare and
6 submit to the Committee on Health, Education, Labor,
7 and Pensions of the Senate and the Committee on Energy
8 and Commerce of the House of Representatives, a report
9 that—

10 “(1) describes the actions of the Secretary
11 under this section, including—

12 “(A) the number of covered drugs and de-
13 scription of the types of drugs the Secretary
14 has selected for labeling changes and the ra-
15 tionale for such recommended changes; and

16 “(B) the number of times the Secretary
17 entered into discussions concerning a disagree-
18 ment with an application holder or holders and
19 a summary of the decision regarding a labeling
20 change, if any; and

21 “(2) includes any recommendations of the Sec-
22 retary for modifying the program under this sec-
23 tion.”.

1 **SEC. 365. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
2 **TION DRUG BENEFITS.**

3 (a) IN GENERAL.—Subpart II of part A of title
4 XXVII of the Public Health Service Act (42 U.S.C.
5 300gg–11 et seq.) is amended by adding at the end the
6 following:

7 **“SEC. 2729A. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
8 **TION DRUG BENEFITS.**

9 “A group health plan or a health insurance issuer of-
10 fering group or individual health insurance coverage shall
11 not, and shall ensure that any entity that provides phar-
12 macy benefits management services under a contract with
13 any such health plan or health insurance coverage does
14 not, receive from a drug manufacturer a reduction in price
15 or other remuneration with respect to any prescription
16 drug received by an enrollee in the plan or coverage and
17 covered by the plan or coverage, unless—

18 “(1) any such reduction in price is reflected at
19 the point of sale to the enrollee; and

20 “(2) any such other remuneration is a flat fee-
21 based service fee that a manufacturer of prescription
22 drugs pays to a pharmacy benefit manager for serv-
23 ices rendered to the manufacturer that relate to ar-
24 rangements by the pharmacy benefit manager to
25 provide pharmacy benefit management services to a
26 health plan or health insurance issuer, if certain

1 conditions established by the Secretary are met, in-
2 cluding requirements that the fees are transparent
3 to the health plan or health insurance issuer.”.

4 (b) EFFECTIVE DATE.—Section 2729A of the Public
5 Health Service Act, as added by subsection (a), shall take
6 effect on January 1, 2021.

7 **SEC. 366. PBM TRANSPARENCY AND ELIMINATION OF DIR**
8 **FEES.**

9 (a) PROHIBITING MEDICARE PDP SPONSORS AND
10 MA–PD ORGANIZATIONS FROM RETROACTIVELY REDUC-
11 ING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHAR-
12 MACIES.—

13 (1) IN GENERAL.—Section 1860D–12(b)(4)(A)
14 of the Social Security Act (42 U.S.C. 1395w–
15 112(b)(4)(A)) is amended by adding at the end the
16 following new clause:

17 “(iv) PROHIBITING RETROACTIVE RE-
18 DUCTIONS IN PAYMENTS ON CLEAN
19 CLAIMS.—Each contract entered into with
20 a PDP sponsor under this part with re-
21 spect to a prescription drug plan offered
22 by such sponsor shall provide that after
23 the date of receipt of a clean claim sub-
24 mitted by a pharmacy, the PDP sponsor
25 (or an agent of the PDP sponsor) may not

1 retroactively reduce payment on such claim
2 directly or indirectly through aggregated
3 effective rate or otherwise except in the
4 case such claim is found to not be a clean
5 claim (such as in the case of a claim lack-
6 ing required substantiating documentation)
7 during the course of a routine audit as
8 permitted pursuant to written agreement
9 between the PDP sponsor (or such an
10 agent) and such pharmacy. The previous
11 sentence shall not prohibit any retroactive
12 increase in payment to a pharmacy pursu-
13 ant to a written agreement between a PDP
14 sponsor (or an agent of such sponsor) and
15 such pharmacy.”.

16 (2) EFFECTIVE DATE.—The amendment made
17 by subsection (a) shall apply with respect to con-
18 tracts entered into on or after January 1, 2021.

19 (b) ELIMINATION OF DIR FEES.—

20 (1) PHARMACY BENEFITS MANAGER STAND-
21 ARDS UNDER THE MEDICARE PROGRAM FOR PRE-
22 SCRIPTIION DRUG PLANS AND MA–PD PLANS.—

23 (A) IN GENERAL.—Section 1860D–12(b)
24 of the Social Security Act (42 U.S.C. 1395w–

1 112(b)) is amended by adding at the end the
2 following new paragraph:

3 “(7) PHARMACY BENEFITS MANAGER TRANS-
4 PARENCY REQUIREMENTS.—Each contract entered
5 into with a PDP sponsor under this part with re-
6 spect to a prescription drug plan offered by such
7 sponsor or with an MA organization offering an
8 MA–PD plan under part C shall provide that the
9 sponsor or organization, respectively, may not enter
10 into a contract with any pharmacy benefits manager
11 (referred to in this paragraph as a ‘PBM’) to man-
12 age the prescription drug coverage provided under
13 such plan, or to control the costs of the prescription
14 drug coverage under such plan, unless the PBM ad-
15 heres to the following criteria when handling person-
16 ally identifiable utilization and claims data or other
17 sensitive patient data:

18 “(A) The PBM may not transmit any per-
19 sonally identifiable utilization, protected health
20 information, or claims data, with respect to a
21 plan enrollee, to a pharmacy owned by a PBM
22 if the plan enrollee has not voluntarily elected
23 in writing or via secure electronic means to fill
24 that particular prescription at the PBM-owned
25 pharmacy.

1 “(B) The PBM may not require that a
2 plan enrollee use a retail pharmacy, mail order
3 pharmacy, specialty pharmacy, or other phar-
4 macy entity providing pharmacy services in
5 which the PBM has an ownership interest or
6 that has an ownership interest in the PBM, or
7 provide an incentive to a plan enrollee to en-
8 courage the enrollee to use a retail pharmacy,
9 mail order pharmacy, specialty pharmacy, or
10 other pharmacy entity providing pharmacy serv-
11 ices in which the PBM has an ownership inter-
12 est or that has an ownership interest in the
13 PBM, if the incentive is applicable only to such
14 pharmacies.”.

15 (B) REGULAR UPDATE OF PRESCRIPTION
16 DRUG PRICING STANDARD.—Paragraph (6) of
17 section 1860D–12(b) of the Social Security Act
18 (42 U.S.C. 1395w–112(b)) is amended to read
19 as follows:

20 “(6) REGULAR UPDATE OF PRESCRIPTION
21 DRUG PRICING STANDARD.—

22 “(A) IN GENERAL.—If the PDP sponsor of
23 a prescription drug plan (or MA organization
24 offering an MA–PD plan) uses a standard for
25 reimbursement (as described in subparagraph

1 (B)) of pharmacies based on the cost of a drug,
2 each contract entered into with such sponsor
3 under this part (or organization under part C)
4 with respect to the plan shall provide that the
5 sponsor (or organization) shall—

6 “(i) update such standard not less fre-
7 quently than once every 7 days, beginning
8 with an initial update on January 1 of
9 each year, to accurately reflect the market
10 price of acquiring the drug;

11 “(ii) disclose to applicable pharmacies
12 and the contracting entities of such phar-
13 macies the sources used for making any
14 such update immediately without require-
15 ment of request;

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

23 “(iv) establish a process to appeal, in-
24 vestigate, and resolve disputes regarding
25 individual drug prices that are less than

1 the pharmacy acquisition price for such
2 drug, which must be adjudicated within 7
3 days of the pharmacy filing its appeal; and

4 “(v) provide all such pricing data in
5 an .xml spreadsheet format or a com-
6 parable easily accessible and complete
7 spreadsheet format.

8 “(B) PRESCRIPTION DRUG PRICING
9 STANDARD DEFINED.—For purposes of sub-
10 paragraph (A), a standard for reimbursement
11 of a pharmacy is any methodology or formula
12 for varying the pricing of a drug or drugs dur-
13 ing the term of the pharmacy reimbursement
14 contract that is based on the cost of the drug
15 involved, including drug pricing references and
16 amounts that are based upon average wholesale
17 price, wholesale average cost, average manufac-
18 turer price, average sales price, maximum al-
19 lowable cost (MAC), or other costs, whether
20 publicly available or not.”.

21 (C) EFFECTIVE DATE.—The amendments
22 made by this section shall apply to plan years
23 beginning on or after January 1, 2021.

24 (2) REGULAR UPDATE OF PRESCRIPTION DRUG
25 PRICING STANDARD UNDER TRICARE RETAIL PHAR-

1 MACY PROGRAM.—Section 1074g(d) of title 10,
2 United States Code, is amended by adding at the
3 end the following new paragraph:

4 “(3) To the extent practicable, with respect to the
5 TRICARE retail pharmacy program described in sub-
6 section (a)(2)(E)(ii), the Secretary shall ensure that a con-
7 tract entered into with a TRICARE managed care support
8 contractor includes requirements described in section
9 1860D–12(b)(6) of the Social Security Act (42 U.S.C.
10 1395w–112(b)(6)) to ensure the provision of information
11 regarding the pricing standard for prescription drugs.”.

12 (3) PRESCRIPTION DRUG TRANSPARENCY IN
13 THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-
14 GRAM.—

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

18 “(p) A contract may not be made or a plan approved
19 under this chapter under which a carrier has an agree-
20 ment with a pharmacy benefits manager (in this sub-
21 section referred to as a ‘PBM’) to manage prescription
22 drug coverage or to control the costs of the prescription
23 drug coverage unless the carrier and PBM adhere to the
24 following criteria:

1 “(1) The PBM may not transmit any personally
2 identifiable utilization, protected health information,
3 or claims data with respect to an individual enrolled
4 under such contract or plan to a pharmacy owned by
5 the PBM if the individual has not voluntarily elected
6 in writing or via secure electronic means to fill that
7 particular prescription at such a pharmacy.

8 “(2) The PBM may not require that an indi-
9 vidual enrolled under such contract or plan use a re-
10 tail pharmacy, mail order pharmacy, specialty phar-
11 macy, or other pharmacy entity providing pharmacy
12 services in which the PBM has an ownership interest
13 or that has an ownership interest in the PBM or
14 provide an incentive to a plan enrollee to encourage
15 the enrollee to use a retail pharmacy, mail order
16 pharmacy, specialty pharmacy, or other pharmacy
17 entity providing pharmacy services in which the
18 PBM has an ownership interest or that has an own-
19 ership interest in the PBM, if the incentive is appli-
20 cable only to such pharmacies.

21 “(q)(1) If a contract made or plan approved under
22 this chapter provides for a standard for reimbursement
23 (as described in paragraph (2)) with respect to a prescrip-
24 tion drug plan, such contract or plan shall provide that
25 the applicable carrier—

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

5 “(B) disclose to applicable pharmacies and the
6 contracting entities of such pharmacies the sources
7 used for making any such update immediately with-
8 out requirement of request;

9 “(C) if the source for such a standard for reim-
10 bursement is not publicly available, disclose to the
11 applicable pharmacies and contracting entities of
12 such pharmacies all individual drug prices to be so
13 updated in advance of the use of such prices for the
14 reimbursement of claims;

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

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

23 “(2) For purposes of paragraph (1), a standard for
24 reimbursement of a pharmacy is any methodology or for-
25 mula for varying the pricing of a drug or drugs during

1 the term of the pharmacy reimbursement contract that is
2 based on the cost of the drug involved, including drug pric-
3 ing references and amounts that are based upon average
4 wholesale price, wholesale average cost, average manufac-
5 turer price, average sales price, maximum allowable cost,
6 or other costs, whether publicly available or not.”.

7 (B) APPLICATION.—The amendment made
8 by subparagraph (A) shall apply to any contract
9 entered into under section 8902 of title 5,
10 United States Code, on or after the date of en-
11 actment of this section.

12 **SEC. 367. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
13 **EFIT MANAGER SERVICES.**

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

18 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**
19 **BENEFIT MANAGER SERVICES.**

20 “(a) IN GENERAL.—A group health plan or health
21 insurance issuer offering group health insurance coverage
22 or an entity or subsidiary providing pharmacy benefits
23 management services shall not enter into a contract with
24 a drug manufacturer, distributor, wholesaler, subcon-
25 tractor, rebate aggregator, or any associated third party

1 that limits the disclosure of information to plan sponsors
2 in such a manner that prevents the plan or coverage, or
3 an entity or subsidiary providing pharmacy benefits man-
4 agement services on behalf of a plan or coverage from
5 making the reports described in subsection (b).

6 “(b) REPORTS TO GROUP PLAN SPONSORS.—

7 “(1) IN GENERAL.—Beginning with the first
8 plan year that begins after the date of enactment of
9 the Fair Care Act of 2020, not less frequently than
10 once every 6 months, a health insurance issuer offer-
11 ing group health insurance coverage or an entity
12 providing pharmacy benefits management services
13 on behalf of a group health plan shall submit to the
14 plan sponsor (as defined in section 3(16)(B) of the
15 Employee Retirement Income Security Act of 1974)
16 of such group health plan or health insurance cov-
17 erage a report in accordance with this subsection
18 and make such report available to the plan sponsor
19 in a machine-readable format. Each such report
20 shall include, with respect to the applicable group
21 health plan or health insurance coverage—

22 “(A) information collected from drug man-
23 ufacturers by such issuer or entity on the total
24 amount of copayment assistance dollars paid, or
25 copayment cards applied, that were funded by

1 the drug manufacturer with respect to the en-
2 rollees in such plan or coverage;

3 “(B) a list of each covered drug dispensed
4 during the reporting period, including, with re-
5 spect to each such drug during the reporting
6 period—

7 “(i) the brand name, chemical entity,
8 and National Drug Code;

9 “(ii) the number of enrollees for
10 whom the drug was filled during the plan
11 year, the total number of prescription fills
12 for the drug (including original prescrip-
13 tions and refills), and the total number of
14 dosage units of the drug dispensed across
15 the plan year, including whether the dis-
16 pensing channel was by retail, mail order,
17 or specialty pharmacy;

18 “(iii) the wholesale acquisition cost,
19 listed as cost per days supply and cost per
20 pill, or in the case of a drug in another
21 form, per dose;

22 “(iv) the total out-of-pocket spending
23 by enrollees on such drug, including en-
24 rollee spending through copayments, coin-
25 surance, and deductibles; and

1 “(v) for any drug for which gross
2 spending of the group health plan or
3 health insurance coverage exceeded
4 \$10,000 during the reporting period—

5 “(I) a list of all other available
6 drugs in the same therapeutic cat-
7 egory or class, including brand name
8 drugs and biological products and ge-
9 neric drugs or biosimilar biological
10 products that are in the same thera-
11 peutic category or class; and

12 “(II) the rationale for preferred
13 formulary placement of a particular
14 drug or drugs in that therapeutic cat-
15 egory or class;

16 “(C) a list of each therapeutic category or
17 class of drugs that were dispensed under the
18 health plan or health insurance coverage during
19 the reporting period, and, with respect to each
20 such therapeutic category or class of drugs,
21 during the reporting period—

22 “(i) total gross spending by the plan,
23 before manufacturer rebates, fees, or other
24 manufacturer remuneration;

1 “(ii) the number of enrollees who
2 filled a prescription for a drug in that cat-
3 egory or class;

4 “(iii) if applicable to that category or
5 class, a description of the formulary tiers
6 and utilization mechanisms (such as prior
7 authorization or step therapy) employed
8 for drugs in that category or class;

9 “(iv) the total out-of-pocket spending
10 by enrollees, including enrollee spending
11 through copayments, coinsurance, and
12 deductibles; and

13 “(v) for each therapeutic category or
14 class under which 3 or more drugs are in-
15 cluded on the formulary of such plan or
16 coverage—

17 “(I) the amount received, or ex-
18 pected to be received, from drug man-
19 ufacturers in rebates, fees, alternative
20 discounts, or other remuneration—

21 “(aa) to be paid by drug
22 manufacturers for claims in-
23 curred during the reporting pe-
24 riod; or

1 “(bb) that is related to utili-
2 zation of drugs, in such thera-
3 peutic category or class;

4 “(II) the total net spending, after
5 deducting rebates, price concessions,
6 alternative discounts or other remu-
7 neration from drug manufacturers, by
8 the health plan or health insurance
9 coverage on that category or class of
10 drugs; and

11 “(III) the net price per course of
12 treatment or 30-day supply incurred
13 by the health plan or health insurance
14 coverage and its enrollees, after man-
15 ufacturer rebates, fees, and other re-
16 muneration for drugs dispensed within
17 such therapeutic category or class
18 during the reporting period;

19 “(D) total gross spending on prescription
20 drugs by the plan or coverage during the re-
21 porting period, before rebates and other manu-
22 facturer fees or remuneration;

23 “(E) total amount received, or expected to
24 be received, by the health plan or health insur-
25 ance coverage in drug manufacturer rebates,

1 fees, alternative discounts, and all other remuneration received from the manufacturer or any
2 third party, other than the plan sponsor, related to utilization of drug or drug spending
3 under that health plan or health insurance coverage during the reporting period;
4
5

6 “(F) the total net spending on prescription drugs by the health plan or health insurance
7 coverage during the reporting period; and
8
9

10 “(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration
11 to brokers, consultants, advisors, or any other individual or firm who referred the group health
12 plan’s or health insurance issuer’s business to the pharmacy benefit manager.
13
14
15

16 “(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage
17 and entities providing pharmacy benefits management services on behalf of a group health plan
18 shall provide information under paragraph (1) in a manner consistent with the privacy, security, and
19 breach notification regulations promulgated under section 264(c) of the Health Insurance Portability
20 and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of
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1 such information according to such privacy regula-
2 tions.

3 “(3) DISCLOSURE AND REDISCLOSURE.—

4 “(A) LIMITATION TO BUSINESS ASSOCI-
5 ATES.—A group health plan receiving a report
6 under paragraph (1) may disclose such informa-
7 tion only to business associates of such plan as
8 defined in section 160.103 of title 45, Code of
9 Federal Regulations (or successor regulations).

10 “(B) CLARIFICATION REGARDING PUBLIC
11 DISCLOSURE OF INFORMATION.—Nothing in
12 this section prevents a health insurance issuer
13 offering group health insurance coverage or an
14 entity providing pharmacy benefits management
15 services on behalf of a group health plan from
16 placing reasonable restrictions on the public dis-
17 closure of the information contained in a report
18 described in paragraph (1), except that such
19 issuer or entity may not restrict disclosure of
20 such report to governmental agencies pursuant
21 to an investigation or enforcement action.

22 “(C) LIMITED FORM OF REPORT.—The
23 Secretary shall define through rulemaking a
24 limited form of the report under paragraph (1)
25 required of plan sponsors who are drug manu-

1 facturers, drug wholesalers, or other direct par-
2 ticipants in the drug supply chain, in order to
3 prevent anti-competitive behavior.

4 “(c) LIMITATIONS ON SPREAD PRICING.—

5 “(1) PRESCRIPTION DRUG TRANSACTIONS WITH
6 PHARMACIES INDEPENDENT OF THE ISSUER OR
7 PHARMACY BENEFITS MANAGER.—If the pharmacy
8 that dispenses a prescription drug to an enrollee in
9 a group health plan or group or individual health in-
10 surance coverage is not wholly or partially owned by
11 such plan, such issuer, or an entity providing phar-
12 macy benefit management services under such plan
13 or coverage, such plan, issuer, or entity shall not
14 charge the plan, issuer, or enrollee a price for such
15 prescription drug that exceeds the price paid to the
16 pharmacy.

17 “(2) INTRA-COMPANY PRESCRIPTION DRUG
18 TRANSACTIONS.—If the mail order, specialty, or re-
19 tail pharmacy that dispenses a prescription drug to
20 an enrollee in a group health plan or health insur-
21 ance coverage is wholly or partially owned by, and
22 submits claims to, such health insurance issuer or
23 an entity providing pharmacy benefit management
24 services under a group health plan or group or indi-
25 vidual health insurance coverage, the price charged

1 for such drug by such pharmacy to such group
2 health plan or health insurance issuer offering group
3 or individual health insurance coverage may not ex-
4 ceed the lesser of—

5 “(A) the amount paid to the pharmacy for
6 acquisition of the drug; or

7 “(B) the median price charged to the
8 group health plan or health insurance issuer
9 when the same drug is dispensed to enrollees in
10 the plan or coverage by other similarly situated
11 pharmacies not wholly or partially owned by the
12 health insurance issuer or entity providing
13 pharmacy benefits management services, as de-
14 scribed in paragraph (1).

15 “(3) SUPPLEMENTARY REPORTING FOR INTRA-
16 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A
17 health insurance issuer of group health insurance
18 coverage or an entity providing pharmacy benefits
19 management services under a group health plan or
20 group health insurance coverage that conducts
21 transactions with a wholly or partially owned phar-
22 macy, as described in paragraph (2), shall submit,
23 together with the report under subsection (b), a sup-
24 plementary report every 6 months to the plan spon-
25 sor that includes—

1 “(A) an explanation of any benefit design
2 parameters that encourage enrollees in the plan
3 or coverage to fill prescriptions at mail order,
4 specialty, or retail pharmacies that are wholly
5 or partially owned by that issuer or entity;

6 “(B) the percentage of total prescriptions
7 charged to the plan, coverage, or enrollees in
8 the plan or coverage, that were dispensed by
9 mail order, specialty, or retail pharmacies that
10 are wholly or partially owned by the issuer or
11 entity providing pharmacy benefits management
12 services; and

13 “(C) a list of all drugs dispensed by such
14 wholly or partially-owned pharmacy and
15 charged to the plan or coverage, or enrollees of
16 the plan or coverage, during the applicable
17 quarter, and, with respect to each drug—

18 “(i) the amount charged per course of
19 treatment or 30-day supply with respect to
20 enrollees in the plan or coverage, including
21 amounts charged to the plan or coverage
22 and amounts charged to the enrollee;

23 “(ii) the median amount charged to
24 the plan or coverage, per course of treat-
25 ment or 30-day supply, including amounts

1 paid by the enrollee, when the same drug
2 is dispensed by other pharmacies that are
3 not wholly or partially owned by the issuer
4 or entity and that are included in the
5 pharmacy network of that plan or cov-
6 erage;

7 “(iii) the interquartile range of the
8 costs, per course of treatment or 30-day
9 supply, including amounts paid by the en-
10 rollee, when the same drug is dispensed by
11 other pharmacies that are not wholly or
12 partially owned by the issuer or entity and
13 that are included in the pharmacy network
14 of that plan or coverage; and

15 “(iv) the lowest cost per course of
16 treatment or 30-day supply, for such drug,
17 including amounts charged to the plan or
18 issuer and enrollee, that is available from
19 any pharmacy included in the network of
20 the plan or coverage.

21 “(d) FULL REBATE PASS-THROUGH TO PLAN.—

22 “(1) IN GENERAL.—A pharmacy benefits man-
23 ager, a third-party administrator of a group health
24 plan, a health insurance issuer offering group health
25 insurance coverage, or an entity providing pharmacy

1 benefits management services under such health
2 plan or health insurance coverage shall remit 100
3 percent of rebates, fees, alternative discounts, and
4 all other remuneration received from a pharma-
5 ceutical manufacturer, distributor or any other third
6 party, that are related to utilization of drugs under
7 such health plan or health insurance coverage, to the
8 group health plan.

9 “(2) FORM AND MANNER OF REMITTANCE.—

10 Such rebates, fees, alternative discounts, and other
11 remuneration shall be—

12 “(A) remitted to the group health plan in
13 a timely fashion after the period for which such
14 rebates, fees, or other remuneration is cal-
15 culated, and in no case later than 90 days after
16 the end of such period;

17 “(B) fully disclosed and enumerated to the
18 group health plan sponsor, as described in
19 (b)(1);

20 “(C) available for audit by the plan spon-
21 sor, or a third party designated by a plan spon-
22 sor no less than once per plan year; and

23 “(D) returned to the issuer or entity pro-
24 viding pharmaceutical benefit management
25 services by the group health plan if audits by

1 such issuer or entity indicate that the amounts
2 received are incorrect after such amounts have
3 been paid to the group health plan.

4 “(3) AUDIT OF REBATE CONTRACTS.—A phar-
5 macy benefits manager, a third-party administrator
6 of a group health plan, a health insurance issuer of-
7 fering group health insurance coverage, or an entity
8 providing pharmacy benefits management services
9 under such health plan or health insurance coverage
10 shall make rebate contracts with drug manufactur-
11 ers available for audit by such plan sponsor or des-
12 ignated third party, subject to confidentiality agree-
13 ments to prevent re-disclosure of such contracts.

14 “(e) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary, in consulta-
16 tion with the Secretary of Labor and the Secretary
17 of the Treasury, shall enforce this section.

18 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
19 TION.—A health insurance issuer or an entity pro-
20 viding pharmacy benefit management services that
21 violates subsection (a), fails to provide information
22 required under subsection (b), engages in spread
23 pricing as defined in subsection (c), or fails to com-
24 ply with the requirements of subsection (d), or a
25 drug manufacturer that fails to provide information

1 under subsection (b)(1)(A), in a timely manner shall
2 be subject to a civil monetary penalty in the amount
3 of \$10,000 for each day during which such violation
4 continues or such information is not disclosed or re-
5 ported.

6 “(3) FALSE INFORMATION.—A health insurance
7 issuer, entity providing pharmacy benefit manage-
8 ment services, or drug manufacturer that knowingly
9 provides false information under this section shall be
10 subject to a civil money penalty in an amount not
11 to exceed \$100,000 for each item of false informa-
12 tion. Such civil money penalty shall be in addition to
13 other penalties as may be prescribed by law.

14 “(4) PROCEDURE.—The provisions of section
15 1128A of the Social Security Act, other than sub-
16 section (a) and (b) and the first sentence of sub-
17 section (c)(1) of such section shall apply to civil
18 monetary penalties under this subsection in the
19 same manner as such provisions apply to a penalty
20 or proceeding under section 1128A of the Social Se-
21 curity Act.

22 “(5) SAFE HARBOR.—The Secretary may waive
23 penalties under paragraph (2), or extend the period
24 of time for compliance with a requirement of this
25 section, for an entity in violation of this section that

1 has made a good-faith effort to comply with this sec-
2 tion.

3 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to prohibit payments to entities
5 offering pharmacy benefits management services for bona
6 fide services using a fee structure not contemplated by this
7 section, provided that such fees are transparent to group
8 health plans and health insurance issuers.

9 “(g) DEFINITIONS.—In this section—

10 “(1) the term ‘similarly situated pharmacy’
11 means, with respect to a particular pharmacy, an-
12 other pharmacy that is approximately the same size
13 (as measured by the number of prescription drugs
14 dispensed), and that serves patients in the same geo-
15 graphical area, whether through physical locations or
16 mail order; and

17 “(2) the term ‘wholesale acquisition cost’ has
18 the meaning given such term in section
19 1847A(c)(6)(B) of the Social Security Act.”.

20 **SEC. 368. STUDY BY COMPTROLLER GENERAL OF UNITED**
21 **STATES.**

22 (a) IN GENERAL.—The Comptroller General of the
23 United States (referred to in this section as the “Comp-
24 troller General”) shall, in consultation with appropriate

1 stakeholders, conduct a study on the role of pharmacy
2 benefit managers.

3 (b) PERMISSIBLE EXAMINATION.—In conducting the
4 study required under subsection (a), the Comptroller Gen-
5 eral may examine various qualitative and quantitative as-
6 pects of the role of pharmacy benefit managers, such as
7 the following:

8 (1) The role that pharmacy benefit managers
9 play in the pharmaceutical supply chain.

10 (2) The state of competition among pharmacy
11 benefit managers, including the market share for the
12 Nation's largest pharmacy benefit managers.

13 (3) The use of rebates and fees by pharmacy
14 benefit managers, including—

15 (A) the extent to which rebates are passed
16 on to health plans and whether such rebates are
17 passed on to individuals enrolled in such plans;

18 (B) the extent to which rebates are kept by
19 such pharmacy benefit managers; and

20 (C) the role of any fees charged by such
21 pharmacy benefit managers.

22 (4) Whether pharmacy benefit managers struc-
23 ture their formularies in favor of high-rebate pre-
24 scription drugs over lower-cost, lower-rebate alter-
25 natives.

1 “(A) SECRETARIAL PROVISION OF INFOR-
2 MATION.—Not later than 6 months after the
3 end of each rebate period (as defined in para-
4 graph (2)(A)) beginning on or after January 1,
5 2021, the Secretary shall, for each rebatable
6 drug (as defined in paragraph (2)(B)), report
7 to each manufacturer of such rebatable drug
8 the following for such rebate period:

9 “(i) Information on the total number
10 of units of the billing and payment code
11 described in subparagraph (A)(i) of para-
12 graph (3) with respect to such rebatable
13 drug and rebate period.

14 “(ii) Information on the amount (if
15 any) of the excess average sales price in-
16 crease described in subparagraph (A)(ii) of
17 such paragraph for such rebatable drug
18 and rebate period.

19 “(iii) The rebate amount specified
20 under such paragraph for such rebatable
21 drug and rebate period.

22 “(B) MANUFACTURER REBATE.—

23 “(i) IN GENERAL.—Subject to clause
24 (ii), for each rebate period beginning on or
25 after January 1, 2021, the manufacturer

1 of a rebatable drug shall, for such drug,
2 not later than 30 days after the date of re-
3 ceipt from the Secretary of the information
4 and rebate amount pursuant to subpara-
5 graph (A) for such rebate period, provide
6 to the Secretary a rebate that is equal to
7 the amount specified in paragraph (3) for
8 such drug for such rebate period.

9 “(ii) EXEMPTION FOR SHORTAGES.—

10 The Secretary may reduce or waive the re-
11 bate under this subparagraph with respect
12 to a rebatable drug that is listed on the
13 drug shortage list maintained by the Food
14 and Drug Administration pursuant to sec-
15 tion 506E of the Federal Food, Drug, and
16 Cosmetic Act.

17 “(C) REQUEST FOR RECONSIDERATION.—

18 The Secretary shall establish procedures under
19 which a manufacturer of a rebatable drug may
20 request a reconsideration by the Secretary of
21 the rebate amount specified under paragraph
22 (3) for such rebatable drug and rebate period,
23 as reported to the manufacturer pursuant to
24 subparagraph (A)(iii).

1 “(2) REBATE PERIOD AND REBATABLE DRUG
2 DEFINED.—In this subsection:

3 “(A) REBATE PERIOD.—The term ‘rebate
4 period’ means a calendar quarter beginning on
5 or after January 1, 2021.

6 “(B) REBATABLE DRUG.—The term
7 ‘rebateable drug’ means a single source drug or
8 biological (other than a biosimilar biological
9 product)—

10 “(i) described in section
11 1842(o)(1)(C) for which the payment
12 amount is provided under this section; or

13 “(ii) for which payment is made sepa-
14 rately under section 1833(i) or section
15 1833(t) and for which the payment
16 amount is calculated based on the payment
17 amount under this section.

18 “(3) REBATE AMOUNT.—

19 “(A) IN GENERAL.—For purposes of para-
20 graph (1)(B), the amount specified in this para-
21 graph for a rebatable drug assigned to a billing
22 and payment code for a rebate period is, subject
23 to paragraph (4), the amount equal to the prod-
24 uct of—

1 “(i) subject to subparagraph (B), the
2 total number of units of the billing and
3 payment code for such rebatable drug fur-
4 nished during the rebate period; and

5 “(ii) the amount (if any) by which—

6 “(I) the amount determined
7 under subsection (b)(4) for such
8 rebatable drug during the rebate pe-
9 riod; exceeds

10 “(II) the inflation-adjusted base
11 payment amount determined under
12 subparagraph (C) of this paragraph
13 for such rebatable drug during the re-
14 bate period.

15 “(B) EXCLUDED UNITS.—For purposes of
16 subparagraph (A)(i), the total number of units
17 of the billing and payment code for rebatable
18 drugs furnished during a rebate period shall not
19 include units with respect to which the manu-
20 facturer provides a discount under the program
21 under section 340B of the Public Health Serv-
22 ice Act or a rebate under section 1927.

23 “(C) DETERMINATION OF INFLATION-AD-
24 JUSTED PAYMENT AMOUNT.—The inflation-ad-
25 justed payment amount determined under this

1 subparagraph for a rebatable drug for a rebate
2 period is—

3 “(i) the amount determined under
4 subsection (b)(4) for such rebatable drug
5 in the payment amount benchmark quarter
6 (as defined in subparagraph (D)); in-
7 creased by

8 “(ii) the percentage by which the re-
9 bate period CPI-U (as defined in subpara-
10 graph (F)) for the rebate period exceeds
11 the benchmark period CPI-U (as defined
12 in subparagraph (E)).

13 “(D) PAYMENT AMOUNT BENCHMARK
14 QUARTER.—The term ‘payment amount bench-
15 mark quarter’ means the calendar quarter be-
16 ginning July 1, 2019.

17 “(E) BENCHMARK PERIOD CPI-U.—The
18 term ‘benchmark period CPI-U’ means the con-
19 sumer price index for all urban consumers
20 (United States city average) for July 2019.

21 “(F) REBATE PERIOD CPI-U.—The term
22 ‘rebate period CPI-U’ means, with respect to a
23 rebate period, the consumer price index for all
24 urban consumers (United States city average)
25 for the last month of the calendar quarter that

1 is two calendar quarters prior to the rebate pe-
2 riod.

3 “(4) APPLICATION TO NEW DRUGS.—In the
4 case of a rebatable drug first approved or licensed
5 by the Food and Drug Administration after July 1,
6 2019, the following shall apply:

7 “(A) DURING INITIAL PERIOD.—For quar-
8 ters during the initial period in which the pay-
9 ment amount for such drug is determined using
10 the methodology described in subsection
11 (c)(4)—

12 “(i) clause (ii)(I) of paragraph (3)(A)
13 shall be applied as if the reference to ‘the
14 amount determined under subsection
15 (b)(4),’ were a reference to ‘the wholesale
16 acquisition cost applicable under subsection
17 (c)(4)’;

18 “(ii) clause (i) of paragraph (3)(C)
19 shall be applied—

20 “(I) as if the reference to ‘the
21 amount determined under subsection
22 (b)(4),’ were a reference to ‘the whole-
23 sale acquisition cost applicable under
24 subsection (c)(4)’; and

1 “(II) as if the term ‘payment
2 amount benchmark quarter’ were de-
3 fined under paragraph (3)(D) as the
4 first full calendar quarter after the
5 day on which the drug was first mar-
6 keted; and

7 “(iii) clause (ii) of paragraph (3)(C)
8 shall be applied as if the term ‘benchmark
9 period CPI-U’ were defined under para-
10 graph (4)(E) as if the reference to ‘July
11 2019’ under such paragraph were a ref-
12 erence to ‘the first month of the first full
13 calendar quarter after the day on which
14 the drug was first marketed’.

15 “(B) AFTER INITIAL PERIOD.—For quar-
16 ters beginning after such initial period—

17 “(i) clause (i) of paragraph (3)(C)
18 shall be applied as if the term ‘payment
19 amount benchmark quarter’ were defined
20 under paragraph (3)(D) as the first full
21 calendar quarter for which the Secretary is
22 able to compute an average sales price for
23 the rebatable drug; and

24 “(ii) clause (ii) of paragraph (3)(C)
25 shall be applied as if the term ‘benchmark

1 period CPI–U’ were defined under para-
2 graph (4)(E) as if the reference to ‘July
3 2019’ under such paragraph were a ref-
4 erence to ‘the first month of the first full
5 calendar quarter for which the Secretary is
6 able to compute an average sales price for
7 the rebatable drug’.

8 “(5) REBATE DEPOSITS.—Amounts paid as re-
9 bates under paragraph (1)(B) shall be deposited into
10 the Federal Supplementary Medical Insurance Trust
11 Fund established under section 1841.

12 “(6) ENFORCEMENT.—

13 “(A) CIVIL MONEY PENALTY.—

14 “(i) IN GENERAL.—The Secretary
15 shall impose a civil money penalty on a
16 manufacturer that fails to comply with the
17 requirements under paragraph (1)(B) with
18 respect to providing a rebate for a
19 rebatable drug for a rebate period for each
20 such failure in an amount equal to the sum
21 of—

22 “(I) the rebate amount specified
23 pursuant to paragraph (3) for such
24 drug for such rebate period; and

25 “(II) 25 percent of such amount.

1 “(ii) APPLICATION.—The provisions
2 of section 1128A (other than subsections
3 (a) (with respect to amounts of penalties
4 or additional assessments) and (b)) shall
5 apply to a civil money penalty under this
6 subparagraph in the same manner as such
7 provisions apply to a penalty or proceeding
8 under section 1128A(a).

9 “(B) NO PAYMENT FOR MANUFACTURERS
10 WHO FAIL TO PAY PENALTY.—If the manufac-
11 turer of a rebatable drug fails to pay a civil
12 money penalty under subparagraph (A) with re-
13 spect to the failure to provide a rebate for a
14 rebatable drug for a rebate period by a date
15 specified by the Secretary after the imposition
16 of such penalty, no payment shall be available
17 under this part for such rebatable drug for cal-
18 endar quarters beginning on or after such date
19 until the Secretary determines the manufac-
20 turer has paid the penalty due under such sub-
21 paragraph.”.

22 (b) IMPLEMENTATION.—Section 1847A(g) of the So-
23 cial Security Act (42 U.S.C. 1395w-3(g)) is amended—

24 (1) in paragraph (4), by striking “and” at the
25 end;

1 (2) in paragraph (5), by striking the period at
2 the end and inserting “; and”; and

3 (3) by adding at the end the following new
4 paragraph:

5 “(6) determination of the rebate amount for a
6 rebtable drug under paragraph (3) of subsection
7 (h), including with respect to a new drug pursuant
8 to paragraph (4) of such subsection, including—

9 “(A) a decision by the Secretary with re-
10 spect to a request for reconsideration under
11 paragraph (1)(C); and

12 “(B) the determination of—

13 “(i) the total number of units of the
14 billing and payment code under paragraph
15 (3)(A)(i); and

16 “(ii) the inflation-adjusted payment
17 amount under paragraph (3)(C).”.

18 (c) CONFORMING AMENDMENT TO PART B ASP CAL-
19 CULATION.—Section 1847A(c)(3) of the Social Security
20 Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting
21 “or subsection (h)” after “section 1927”.

22 **SEC. 372. MARKET BASED PART B PRICING INDEX.**

23 Notwithstanding any provision of part B of title
24 XVIII of the Social Security Act, the Secretary of Health
25 and Human Services may make payments for drugs pay-

1 able under such part based on an international pricing
2 index. In using such an index, the Secretary shall take
3 into account whether the market of each country included
4 in such index is a price-controlled or free market and give
5 more weight under such index to countries with market-
6 based drug policies.

7 **SEC. 373. INNOVATION MODEL TESTING OF MEDICARE**
8 **DRUG PAYMENTS.**

9 Notwithstanding any provision of section 1115A, the
10 Secretary of Health and Human Services may, under such
11 section, test a model to integrate benefits provided for
12 drugs under parts A, B, and D of title XVIII of the Social
13 Security Act.

14 **SEC. 374. MODIFICATION OF MAXIMUM REBATE AMOUNT**
15 **UNDER MEDICAID DRUG REBATE PROGRAM.**

16 (a) IN GENERAL.—Subparagraph (D) of section
17 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r-
18 8(c)(2)) is amended to read as follows:

19 “(D) MAXIMUM REBATE AMOUNT.—

20 “(i) IN GENERAL.—Except as pro-
21 vided in clause (ii), in no case shall the
22 sum of the amounts applied under para-
23 graph (1)(A)(ii) and this paragraph with
24 respect to each dosage form and strength
25 of a single source drug or an innovator

1 multiple source drug for a rebate period
2 exceed—

3 “(I) for rebate periods beginning
4 after December 31, 2009, and before
5 September 30, 2022, 100 percent of
6 the average manufacturer price of the
7 drug; and

8 “(II) for rebate periods beginning
9 on or after October 1, 2022, 125 per-
10 cent of the average manufacturer
11 price of the drug.

12 “(ii) NO MAXIMUM AMOUNT FOR
13 DRUGS IF AMP INCREASES OUTPACE IN-
14 FLATION.—

15 “(I) IN GENERAL.—If the aver-
16 age manufacturer price with respect
17 to each dosage form and strength of
18 a single source drug or an innovator
19 multiple source drug increases on or
20 after October 1, 2021, and such in-
21 creased average manufacturer price
22 exceeds the inflation-adjusted average
23 manufacturer price determined with
24 respect to such drug under subclause
25 (II) for the rebate period, clause (i)

1 shall not apply and there shall be no
2 limitation on the sum of the amounts
3 applied under paragraph (1)(A)(ii)
4 and this paragraph for the rebate pe-
5 riod with respect to each dosage form
6 and strength of the single source drug
7 or innovator multiple source drug.

8 “(II) INFLATION-ADJUSTED AV-
9 ERAGE MANUFACTURER PRICE DE-
10 FINED.—In this clause, the term ‘in-
11 flation-adjusted average manufacturer
12 price’ means, with respect to a single
13 source drug or an innovator multiple
14 source drug and a rebate period, the
15 average manufacturer price for each
16 dosage form and strength of the drug
17 for the calendar quarter beginning
18 July 1, 1990 (without regard to
19 whether or not the drug has been sold
20 or transferred to an entity, including
21 a division or subsidiary of the manu-
22 facturer, after the 1st day of such
23 quarter), increased by the percentage
24 by which the consumer price index for
25 all urban consumers (United States

1 city average) for the month before the
2 month in which the rebate period be-
3 gins exceeds such index for September
4 1990.”.

5 (b) TREATMENT OF SUBSEQUENTLY APPROVED
6 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act
7 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting
8 “and clause (ii)(II) of subparagraph (D)” after “clause
9 (ii)(II) of subparagraph (A)”.

10 (c) TECHNICAL AMENDMENTS.—Section
11 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42
12 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

13 (1) by striking “subparagraph (A)” and insert-
14 ing “paragraph (3)(A)”; and

15 (2) by striking “this subparagraph” and insert-
16 ing “paragraph (3)(C)”.

17 **Subtitle F—Medical Malpractice** 18 **Reform**

19 **SEC. 381. DEFINITIONS.**

20 In this Act:

21 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
22 TEM; ADR.—The term “alternative dispute resolution
23 system” or “ADR” means a system that provides
24 for the resolution of health care lawsuits in a man-

1 ner other than through a civil action brought in a
2 State or Federal court.

3 (2) CLAIMANT.—The term “claimant” means
4 any person who brings a health care lawsuit, includ-
5 ing a person who asserts or claims a right to legal
6 or equitable contribution, indemnity, or subrogation,
7 arising out of a health care liability claim or action,
8 and any person on whose behalf such a claim is as-
9 serted or such an action is brought, whether de-
10 ceased, incompetent, or a minor.

11 (3) COLLATERAL SOURCE BENEFITS.—The
12 term “collateral source benefits” means any amount
13 paid or reasonably likely to be paid in the future to
14 or on behalf of the claimant, or any service, product,
15 or other benefit provided or reasonably likely to be
16 provided in the future to or on behalf of the claim-
17 ant, as a result of the injury or wrongful death, pur-
18 suant to—

19 (A) any State or Federal health, sickness,
20 income-disability, accident, or workers’ com-
21 pensation law;

22 (B) any health, sickness, income-disability,
23 or accident insurance that provides health bene-
24 fits or income-disability coverage;

1 (C) any contract or agreement of any
2 group, organization, partnership, or corporation
3 to provide, pay for, or reimburse the cost of
4 medical, hospital, dental, or income-disability
5 benefits; and

6 (D) any other publicly or privately funded
7 program.

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

12 (5) ECONOMIC DAMAGES.—The term “economic
13 damages” means objectively verifiable monetary
14 losses incurred as a result of the provision or use of
15 (or failure to provide or use) health care services or
16 medical products, such as past and future medical
17 expenses, loss of past and future earnings, cost of
18 obtaining domestic services, loss of employment, and
19 loss of business or employment opportunities, unless
20 otherwise defined under applicable State law. In no
21 circumstances shall damages for health care services
22 or medical products exceed the amount actually paid
23 or incurred by or on behalf of the claimant.

24 (6) FUTURE DAMAGES.—The term “future
25 damages” means any damages that are incurred

1 after the date of judgment, settlement, or other reso-
2 lution (including mediation, or any other form of al-
3 ternative dispute resolution).

4 (7) HEALTH CARE LAWSUIT.—The term
5 “health care lawsuit” means any health care liability
6 claim concerning the provision of goods or services
7 for which coverage was provided in whole or in part
8 via a Federal program, subsidy or tax benefit, or
9 any health care liability action concerning the provi-
10 sion of goods or services for which coverage was pro-
11 vided in whole or in part via a Federal program,
12 subsidy or tax benefit, brought in a State or Federal
13 court or pursuant to an alternative dispute resolu-
14 tion system, against a health care provider regard-
15 less of the theory of liability on which the claim is
16 based, or the number of claimants, plaintiffs, de-
17 fendants, or other parties, or the number of claims
18 or causes of action, in which the claimant alleges a
19 health care liability claim. Such term does not in-
20 clude a claim or action which is based on criminal
21 liability; which seeks civil fines or penalties paid to
22 Federal, State, or local government; or which is
23 grounded in antitrust.

24 (8) HEALTH CARE LIABILITY ACTION.—The
25 term “health care liability action” means a civil ac-

1 tion brought in a State or Federal court or pursuant
2 to an alternative dispute resolution system, against
3 a health care provider regardless of the theory of li-
4 ability on which the claim is based, or the number
5 of plaintiffs, defendants, or other parties, or the
6 number of causes of action, in which the claimant al-
7 leges a health care liability claim.

8 (9) HEALTH CARE LIABILITY CLAIM.—The
9 term “health care liability claim” means a demand
10 by any person, whether or not pursuant to ADR,
11 against a health care provider, including, but not
12 limited to, third-party claims, cross-claims, counter-
13 claims, or contribution claims, which are based upon
14 the provision or use of (or the failure to provide or
15 use) health care services or medical products, re-
16 gardless of the theory of liability on which the claim
17 is based, or the number of plaintiffs, defendants, or
18 other parties, or the number of causes of action.

19 (10) HEALTH CARE PROVIDER.—The term
20 “health care provider” means any person or entity
21 required by State or Federal laws or regulations to
22 be licensed, registered, or certified to provide health
23 care services, and being either so licensed, reg-
24 istered, or certified, or exempted from such require-
25 ment by other statute or regulation, as well as any

1 other individual or entity defined as a health care
2 provider, health care professional, or health care in-
3 stitution under State law.

4 (11) HEALTH CARE SERVICES.—The term
5 “health care services” means the provision of any
6 goods or services (including safety, professional, or
7 administrative services directly related to health
8 care) by a health care provider, or by any individual
9 working under the supervision of a health care pro-
10 vider, that relates to the diagnosis, prevention, or
11 treatment of any human disease or impairment, or
12 the assessment or care of the health of human
13 beings.

14 (12) MEDICAL PRODUCT.—The term “medical
15 product” means a drug, device, or biological product
16 intended for humans, and the terms “drug”, “de-
17 vice”, and “biological product” have the meanings
18 given such terms in sections 201(g)(1) and 201(h)
19 of the Federal Food, Drug and Cosmetic Act (21
20 U.S.C. 321(g)(1) and (h)) and section 351(a) of the
21 Public Health Service Act (42 U.S.C. 262(a)), re-
22 spectively, including any component or raw material
23 used therein, but excluding health care services.

24 (13) NONECONOMIC DAMAGES.—The term
25 “noneconomic damages” means damages for phys-

1 ical and emotional pain, suffering, inconvenience,
2 physical impairment, mental anguish, disfigurement,
3 loss of enjoyment of life, loss of society and compan-
4 ionship, loss of consortium (other than loss of do-
5 mestic service), hedonic damages, injury to reputa-
6 tion, and all other nonpecuniary losses of any kind
7 or nature incurred as a result of the provision or use
8 of (or failure to provide or use) health care services
9 or medical products, unless otherwise defined under
10 applicable State law.

11 (14) RECOVERY.—The term “recovery” means
12 the net sum recovered after deducting any disburse-
13 ments or costs incurred in connection with prosecu-
14 tion or settlement of the claim, including all costs
15 paid or advanced by any person. Costs of health care
16 incurred by the plaintiff and the attorneys’ office
17 overhead costs or charges for legal services are not
18 deductible disbursements or costs for such purpose.

19 (15) REPRESENTATIVE.—The term “represent-
20 ative” means a legal guardian, attorney, person des-
21 ignated to make decisions on behalf of a patient
22 under a medical power of attorney, or any person
23 recognized in law or custom as a patient’s agent.

24 (16) STATE.—The term “State” means each of
25 the several States, the District of Columbia, the

1 Commonwealth of Puerto Rico, the Virgin Islands,
2 Guam, American Samoa, the Northern Mariana Is-
3 lands, the Trust Territory of the Pacific Islands, and
4 any other territory or possession of the United
5 States, or any political subdivision thereof.

6 **SEC. 382. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

7 (a) STATUTE OF LIMITATIONS.—

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

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

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

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

20 (2) TOLLING.—In no event shall the time for
21 commencement of a health care lawsuit exceed 3
22 years after the date of the occurrence of the breach
23 or tort or 3 years after the date the medical or
24 health care treatment that is the subject of the claim

1 is completed (whichever occurs first) unless tolled
2 for any of the following—

3 (A) upon proof of fraud;

4 (B) intentional concealment; or

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

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

1 the failure to bring an action on behalf of the in-
2 jured minor.

3 (b) STATE FLEXIBILITY.—No provision of subsection
4 (a) 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—

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

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

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

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

18 **SEC. 383. COMPENSATING PATIENT INJURY.**

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

24 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
25 health care lawsuit, the amount of noneconomic damages,

1 if available, shall not exceed \$250,000, regardless of the
2 number of parties against whom the action is brought or
3 the number of separate claims or actions brought with re-
4 spect to the same injury.

5 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
6 DAMAGES.—For purposes of applying the limitation in
7 subsection (b), future noneconomic damages shall not be
8 discounted to present value. The jury shall not be in-
9 formed about the maximum award for noneconomic dam-
10 ages. An award for noneconomic damages in excess of
11 \$250,000 shall be reduced either before the entry of judg-
12 ment, or by amendment of the judgment after entry of
13 judgment, and such reduction shall be made before ac-
14 counting for any other reduction in damages required by
15 law. If separate awards are rendered for past and future
16 noneconomic damages and the combined awards exceed
17 \$250,000, the future noneconomic damages shall be re-
18 duced first.

19 (d) FAIR SHARE RULE.—In any health care lawsuit,
20 each party shall be liable for that party's several share
21 of any damages only and not for the share of any other
22 person. Each party shall be liable only for the amount of
23 damages allocated to such party in direct proportion to
24 such party's percentage of responsibility. Whenever a
25 judgment of liability is rendered as to any party, a sepa-

1 rate judgment shall be rendered against each such party
2 for the amount allocated to such party. For purposes of
3 this section, the trier of fact shall determine the propor-
4 tion of responsibility of each party for the claimant's
5 harm.

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

14 **SEC. 384. MAXIMIZING PATIENT RECOVERY.**

15 (a) COURT SUPERVISION OF SHARE OF DAMAGES
16 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
17 suit, the court shall supervise the arrangements for pay-
18 ment of damages to protect against conflicts of interest
19 that may have the effect of reducing the amount of dam-
20 ages awarded that are actually paid to claimants. In par-
21 ticular, in any health care lawsuit in which the attorney
22 for a party claims a financial stake in the outcome by vir-
23 tue of a contingent fee, the court shall have the power
24 to restrict the payment of a claimant's damage recovery
25 to such attorney, and to redirect such damages to the

1 claimant based upon the interests of justice and principles
2 of equity. In no event shall the total of all contingent fees
3 for representing all claimants in a health care lawsuit ex-
4 ceed the following limits:

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

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

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

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

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

22 (c) STATE FLEXIBILITY.—No provision of this sec-
23 tion shall be construed to preempt any State law (whether
24 effective before, on, or after the date of the enactment of
25 this Act) that specifies a lesser percentage or lesser total

1 value of damages which may be claimed by an attorney
2 representing a claimant in a health care lawsuit.

3 **SEC. 385. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
4 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
5 **SUITS.**

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

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

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 specifies periodic payments for future dam-
23 ages at any amount other than \$50,000 or that mandates
24 such payments absent the request of either party.

1 **SEC. 386. PRODUCT LIABILITY FOR HEALTH CARE PRO-**
2 **VIDERS.**

3 A health care provider who prescribes, or who dis-
4 penses pursuant to a prescription, a medical product ap-
5 proved, licensed, or cleared by the Food and Drug Admin-
6 istration shall not be named as a party to a product liabil-
7 ity lawsuit involving such product and shall not be liable
8 to a claimant in a class action lawsuit against the manu-
9 facturer, distributor, or seller of such product.

10 **SEC. 387. EFFECT ON OTHER LAWS.**

11 (a) VACCINE INJURY.—

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

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

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

21 (2) If there is an aspect of a civil action
22 brought for a vaccine-related injury or death to
23 which a Federal rule of law under title XXI of the
24 Public Health Service Act does not apply, then this
25 subtitle or otherwise applicable law (as determined

1 under this subtitle) will apply to such aspect of such
2 action.

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

7 **SEC. 388. LIMITATION ON EXPERT WITNESS TESTIMONY.**

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

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

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

22 (3) that as a proximate result of the defend-
23 ant's negligent act or omission, the claimant suf-
24 fered injuries which would not otherwise have oc-
25 curred,

1 unless the person was licensed to practice, in the State
2 or a contiguous bordering State, a profession or specialty
3 which would make the person's expert testimony relevant
4 to the issues in the case and had practiced this profession
5 or specialty in one of these States during the year pre-
6 ceding the date that the alleged injury or wrongful act
7 occurred.

8 (b) APPLICABILITY.—The requirements set forth in
9 subsection (a) shall also apply to expert witnesses testi-
10 fying for the defendant as rebuttal witnesses.

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

14 **SEC. 389. EXPERT WITNESS QUALIFICATIONS.**

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

20 (1) If the party against whom or on whose be-
21 half the testimony is to be offered is or claims to be
22 a specialist, the expert witness shall specialize at the
23 time of the occurrence that is the basis for the law-
24 suit in the same specialty or claimed specialty as the
25 party against whom or on whose behalf the testi-

1 mony is to be offered. If the party against whom or
2 on whose behalf the testimony is to be offered is or
3 claims to be a specialist who is board certified, the
4 expert witness shall be a specialist who is board cer-
5 tified in that specialty or claimed specialty.

6 (2) During the 1-year period immediately pre-
7 ceding the occurrence of the action that gave rise to
8 the lawsuit, the expert witness shall have devoted a
9 majority of the individual's professional time to one
10 or more of the following:

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

15 (B) The instruction of students in an ac-
16 credited health professional school or accredited
17 residency or clinical research program in the
18 same health profession as the defendant and, if
19 the defendant is or claims to be a specialist, in
20 an accredited health professional school or ac-
21 credited residency or clinical research program
22 in the same specialty or claimed specialty.

23 (3) If the defendant is a general practitioner,
24 the expert witness shall have devoted a majority of
25 the witness's professional time in the 1-year period

1 preceding the occurrence of the action giving rise to
2 the lawsuit to one or more of the following:

3 (A) Active clinical practice as a general
4 practitioner.

5 (B) Instruction of students in an accred-
6 ited health professional school or accredited
7 residency or clinical research program in the
8 same health profession as the defendant.

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

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

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

23 (e) STATE FLEXIBILITY.—No provision of this sec-
24 tion shall be construed to preempt any State law (whether
25 effective before, on, or after the date of the enactment of

1 this Act) that places additional qualification requirements
2 upon any individual testifying as an expert witness.

3 **SEC. 390. COMMUNICATIONS FOLLOWING UNANTICIPATED**
4 **OUTCOME.**

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

17 (b) 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 makes additional communications inadmis-
21 sible as evidence of an admission of liability or as evidence
22 of an admission against interest.

23 **SEC. 391. AFFIDAVIT OF MERIT.**

24 (a) REQUIRED FILING.—Subject to subsection (b),
25 the plaintiff in a health care lawsuit alleging negligence

1 or, if the plaintiff is represented by an attorney, the plain-
2 tiff's attorney shall file simultaneously with the health
3 care lawsuit an affidavit of merit signed by a health pro-
4 fessional who meets the requirements for an expert wit-
5 ness under section 242 of this Act. The affidavit of merit
6 shall certify that the health professional has reviewed the
7 notice and all medical records supplied to him or her by
8 the plaintiff's attorney concerning the allegations con-
9 tained in the notice and shall contain a statement of each
10 of the following:

11 (1) The applicable standard of practice or care.

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

16 (3) The actions that should have been taken or
17 omitted by the health professional or health facility
18 in order to have complied with the applicable stand-
19 ard of practice or care.

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

23 (5) A listing of the medical records reviewed.

24 (b) FILING EXTENSION.—Upon motion of a party for
25 good cause shown, the court in which the complaint is filed

1 may grant the plaintiff or, if the plaintiff is represented
2 by an attorney, the plaintiff's attorney an additional 28
3 days in which to file the affidavit required under sub-
4 section (a).

5 (c) STATE FLEXIBILITY.—No provision of this sec-
6 tion shall be construed to preempt any State law (whether
7 effective before, on, or after the date of the enactment of
8 this Act) that establishes additional requirements for the
9 filing of an affidavit of merit or similar pre-litigation docu-
10 mentation.

11 **SEC. 392. NOTICE OF INTENT TO COMMENCE LAWSUIT.**

12 (a) ADVANCE NOTICE.—A person shall not com-
13 mence a health care lawsuit against a health care provider
14 unless the person has given the health care provider 90
15 days written notice before the action is commenced.

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

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

1 **SEC. 393. LIMITATION ON LIABILITY FOR VOLUNTEER**
2 **HEALTH CARE PROFESSIONALS.**

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

6 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**
7 **HEALTH CARE PROFESSIONALS.**

8 “(a) LIMITATION ON LIABILITY.—A physician shall
9 not be liable under Federal or State law in any civil action
10 for any harm caused by an act or omission of such physi-
11 cian, or attending medical personnel supporting such phy-
12 sician, if such act or omission—

13 “(1) occurs in the course of furnishing qualified
14 charity care (as such term is defined in section
15 199B of the Internal Revenue Code of 1986); and

16 “(2) was not grossly negligent.

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

22 “(c) DEFINITIONS.—In this section:

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

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

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

9 **SEC. 394. RULES OF CONSTRUCTION.**

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

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

24 (2) prohibits the introduction of evidence re-
25 garding collateral source benefits, or mandates or

1 permits subrogation or a lien on collateral source
2 benefits.

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

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

12 **SEC. 395. EFFECTIVE DATE.**

13 This subtitle shall apply to any health care lawsuit
14 brought in a Federal or State court, or subject to an alter-
15 native dispute resolution system, that is initiated on or
16 after the date of the enactment of this subtitle, except that
17 any health care lawsuit arising from an injury occurring
18 prior to the date of the enactment of this subtitle shall
19 be governed by the applicable statute of limitations provi-
20 sions in effect at the time the cause of action accrued.

1 **TITLE IV—MEDICARE AND**
2 **MEDICAID REFORMS**
3 **Subtitle A—Medicaid Reforms**

4 **SEC. 401. MEDICAID PAYMENT REFORM.**

5 (a) IN GENERAL.—Title XIX of the Social Security
6 Act (42 U.S.C. 1396 et seq.) is amended by inserting after
7 section 1903 the following section:

8 **“SEC. 1903A. REFORMED PAYMENT TO STATES.**

9 “(a) REFORMED PAYMENT SYSTEM.—

10 “(1) IN GENERAL.—For quarters beginning on
11 or after the implementation date (as defined in sub-
12 section (k)(1)), in the case of a State that elects (in
13 a time and manner specified by the Secretary) to
14 apply this section, in lieu of amounts otherwise pay-
15 able to such State under this title (including any
16 payments attributable to section 1923), except as
17 otherwise provided in this section, the amount pay-
18 able to such State shall be equal to the sum of the
19 following:

20 “(A) ADJUSTED AGGREGATE BENE-
21 FICIARY-BASED AMOUNT.—The aggregate bene-
22 ficiary-based amount specified in subsection (b)
23 for the quarter and the State, adjusted under
24 subsection (e).

1 “(B) CHRONIC CARE QUALITY BONUS.—
2 The amount (if any) of the chronic care quality
3 bonus payment specified in subsection (f) for
4 the quarter for the State.

5 “(2) REQUIREMENT OF STATE SHARE.—

6 “(A) IN GENERAL.—A State shall make,
7 from non-Federal funds, expenditures in an
8 amount equal to its State share (as determined
9 under subparagraph (B)) for a quarter for
10 items, services, and other costs for which, but
11 for paragraph (1), Federal funds would have
12 been payable under this title.

13 “(B) STATE SHARE.—The State share for
14 a State for a quarter in a fiscal year is equal
15 to the product of—

16 “(i) the aggregate beneficiary-based
17 amount specified in subsection (b) for the
18 quarter and the State; and

19 “(ii) the ratio of—

20 “(I) the State percentage de-
21 scribed in subparagraph (D)(ii) for
22 such State and fiscal year; to

23 “(II) the Federal percentage de-
24 scribed in subparagraph (D)(i) for
25 such State and fiscal year.

1 “(C) NONPAYMENT FOR FAILURE TO PAY
2 STATE SHARE.—

3 “(i) IN GENERAL.—If a State fails to
4 expend the amount required under sub-
5 paragraph (A) for a quarter in a fiscal
6 year, the amount payable to the State
7 under paragraph (1) shall be reduced by
8 the product of the amount by which the
9 State payment is less than the State share
10 and the ratio of—

11 “(I) the Federal percentage de-
12 scribed in subparagraph (D)(i) for
13 such State and fiscal year; to

14 “(II) the State percentage de-
15 scribed in subparagraph (D)(ii) for
16 such State and fiscal year.

17 “(ii) GRACE PERIOD.—A State shall
18 not be considered to have failed to provide
19 payment of its required State share for a
20 quarter under subparagraph (A) if the ag-
21 gregate State payment towards the State’s
22 required State share for the 4-quarter pe-
23 riod beginning with such quarter exceeds
24 the required State share amount for such
25 4-quarter period.

1 “(D) FEDERAL AND STATE PERCENT-
2 AGES.—In this paragraph, with respect to a
3 State and a fiscal year:

4 “(i) FEDERAL PERCENTAGE.—The
5 Federal percentage described in this clause
6 is 75 percent or, if higher, the Federal
7 medical assistance percentage for such
8 State for such fiscal year.

9 “(ii) STATE PERCENTAGE.—The State
10 percentage described in this clause is 100
11 percent minus the Federal percentage de-
12 scribed in clause (i).

13 “(E) RULES FOR CREDITING TOWARD
14 STATE SHARE.—

15 “(i) GENERAL LIMITATION TO MATCH-
16 ABLE EXPENDITURES.—A payment for ex-
17 penditures shall not be counted toward the
18 State share under subparagraph (A) unless
19 Federal payments may be used for such
20 expenditures consistent with paragraph
21 (3)(B).

22 “(ii) FURTHER LIMITATIONS ON AL-
23 LOWABLE EXPENDITURES.—A payment for
24 expenditures shall not be counted towards

1 the State share under subparagraph (A) if
2 the expenditure is for any of the following:

3 “(I) ABORTION.—Expenditures
4 for an abortion.

5 “(II) INTERGOVERNMENTAL
6 TRANSFERS.—An expenditure that is
7 attributable to an intergovernmental
8 transfer.

9 “(III) CERTIFIED PUBLIC EX-
10 PENDITURES.—An expenditure that is
11 attributable to certified public expend-
12 itures.

13 “(iii) CREDITING FRAUD AND ABUSE
14 RECOVERIES.—Amounts recovered by a
15 State through the operation of its Medicaid
16 fraud and abuse control unit described in
17 section 1903(q) shall be fully counted to-
18 ward the State share under subparagraph
19 (A).

20 “(F) CONSTRUCTION.—Nothing in the
21 paragraph shall be construed as preventing a
22 State from expending, from non-Federal funds,
23 an amount under this title in excess of the
24 amount of the State share.

1 “(G) DETERMINATION BASED UPON SUB-
2 MITTED CLAIMS.—In applying this paragraph
3 with respect to expenditures of a State for a
4 quarter, the determination of the expenditures
5 for such State for such quarter shall be made
6 after the end of the period (which, as of the
7 date of the enactment of this section, is 2
8 years) for which the Secretary accepts claims
9 for payment under this title with respect to
10 such quarter.

11 “(3) USE OF FEDERAL PAYMENTS.—

12 “(A) APPLICATION OF MEDICAID LIMITA-
13 TIONS.—A State may only use Federal pay-
14 ments received under subsection (a) for expend-
15 itures for which Federal funds would have been
16 payable under this title but for this section.

17 “(B) LIMITATION FOR CERTAIN ELIGI-
18 BLES.—

19 “(i) APPLICATION OF 100 PERCENT
20 FEDERAL POVERTY LINE LIMIT ON ELIGI-
21 BILITY.—Subject to clause (iii), a State
22 may not use such Federal payments to
23 provide medical assistance for an indi-
24 vidual who has an income (as determined
25 under clause (ii)) that exceeds 100 percent

1 of the poverty line (as defined in section
2 2110(c)(5)) applicable to a family of the
3 size involved.

4 “(ii) DETERMINATION OF INCOME
5 USING MODIFIED ADJUSTED GROSS IN-
6 COME WITHOUT ANY 5 PERCENT IN-
7 CREASE.—In determining income for pur-
8 poses of clause (i) under section
9 1902(e)(14) (relating to modified adjusted
10 gross income), the following rules shall
11 apply:

12 “(I) APPLICATION OF SPEND
13 DOWN.—The State shall take into ac-
14 count the costs incurred for medical
15 care or for any other type of remedial
16 care recognized under State law in the
17 same manner and to the same extent
18 that such State takes such costs into
19 account for purposes of section
20 1902(a)(17).

21 “(II) DISREGARD OF 5 PERCENT
22 INCREASE.—Subparagraph (I) of sec-
23 tion 1902(e)(14) (relating to a 5 per-
24 cent reduction) shall not apply.

1 “(iii) EXCEPTION.—Clause (i) shall
2 not apply to an individual who is—

3 “(I) a woman described in clause
4 (i) of section 1903(v)(4)(A);

5 “(II) a child who is an individual
6 described in clause (i) of section
7 1905(a);

8 “(III) enrolled in a State plan
9 under this title as of the date of the
10 enactment of this section for the pe-
11 riod of continuous enrollment; or

12 “(IV) described in section
13 1902(e)(14)(D) (relating to modified
14 adjusted gross income).

15 “(iv) CLARIFICATION RELATED TO
16 COMMUNITY SPOUSE.—Nothing in this
17 subparagraph shall supersede the applica-
18 tion of section 1924 (related to community
19 spouse income and assets).

20 “(4) EXCEPTIONS FOR PASS-THROUGH PAY-
21 MENTS.—

22 “(A) IN GENERAL.—Paragraph (1) shall
23 not apply, and amounts shall continue to be
24 payable under this title (and not under sub-
25 section (a)), in the case of the following pay-

1 ments (and related administrative costs and ex-
2 penditures):

3 “(i) PAYMENTS TO TERRITORIES.—

4 Payments to a State other than the 50
5 States and the District of Columbia.

6 “(ii) MEDICARE COST-SHARING.—

7 Payments attributable to Medicare cost-
8 sharing under section 1905(p).

9 “(iii) PEDIATRIC VACCINES.—Pay-

10 ments attributable to section 1928.

11 “(iv) EMERGENCY SERVICES FOR CER-

12 TAIN INDIVIDUALS.—Payments for treat-
13 ment of emergency medical conditions at-
14 tributable to the application of section
15 1903(v)(2).

16 “(v) INDIAN HEALTH CARE FACILI-

17 TIES.—Payments for medical assistance
18 described in the third sentence of section
19 1905(b).

20 “(vi) EMPLOYER-SPONSORED INSUR-

21 ANCE (ESI).—Payments for medical assist-
22 ance attributable to payments to employers
23 for employer-sponsored health benefits cov-
24 erage.

1 “(vii) OTHER POPULATIONS WITH
2 LIMITED BENEFIT COVERAGE.—Other pay-
3 ments that are determined by the Sec-
4 retary to be related to a specified popu-
5 lation for which the medical assistance
6 under this title is limited and does not in-
7 clude any inpatient, nursing facility, or
8 long-term care services.

9 “(B) CERTAIN EXPENSES.—Paragraph (1)
10 shall not apply, and amounts shall continue to
11 be payable under this title (and not under sub-
12 section (a)), in the case of the following:

13 “(i) ADMINISTRATION OF MEDICARE
14 PRESCRIPTION DRUG BENEFIT.—Expendi-
15 tures described in section 1935(b) (relating
16 to administration of the Medicare prescrip-
17 tion drug benefit).

18 “(ii) PAYMENTS FOR HIT BONUSES.—
19 Payments under section 1903(a)(3)(F) (re-
20 lating to payments to encourage the adop-
21 tion and use of certified EHR technology).

22 “(iii) PAYMENTS FOR DESIGN, DEVEL-
23 OPMENT, AND INSTALLATION OF MMIS AND
24 ELIGIBILITY SYSTEMS.—Payments under
25 subparagraphs (A)(i) and (H)(i) of section

1 1903(a)(3) for expenditures for design, de-
2 velopment, and installation of the Medicaid
3 management information systems and
4 mechanized verification and information
5 retrieval systems (related to eligibility).

6 “(5) PAYMENT OF AMOUNTS.—

7 “(A) IN GENERAL.—Except as the Sec-
8 retary may otherwise provide, amounts shall be
9 payable to a State under subsection (a) in the
10 same manner as amounts are payable under
11 subsection (d) of section 1903 to a State under
12 subsection (a) of such section.

13 “(B) INFORMATION AND FORMS.—

14 “(i) SUBMISSION.—As a condition of
15 receiving payment under subsection (a), a
16 State shall submit such information, in
17 such form, and manner, as the Secretary
18 shall specify, including information nec-
19 essary to make the computations under
20 subsections (e)(2)(C) and (e).

21 “(ii) UNIFORM REPORTING.—The
22 Secretary shall develop such forms as may
23 be needed to assure a system of uniform
24 reporting of such information across
25 States.

1 “(C) REQUIRED REPORTING OF INFORMA-
2 TION ON MEDICAL LOSS RATIOS FOR MANAGED
3 CARE.—The information required to be reported
4 under subparagraph (B)(i) shall include infor-
5 mation on the medical loss ratio with respect to
6 coverage provided under each Medicaid man-
7 aged care plan with a contract with the State
8 under section 1903(m) or 1932.

9 “(b) AGGREGATE BENEFICIARY-BASED AMOUNT.—

10 “(1) IN GENERAL.—The aggregate beneficiary-
11 based amount specified in this subsection for a State
12 for a quarter is equal to the sum of the products,
13 for each of the categories of Medicaid beneficiaries
14 specified in paragraph (2), of the following:

15 “(A) BENEFICIARY-BASED QUARTERLY
16 AMOUNT.—The beneficiary-based quarterly
17 amount for such category computed under sub-
18 section (c) for such State for such quarter.

19 “(B) NUMBER OF INDIVIDUALS IN CAT-
20 EGORY.—Subject to subsection (d), the average
21 number of Medicaid beneficiaries enrolled in
22 such category in the State in such quarter.

23 “(2) CATEGORIES.—The categories specified in
24 this paragraph are the following:

1 “(A) ELDERLY.—A category of Medicaid
2 beneficiaries who are 65 years of age or older.

3 “(B) BLIND OR DISABLED.—A category of
4 Medicaid beneficiaries not described in subpara-
5 graph (A) who are described in section
6 1937(a)(2)(B)(ii).

7 “(C) CHILDREN.—A category of Medicaid
8 beneficiaries not described in subparagraph (B)
9 who are under 21 years of age.

10 “(D) OTHER ADULTS.—A category of any
11 Medicaid beneficiaries who are not described in
12 a previous subparagraph of this paragraph.

13 “(c) COMPUTATION OF PER BENEFICIARY, PER CAT-
14 EGORY QUARTERLY AMOUNT.—

15 “(1) IN GENERAL.—For a State, for each cat-
16 egory of beneficiary for a quarter—

17 “(A) FIRST REFORM YEAR.—For quarters
18 in the first reform year (as defined in sub-
19 section (k)(2)), the beneficiary-based quarterly
20 amount is equal to $\frac{1}{4}$ of the base average per
21 beneficiary Federal payments for such State for
22 such category determined under paragraph (2),
23 increased by a factor that reflects the sum of
24 the following:

1 “(i) HISTORICAL MEDICAL CARE COM-
2 PONENT OF CPI THROUGH PREVIOUS RE-
3 FORM YEAR.—The percentage increase in
4 the historical medical care component of
5 the Consumer Price Index for all urban
6 consumers (U.S. city average) from the
7 midpoint of the base fiscal year (as defined
8 in paragraph (6)) to the midpoint of the
9 fiscal year preceding the first reform year.

10 “(ii) PROJECTED MEDICAL CARE COM-
11 PONENT OF CPI FOR THE FIRST REFORM
12 YEAR.—The percentage increase in the
13 projected medical care component of the
14 Consumer Price Index for all urban con-
15 sumers (U.S. city average) from the mid-
16 point of the previous fiscal year referred to
17 in clause (i) to the midpoint of the first re-
18 form year.

19 “(B) SECOND AND THIRD REFORM
20 YEARS.—The beneficiary-based quarterly
21 amount for a State for a category for quarters
22 in the second reform year or the third reform
23 year is equal to the beneficiary-based quarterly
24 amount under this paragraph for such State
25 and category for the previous reform year in-

1 creased by the per beneficiary percentage in-
2 crease (as defined in subparagraph (E)) for
3 such category and reform year.

4 “(C) FOURTH THROUGH TENTH REFORM
5 YEARS.—The beneficiary-based quarterly
6 amount for a State for a category for quarters
7 in a reform year beginning with the fourth re-
8 form year and ending with the tenth reform
9 year is—

10 “(i) in the case of a State that is a
11 high per beneficiary State or a low per
12 beneficiary State (as defined in paragraph
13 (4)(B)(iii)) for the category, the amount
14 determined under clause (i) or (ii) of para-
15 graph (4)(B) for such State, category, and
16 reform year; or

17 “(ii) in the case of any other State,
18 the beneficiary-based quarterly amount
19 under this paragraph for such State and
20 category for the previous reform year in-
21 creased by the per beneficiary percentage
22 increase for such category and reform
23 year.

24 “(D) ELEVENTH REFORM YEAR AND SUB-
25 SEQUENT REFORM YEARS.—The beneficiary-

1 based quarterly amount for a State for a cat-
2 egory for quarters in a reform year beginning
3 with the eleventh reform year is equal to the
4 beneficiary-based quarterly amount under this
5 paragraph for such State and category for the
6 previous reform year increased by the per bene-
7 ficiary percentage increase for such category
8 and reform year.

9 “(E) ANNUAL PERCENTAGE INCREASE BE-
10 GINNING WITH SECOND REFORM YEAR.—For
11 purposes of this subsection, the term ‘per bene-
12 ficiary percentage increase’ means, for a reform
13 year, the sum of—

14 “(i) the projected percentage change
15 in nominal gross domestic product from
16 the midpoint of the previous reform year to
17 the midpoint of the reform year for which
18 the percentage increase is being applied;
19 and

20 “(ii) one percentage point.

21 “(2) BASE PER BENEFICIARY, PER CATEGORY
22 AMOUNT FOR EACH STATE.—

23 “(A) AVERAGE PER CATEGORY.—

24 “(i) IN GENERAL.—The Secretary
25 shall determine, consistent with this para-

1 graph and paragraph (3), a base per bene-
2 ficiary, per category amount for each of
3 the 50 States and the District of Columbia
4 equal to the average amount, per Medicaid
5 beneficiary, of Federal payments under
6 this title, including payments attributable
7 to disproportionate share hospital pay-
8 ments under section 1923, for each of the
9 categories of beneficiaries under subsection
10 (b)(2) for the base fiscal year for each of
11 the 50 States and the District of Colum-
12 bia.

13 “(ii) BEST AVAILABLE DATA.—The
14 determination under clause (i) shall ini-
15 tially be estimated by the Secretary, based
16 upon the best available data at the time
17 the determination is made.

18 “(iii) UPDATES.—The determination
19 under clause (i) shall be updated by the
20 Secretary on an annual basis based upon
21 improved data. The Secretary shall adjust
22 the amounts under subsection (a)(1)(A) to
23 reflect changes in the amounts so deter-
24 mined based on such updates.

1 “(B) EXCLUSION OF PASS-THROUGH PAY-
2 MENTS.—In computing base per beneficiary,
3 per category amounts under subparagraph
4 (A)(i) the Secretary shall exclude payments de-
5 scribed in subsection (a)(4).

6 “(C) STANDARDIZATION.—

7 “(i) IN GENERAL.—In computing each
8 such amount, the Secretary shall stand-
9 ardize the amount in order to remove the
10 variation attributable to the following:

11 “(I) RISK FACTORS.—Such risk
12 factors as age, health and disability
13 status (including high cost medical
14 conditions), gender, institutional sta-
15 tus, and such other factors as the
16 Secretary determines to be appro-
17 priate, so as to ensure actuarial
18 equivalence.

19 “(II) GEOGRAPHIC.—Variations
20 in costs on a county-by-county basis.

21 “(ii) METHOD OF STANDARDIZA-
22 TION.—

23 “(I) CONSULTATION IN DEVEL-
24 OPMENT OF RISK STANDARDIZA-
25 TION.—In developing the methodology

1 for risk standardization for purposes
2 of clause (i)(I), the Secretary shall
3 consult with the Medicaid and CHIP
4 Payment and Access Commission, the
5 Medicare Payment Advisory Commis-
6 sion, and the National Association of
7 Medicaid Directors.

8 “(II) METHOD FOR RISK STAND-
9 ARDIZATION.—In carrying out clause
10 (i)(I), the Secretary may apply the
11 hierarchal condition category method-
12 ology under section 1853(a)(1)(C). If
13 the Secretary uses such methodology,
14 the Secretary shall adjust the applica-
15 tion of such methodology to take into
16 account the differences in services
17 provided under this title compared to
18 title XVIII, such as the coverage of
19 long term care, pregnancy, and pedi-
20 atric services.

21 “(III) METHOD FOR GEOGRAPHIC
22 STANDARDIZATION.—The Secretary
23 shall apply the standardization under
24 clause (i)(II) in a manner similar to

1 that applied under section
2 1853(e)(4)(A)(iii).

3 “(iii) APPLICATION ON A NATIONAL,
4 BUDGET NEUTRAL BASIS.—The standard-
5 ization under clause (i) shall be designed
6 and implemented on a uniform national
7 basis and shall be budget neutral so as to
8 not result in any aggregate change in pay-
9 ments under subsection (a).

10 “(iv) RESPONSE TO NEW RISK.—Sub-
11 ject to clause (iii), the Secretary may ad-
12 just the standardization under clause (i) to
13 respond promptly to new instances of com-
14 municable diseases and other public health
15 hazards.

16 “(v) REFERENCE TO APPLICATION OF
17 RISK ADJUSTMENT.—For rules related to
18 the application of risk adjustment to
19 amounts under subsection (a)(1)(A), see
20 subsection (e).

21 “(D) ADJUSTMENT FOR TEMPORARY FMAP
22 INCREASES.—In computing each base per bene-
23 ficiary, per category amounts under subpara-
24 graph (A)(i) the Secretary shall disregard por-
25 tions of payments that are attributable to a

1 temporary increase in the Federal matching
2 rates, including those attributable to the fol-
3 lowing:

4 “(i) PPACA DISASTER FMAP.—Sec-
5 tion 1905(aa).

6 “(ii) ARRA.—Section 5001 of the
7 American Recovery and Reinvestment Act
8 of 2009 (42 U.S.C. 1396d note).

9 “(iii) EXTRAORDINARY EMPLOYER
10 PENSION CONTRIBUTION.—Section 614 of
11 the Children’s Health Insurance Program
12 Reauthorization Act of 2009 (42 U.S.C.
13 1396d note).

14 “(3) ALLOCATION OF NONMEDICAL ASSISTANCE
15 PAYMENTS.—The Secretary shall establish rules for
16 the allocation of payments under this title (other
17 than those payments described in paragraph (1) or
18 (5) of section 1903(a) and including such payments
19 attributable to section 1923)—

20 “(A) among different categories of bene-
21 ficiaries; and

22 “(B) between payments included under
23 subsection (a)(1) and payments described in
24 subsection (a)(4).

1 “(4) TRANSITION TO A CORRIDOR AROUND THE
2 NATIONAL AVERAGE.—

3 “(A) DETERMINATION OF NATIONAL AVER-
4 AGE BASE PER BENEFICIARY, PER CATEGORY
5 AMOUNT.—Subject to subparagraph (C), the
6 Secretary shall determine a national average
7 base per beneficiary, per category amount equal
8 to the average of the base per beneficiary, per
9 category amounts for each of the 50 States and
10 the District of Columbia determined under
11 paragraph (2), weighted by the average number
12 of beneficiaries in each such category and State
13 as determined by the Secretary consistent with
14 subsection (d) for the base fiscal year.

15 “(B) TRANSITION ADJUSTMENT.—

16 “(i) HIGH PER BENEFICIARY
17 STATES.—In the case of a high per bene-
18 ficiary State (as defined in clause (iii)(I))
19 for a category, the beneficiary-based quar-
20 terly amount for such State and category
21 for a quarter in a reform year (beginning
22 with the fourth reform year and ending
23 with the tenth reform year) is equal to the
24 sum of—

1 “(I) the product of the State-spe-
2 cific factor for such reform year (as
3 defined in clause (iv)) and the bene-
4 ficiary-based quarterly amount that
5 would otherwise be determined under
6 paragraph (1) for such State and cat-
7 egory if the State were a State de-
8 scribed in clause (ii) of paragraph
9 (1)(C), instead of a State described in
10 clause (i) of such paragraph; and

11 “(II) the product of 1 minus the
12 State-specific factor for such reform
13 year and the beneficiary-based quar-
14 terly amount that would otherwise be
15 determined under paragraph (1) for a
16 State and category if the base per
17 beneficiary, per category amount de-
18 termined under paragraph (2) for the
19 State and category were equal to 110
20 percent of the national average base
21 per beneficiary, per category amount
22 determined under subparagraph (A)
23 for such category.

24 “(ii) LOW PER BENEFICIARY
25 STATES.—In the case of a low per bene-

1 beneficiary State (as defined in clause (iii)(II))
2 for a category, the beneficiary-based quar-
3 terly amount for such State and category
4 for a quarter in a reform year (beginning
5 with the fourth reform year and ending
6 with the tenth reform year) is equal to the
7 sum of—

8 “(I) the product of the State-spe-
9 cific factor for such reform year and
10 the beneficiary-based quarterly
11 amount that would otherwise be deter-
12 mined under paragraph (1) for such
13 State and category if the State were
14 a State described in clause (ii) of
15 paragraph (1)(C), instead of a State
16 described in clause (i) of such para-
17 graph; and

18 “(II) the product of 1 minus the
19 State-specific factor for such reform
20 year and the beneficiary-based quar-
21 terly amount that would otherwise be
22 determined under paragraph (1) for a
23 State and category if the base per
24 beneficiary, per category amount de-
25 termined under paragraph (2) for the

1 State and category were equal to 90
2 percent of the national average base
3 per beneficiary, per category amount
4 determined under subparagraph (A)
5 for such category.

6 “(iii) HIGH AND LOW PER BENE-
7 FICIARY STATES DEFINED.—In this sub-
8 paragraph:

9 “(I) HIGH PER BENEFICIARY
10 STATE.—The term ‘high per bene-
11 ficiary State’ means, with respect to a
12 category, a State for which the base
13 per beneficiary, per category amount
14 determined under paragraph (2) for
15 such category is greater than 110 per-
16 cent of the national average base per
17 beneficiary, per category amount de-
18 termined under subparagraph (A) for
19 such category.

20 “(II) LOW PER BENEFICIARY
21 STATE.—The term ‘low per bene-
22 ficiary State’ means, with respect to a
23 category, a State for which the base
24 per beneficiary, per category amount
25 determined under paragraph (2) for

1 such category is less than 90 percent
2 of the national average base per bene-
3 ficiary, per category amount deter-
4 mined under subparagraph (A) for
5 such category.

6 “(iv) STATE-SPECIFIC FACTOR.—In
7 this subparagraph, the term ‘State-specific
8 factor’ means—

9 “(I) for the fourth reform year,
10 $\frac{7}{8}$; and

11 “(II) for a subsequent reform
12 year, the State-specific factor under
13 this clause for the previous reform
14 year minus $\frac{1}{8}$.

15 “(C) NO ADDITIONAL EXPENDITURES.—

16 “(i) DETERMINATION OF INCREASE IN
17 FEDERAL EXPENDITURES.—For each cat-
18 egory for each reform year (beginning with
19 the fourth reform year and ending with the
20 tenth reform year), the Secretary shall de-
21 termine whether the application of this
22 paragraph—

23 “(I) to the category for the re-
24 form year will result in an aggregate

1 increase in the aggregate Federal ex-
2 penditures under subsection (a); and

3 “(II) to all the categories for the
4 reform year will result in a net aggre-
5 gate increase in the aggregate Federal
6 expenditures under subsection (a).

7 “(ii) ADJUSTMENT.—If the Secretary
8 determines under clause (i)(II) that the
9 application of this paragraph to all the cat-
10 egories for a reform year will result in a
11 net aggregate increase in the aggregate
12 Federal expenditures under subsection (a),
13 the Secretary shall reduce the national av-
14 erage base per beneficiary, per category
15 amount computed under subparagraph (A)
16 for each of the categories determined
17 under clause (i)(I) for which there will be
18 an aggregate increase in the aggregate
19 Federal expenditures under subsection (a)
20 by such uniform percentage as will ensure
21 that there is no net aggregate Federal ex-
22 penditure increase described in clause
23 (i)(II) for the reform year.

24 “(5) REPORTS ON PER BENEFICIARY RATES;
25 APPEALS.—

1 “(A) REPORT TO STATES.—Not later than
2 8 months after the date of the enactment of
3 this section, the Secretary shall submit to each
4 State the Secretary’s initial determination of—

5 “(i) the base per beneficiary, per cat-
6 egory amounts under paragraph (2) for
7 such State; and

8 “(ii) the national average base per
9 beneficiary, per category amounts under
10 paragraph (4)(A).

11 “(B) OPPORTUNITY TO APPEAL.—Not
12 later than 3 months after the date a State re-
13 ceives notice of the Secretary’s initial deter-
14 mination of such base per beneficiary, per cat-
15 egory amounts for such State under subpara-
16 graph (A)(i), the State may file with the Sec-
17 retary, in a form and manner specified by the
18 Secretary, an appeal of such determination.

19 “(C) DETERMINATION ON APPEAL.—Not
20 later than 3 months after receiving such an ap-
21 peal, the Secretary shall make a final deter-
22 mination on such amounts for such State. If no
23 such appeal is received for a State, the Sec-
24 retary’s initial determination under subpara-
25 graph (A)(i) shall become final.

1 “(6) BASE FISCAL YEAR DEFINED.—In this
2 section, the term ‘base fiscal year’ means the latest
3 fiscal year, ending before the date of the enactment
4 of this section, for which the Secretary determines
5 that adequate data are available to make the com-
6 putations required under this subsection.

7 “(d) NOT COUNTING INDIVIDUALS TO ACCOUNT FOR
8 EXCLUDED PAYMENTS.—Under rules specified by the
9 Secretary, individuals shall not be counted as Medicaid
10 beneficiaries for purposes of subsection (b)(1)(B) and sub-
11 section (c)(2)(A) to the extent that such individuals—

12 “(1) are receiving medical assistance for which
13 payments described under subsection (a)(4)(A) are
14 made; or

15 “(2) would not have been eligible to enroll
16 under the State plan (or waiver of such plan) in the
17 State in which such individual is so enrolled if the
18 rules for eligibility for enrollment under such plan
19 (or waiver) were the same as such rules for eligi-
20 bility in effect as of January 1, 2009.

21 “(e) RISK ADJUSTMENT.—

22 “(1) IN GENERAL.—The amount under sub-
23 section (a)(1)(A) shall be adjusted under this sub-
24 section in an appropriate manner, specified by the

1 Secretary and consistent with paragraph (2), to take
2 into account—

3 “(A) the factors described in subsection
4 (c)(2)(C)(i)(I) within a category of bene-
5 ficiaries; and

6 “(B) variations in costs on a county-by-
7 county basis for medical assistance and admin-
8 istrative expenses.

9 “(2) METHOD OF ADJUSTMENT.—

10 “(A) IN GENERAL.—The adjustments
11 under paragraph (1) shall be made in a manner
12 similar to the manner in which similar adjust-
13 ments are made under subsection (c)(2)(C) and
14 consistent with the requirements of clause (iii)
15 of such subsection and subparagraph (B).

16 “(B) BIENNIAL UPDATE OF RISK ADJUST-
17 MENT METHODOLOGY.—In applying clause
18 (i)(I) of subsection (c)(2)(C) for purposes of
19 subparagraph (A), the Secretary shall, in con-
20 sultation with the entities described in clause
21 (ii)(I) of such subsection, update the risk ad-
22 justment methodology applied as appropriate
23 not less often than every 2 years.

24 “(f) CHRONIC CARE QUALITY BONUS PAYMENTS.—

1 “(1) DETERMINATION OF BONUS PAYMENTS.—
2 If the Secretary determines that, based on the re-
3 ports under paragraph (5), with respect to cat-
4 egories of chronic disease for which chronic care per-
5 formance targets had been established under para-
6 graph (3) for each category of Medicaid beneficiaries
7 specified under subsection (b)(2) such targets have
8 been met by a State for a reform year, the Secretary
9 shall make an additional payment to such State in
10 the amount specified in paragraph (6) for each quar-
11 ter in the succeeding reform year. Such payments
12 shall be made in a manner specified by the Secretary
13 and may only be used consistent with subsection
14 (a)(3).

15 “(2) IDENTIFICATION OF CATEGORIES OF
16 CHRONIC DISEASE.—The Secretary shall determine
17 the categories of chronic disease for which bonus
18 payments may be available under this subsection for
19 each category of Medicaid beneficiaries.

20 “(3) ADOPTION OF QUALITY MEASUREMENT
21 SYSTEM AND IDENTIFICATION OF PERFORMANCE
22 TARGETS.—

23 “(A) SYSTEM AND DATA.—With respect to
24 the categories of chronic disease under para-
25 graph (2), the Secretary shall adopt a quality

1 measurement system that uses data described
2 in paragraph (4) and is similar to the Five-Star
3 Quality Rating System used to indicate the per-
4 formance of Medicare Advantage plans under
5 part C of title XVIII.

6 “(B) TARGETS.—Using such system and
7 data, the Secretary shall establish for each re-
8 form year the chronic care performance targets
9 for purposes of the payments under paragraph
10 (1). Such performance targets shall be estab-
11 lished in consultation with States, associations
12 representing individuals with chronic illnesses,
13 entities providing treatment to such individuals
14 for such chronic illnesses, and other stake-
15 holders, including the National Association of
16 Medicaid Directors and the National Governors
17 Association.

18 “(4) DATA TO BE USED.—The data to be used
19 under paragraph (3) shall include—

20 “(A) data collected through methods such
21 as—

22 “(i) the ‘Healthcare Effectiveness
23 Data and Information Set’ (also known as
24 ‘HEDIS’) (or an appropriate successor
25 performance measurement tool);

1 “(ii) the ‘Consumer Assessment of
2 Healthcare Providers and Systems’ (also
3 known as ‘CAHPS’) (or an appropriate
4 successor performance measurement tool);
5 and

6 “(iii) the ‘Health Outcomes Survey’
7 (also known as ‘HOS’) (or an appropriate
8 successor performance measurement tool);
9 and

10 “(B) other data collected by the State.

11 “(5) REPORTS.—

12 “(A) IN GENERAL.—Each State shall col-
13 lect, analyze, and report to the Secretary, at a
14 frequency and in a manner to be established by
15 the Secretary, data described in paragraph (4)
16 that permit the Secretary to monitor the State’s
17 performance relative to the chronic care per-
18 formance targets established under paragraph
19 (3).

20 “(B) REVIEW AND VERIFICATION.—The
21 Secretary may review the data collected by the
22 State under subparagraph (A) to verify the
23 State’s analysis of such data with respect to the
24 performance targets under paragraph (3).

25 “(6) AMOUNT OF BONUS PAYMENTS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graphs (B) and (C), with respect to each cat-
3 egory of Medicaid beneficiaries, in the case of
4 a State that the Secretary determines, based on
5 the chronic care performance targets set under
6 paragraph (3) for a reform year for such cat-
7 egory, performs—

8 “(i) in the top five States in such cat-
9 egory, subject to subparagraph (C)(ii), the
10 amount of the bonus for each quarter in
11 the succeeding reform year shall be 10 per-
12 cent of the payment amount otherwise paid
13 to the State under subsection (a) for indi-
14 viduals enrolled under the plan within such
15 category;

16 “(ii) in the next five States in such
17 category, subject to subparagraph (C)(ii),
18 the amount of the bonus for each such
19 quarter shall be 5 percent of the payment
20 amount otherwise paid to the State under
21 subsection (a) for individuals enrolled
22 under the plan within such category;

23 “(iii) in the next five States in such
24 category, subject to clauses (i) and (iii) of
25 subparagraph (C), the amount of the

1 bonus for each such quarter shall be 3 per-
2 cent of the payment amount otherwise paid
3 to the State under subsection (a) for indi-
4 viduals enrolled under the plan within such
5 category;

6 “(iv) in the next five States in such
7 category, subject to clauses (i) and (iii) of
8 subparagraph (C), the amount of the
9 bonus for each such quarter shall be 2 per-
10 cent of the payment amount otherwise paid
11 to the State under subsection (a) for indi-
12 viduals enrolled under the plan within such
13 category; and

14 “(v) in the next five States in such
15 category, subject to clauses (i) and (iii) of
16 subparagraph (C), the amount of the
17 bonus for each such quarter shall be 1 per-
18 cent of the payment amount otherwise paid
19 to the State under subsection (a) for indi-
20 viduals enrolled under the plan within such
21 category.

22 “(B) AGGREGATE ANNUAL LIMIT FOR
23 EACH CATEGORY OF MEDICAID BENE-
24 FICIARIES.—

1 “(i) IN GENERAL.—In no case may
2 the aggregate amount of bonuses under
3 this subsection for quarters in a reform
4 year for a category of Medicaid bene-
5 ficiaries exceed the limit specified in clause
6 (ii) for the reform year.

7 “(ii) LIMIT.—The limit specified in
8 this clause—

9 “(I) for the second reform year is
10 equal to \$250,000,000; or

11 “(II) for a subsequent reform
12 year is equal to the limit specified in
13 this clause for the previous reform
14 year increased by the per beneficiary
15 percentage increase determined under
16 paragraph (1)(E) of subsection (e).

17 “(C) LIMITATION AND PRORATION OF BO-
18 NUSES BASED ON APPLICATION OF AGGREGATE
19 LIMIT.—

20 “(i) NO BONUS FOR THIRD OR SUBSE-
21 QUENT TIERS UNLESS AGGREGATE LIMIT
22 NOT REACHED ON FIRST TWO TIERS.—No
23 bonus shall be payable under clause (iii),
24 (iv), or (v) of subparagraph (A) for a cat-
25 egory of Medicaid beneficiaries for a quar-

1 ter in a reform year unless the aggregate
2 amount of bonuses under clauses (i) and
3 (ii) of such subparagraph for such category
4 and reform year is less than the limit spec-
5 ified in subparagraph (B)(ii) for the re-
6 form year.

7 “(ii) PRORATION FOR FIRST TWO
8 TIERS.—If the aggregate amount of bo-
9 nuses under clauses (i) and (ii) of subpara-
10 graph (A) for a category of Medicaid bene-
11 ficiaries for quarters in a reform year ex-
12 ceeds the limit specified in subparagraph
13 (B)(ii) for the reform year, the amount of
14 each such bonus shall be prorated in a
15 manner so the aggregate amount of such
16 bonuses is equal to such limit.

17 “(iii) PRORATION FOR NEXT THREE
18 TIERS.—If the aggregate amount of bo-
19 nuses under clauses (i) and (ii) of subpara-
20 graph (A) for a category of Medicaid bene-
21 ficiaries for quarters in a reform year is
22 less than the limit specified in subpara-
23 graph (B)(ii) for the reform year, but the
24 aggregate amount of bonuses under clauses
25 (i) through (v) of subparagraph (A) for the

1 category and such quarters in the reform
2 year exceeds the limit specified in subpara-
3 graph (B)(ii) for the reform year, the
4 amount of each bonus in clauses (iii), (iv),
5 and (v) of subparagraph (A) shall be pro-
6 rated in a manner so the aggregate
7 amount of all the bonuses under subpara-
8 graph (A) is equal to such limit.

9 “(g) STATE OPTION FOR RECEIVING MEDICARE PAY-
10 MENTS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVID-
11 UALS.—

12 “(1) IN GENERAL.—Under this subsection a
13 State may elect for quarters beginning on or after
14 the implementation date in a reform year to receive
15 payment from the Secretary under paragraph (3).
16 As a condition of receiving such payment, the State
17 shall agree to provide to full-benefit dual eligible in-
18 dividuals eligible for medical assistance under the
19 State plan—

20 “(A) the medical assistance to which such
21 eligible individuals would otherwise be entitled
22 under this title; and

23 “(B) any items and services which such eli-
24 gible individuals would otherwise receive under
25 title XVIII.

1 “(2) PROVIDER PAYMENT REQUIREMENT.—

2 “(A) IN GENERAL.—A State electing the
3 option under this subsection shall provide pay-
4 ment to health care providers for the items and
5 services described under paragraph (1)(B) at a
6 rate that is not less than the rate at which pay-
7 ments would be made to such providers for such
8 items and services under title XVIII.

9 “(B) FLEXIBILITY IN PAYMENT METH-
10 ODS.—Nothing in subparagraph (A) shall be
11 construed as preventing a State from using al-
12 ternative payment methodologies (such as bun-
13 dled payments or the use of accountable care
14 organizations (as such term is used in section
15 1899)) for purposes of making payments to
16 health care providers for items and services pro-
17 vided to dual eligible individuals in the State
18 under the option under this subsection.

19 “(3) PAYMENTS TO STATES IN LIEU OF MEDI-
20 CARE PAYMENTS.—With respect to a full-benefit
21 dual eligible individual, in the case of a State that
22 elects the option under paragraph (1) for quarters in
23 a reform year—

24 “(A) the Secretary shall not make any pay-
25 ment under title XVIII for items and services

1 furnished to such individual for such quarters;
2 and

3 “(B) the Secretary shall pay to the State,
4 in addition to the amounts paid to such State
5 under subsection (a), the amount that the Sec-
6 retary would, but for this subsection, otherwise
7 pay under title XVIII for items and services
8 furnished to such an individual in such State
9 for such quarters.

10 “(4) FULL-BENEFIT DUAL ELIGIBLE INDI-
11 VIDUAL DEFINED.—In this subsection, the term
12 ‘full-benefit dual eligible individual’ means an indi-
13 vidual who meets the requirements of section
14 1935(e)(6)(A)(ii).

15 “(h) AUDITS.—The Secretary shall conduct such au-
16 dits on the number and classification of Medicaid bene-
17 ficiaries under such subsections and expenditures under
18 this section as may be necessary to ensure appropriate
19 payments under this section.

20 “(i) TREATMENT OF WAIVERS.—

21 “(1) NO IMPACT ON CURRENT WAIVERS.—In
22 the case of a waiver of requirements of this title pur-
23 suant to section 1115 or other law that is in effect
24 as of the date of the enactment of this section, noth-
25 ing in this section shall be construed to affect such

1 waiver for the period of the waiver as approved as
2 of such date.

3 “(2) APPLICATION OF BUDGET NEUTRALITY TO
4 SUBSEQUENT WAIVERS AND RENEWALS TAKING SEC-
5 TION INTO ACCOUNT.—In the case of a waiver of re-
6 quirements of this title pursuant to section 1115 or
7 other law that is approved or renewed after the date
8 of the enactment of this section, to the extent that
9 such approval or renewal is conditioned upon a dem-
10 onstration of budget neutrality, budget neutrality
11 shall be determined taking into account the applica-
12 tion of this section.

13 “(j) REPORT TO CONGRESS.—Not later than Janu-
14 ary 1 of the second reform year, the Secretary shall submit
15 to Congress a report on the implementation of this section.

16 “(k) DEFINITIONS.—In this section:

17 “(1) IMPLEMENTATION DATE.—The term ‘im-
18 plementation date’ means—

19 “(A) July 1, 2021, if this section is en-
20 acted on or before July 1, 2020; or

21 “(B) July 1, 2022, if this section is en-
22 acted after July 1, 2020.

23 “(2) REFORM YEARS.—

24 “(A) The term ‘reform year’ means a fiscal
25 year beginning with the first reform year.

1 “(B) The term ‘first reform year’ means
2 the fiscal year in which the implementation date
3 occurs.

4 “(C) The terms ‘second’, ‘third’, and suc-
5 cessive similar terms mean, with respect to a
6 reform year, the second, third, or successive re-
7 form year, respectively, succeeding the first re-
8 form year.”.

9 (b) CONFORMING AMENDMENTS.—

10 (1) CONTINUED APPLICATION OF CLAWBACK
11 PROVISIONS.—

12 (A) CONTINUED APPLICATION.—Sub-
13 sections (a) and (c)(1)(C) of section 1935 of
14 such Act (42 U.S.C. 1396u–5) are each amend-
15 ed by inserting “or 1903A(a)” after “1903(a)”.

16 (B) TECHNICAL AMENDMENT.—Section
17 1935(d)(1) of the Social Security Act (42
18 U.S.C. 1396u–5(d)(1)) is amended by inserting
19 “except as provided in section 1903A(g)” after
20 “any other provision of this title”.

21 (2) PAYMENT RULES UNDER SECTION 1903.—

22 (A) Section 1903(a) of the Social Security
23 Act (42 U.S.C. 1396b(a)) is amended, in the
24 matter before paragraph (1), by inserting “and

1 section 1903A” after “except as otherwise pro-
2 vided in this section”.

3 (B) Section 1903(d) of such Act (42
4 U.S.C. 1396b(d)) is amended—

5 (i) in paragraph (1), by inserting
6 “and under section 1903A” after “sub-
7 sections (a) and (b)”;

8 (ii) in paragraph (2)—

9 (I) in subparagraph (A), by in-
10 sserting “or section 1903A” after “was
11 made under this section”; and

12 (II) in subparagraph (B), by in-
13 sserting “or section 1903A” after
14 “under subsection (a)”;

15 (iii) in paragraph (4)—

16 (I) by striking “under this sub-
17 section” and inserting “, with respect
18 to this section or section 1903A,
19 under this subsection”; and

20 (II) by striking “under this sec-
21 tion” and inserting “under the respec-
22 tive section”; and

23 (iv) in paragraph (5), by inserting “or
24 section 1903A” after “overpayment under
25 this section”.

1 (3) CONFORMING WAIVER AUTHORITY.—Section
2 1115(a)(2)(A) of the Social Security Act (42 U.S.C.
3 1315(a)(2)(A)) is amended by striking “or 1903”
4 and inserting “1903, or 1903A”.

5 (4) REPORT ON ADDITIONAL CONFORMING
6 AMENDMENTS NEEDED.—Not later than 6 months
7 after the date of the enactment of this Act, the Sec-
8 retary of Health and Human Services shall submit
9 to Congress a report that includes a description of
10 any additional technical and conforming amend-
11 ments to law that are required to properly carry out
12 this Act.

13 **SEC. 402. INCOME LIMITATIONS FOR REFUNDABLE CRED-**
14 **ITS FOR COVERAGE UNDER A QUALIFIED**
15 **HEALTH PLAN.**

16 (a) IN GENERAL.—Subparagraphs (A) and (B) of
17 section 36B(c)(1) of the Internal Revenue Code of 1986
18 are amended by inserting after “100 percent” each place
19 such term appears the following: “(or, in the case of a
20 taxpayer enrolled through an Exchange utilized by such
21 State that makes the election described in section 1903A
22 of the Social Security Act, the percentage established by
23 such State under part A of title IV of such Act for pur-
24 poses of eligibility under title XIX of such Act as of Janu-
25 ary 1, 2009)”.

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

4 **SEC. 403. MEDICAID ELIGIBILITY DETERMINATIONS.**

5 (a) STATE FLEXIBILITY TO USE CONTRACTORS TO
6 MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF
7 STATE.—Section 1902(a)(5) of the Social Security Act
8 (42 U.S.C. 1396a(a)(5)) is amended by inserting before
9 the semicolon at the end the following: “, but such deter-
10 minations of eligibility may be made, at the option of a
11 State, under a contract with another State or local agency
12 or a contractor so long as the contract does not provide
13 incentives for the agency or contractor to delay eligibility
14 determinations or to deny eligibility for individuals other-
15 wise eligible for medical assistance”.

16 (b) FREQUENCY OF ELIGIBILITY REDETERMINA-
17 TIONS.—Section 1902(e)(14) of the Social Security Act
18 (42 U.S.C. 1396a(e)(14)) is amended by adding at the
19 end the following:

20 “(L) FREQUENCY OF ELIGIBILITY REDE-
21 TERMINATIONS.—Beginning on October 1,
22 2019, and notwithstanding subparagraph (H),
23 in the case of an individual whose eligibility for
24 medical assistance under the State plan under
25 this title (or a waiver of such plan) is deter-

1 mined based on the application of modified ad-
2 justed gross income under subparagraph (A)
3 and who is so eligible on the basis of clause
4 (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection
5 (a)(10)(A), at the option of the State, the State
6 plan may provide that the individual’s eligibility
7 shall be redetermined every 6 months (or such
8 shorter number of months as the State may
9 elect).”.

10 **SEC. 404. LOWERING SAFE HARBOR THRESHOLD WITH RE-**
11 **SPECT TO STATE TAXES ON HEALTH CARE**
12 **PROVIDERS.**

13 Section 1903(w)(4)(C)(ii) of the Social Security Act
14 (42 U.S.C. 1396b(w)(4)(C)(ii)) is amended—

15 (1) by striking “of fiscal years beginning” and
16 inserting “of fiscal years—

17 “(I) beginning”; and

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

20 “(II) beginning on or after January 1,
21 2021, and before January 1, 2030, ‘4 percent’
22 shall be substituted for ‘6 percent’ each place it
23 appears;

24 “(III) beginning on or after January 1,
25 2030, and before January 1, 2035, ‘3 percent’

1 shall be substituted for ‘6 percent’ each place it
2 appears;

3 “(IV) beginning on or after January 1,
4 2035, and before January 1, 2040, ‘2 percent’
5 shall be substituted for ‘6 percent’ each place it
6 appears;

7 “(V) beginning on or after January 1,
8 2040, and before January 1, 2045, ‘1 percent’
9 shall be substituted for ‘6 percent’ each place it
10 appears; and

11 “(VI) beginning on or after January 1,
12 2045, ‘0 percent’ shall be substituted for ‘6 per-
13 cent’ each place it appears.”.

14 **SEC. 405. PROVIDING FOR STATE APPROVAL AND IMPLE-**
15 **MENTATION OF SPECIFIED WAIVERS UNDER**
16 **THE MEDICAID PROGRAM.**

17 Section 1115 of the Social Security Act (42 U.S.C.
18 1315) is amended—

19 (1) in subsection (d)—

20 (A) in paragraph (1), by striking “An ap-
21 plication” and inserting “Subject to paragraph
22 (4), an application”; and

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

1 “(4)(A) An experimental, pilot, or demonstra-
2 tion project undertaken under subsection (a) may be
3 approved or renewed by a State if such project is de-
4 scribed in subparagraph (B).

5 “(B) An experimental, pilot, or demonstration
6 project is described in this subparagraph if such
7 project provides for a waiver of requirements with
8 respect to a State plan (or a waiver of such plan)
9 under title XIX such that—

10 “(i) individuals enrolled under such plan
11 (or such waiver) may elect to participate in
12 such project with respect to a year; and

13 “(ii) such individuals who elect to so par-
14 ticipate are furnished with primary care serv-
15 ices (as described in section 223(c)(1)(D)(ii)(I)
16 of the Internal Revenue Code of 1986) through
17 a direct primary care service arrangement (as
18 defined in such section).

19 “(C) For purposes of a State’s approval or re-
20 newal of an experimental, pilot, or demonstration
21 project under subparagraph (A), each reference to
22 ‘the Secretary’ in subsection (a) shall be deemed to
23 be a reference to ‘the State.’”; and

1 (2) in subsection (e), by inserting “(other than
2 such a project that is described in paragraph
3 (4)(B))” before the period at the end.

4 **SEC. 406. DEDUCTION FOR QUALIFIED CHARITY CARE.**

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

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

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

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

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

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

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

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

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

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

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

13 “(B) to an individual enrolled—

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

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

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

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

1 items and services shall be the amount determined
2 under the fee schedule under section 1848 for such
3 items and services furnished if furnished in a physi-
4 cian office setting.

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

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

12 **SEC. 412. ELIMINATING FEHBP ELIGIBILITY FOR ANNU-**
13 **ITANTS.**

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

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

19 (2) by adding at the end the following: “. An
20 individual who is entitled to benefits under part A
21 of title XVIII of the Social Security Act (42 U.S.C.
22 1395c et seq.) by reason of section 226 or 226A of
23 such Act (42 U.S.C. 426, 426–1), or otherwise eligi-
24 ble to enroll under such part pursuant to section
25 1818 or 1818A of such Act (42 U.S.C. 1395i–2,

1 1395i–2a), and who first becomes an annuitant after
2 the date of enactment of this sentence may not con-
3 tinue enrollment in any health benefits plan under
4 this chapter.”.

5 **SEC. 413. ELIMINATION OF MEDICARE ELIGIBILITY FOR**
6 **CERTAIN INDIVIDUALS.**

7 (a) ENROLLMENT PROHIBITION.—

8 (1) PART B.—Section 1836 of the Social Secu-
9 rity Act (42 U.S.C. 1395o) is amended by striking
10 the period at the end and inserting “, except that an
11 individual who attains age 65 on or after January
12 1, 2030, and is an individual who, upon attaining
13 such age, has earned \$10,000,000 or more in life-
14 time wages, shall not be eligible to so enroll.”.

15 (2) PART D.—Section 1860D–1(a)(3)(A) of
16 such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amend-
17 ed by striking the period at the end and inserting
18 “, excluding an individual who, upon attaining age
19 65, has earned \$10,000,000 or more in lifetime
20 wages.”.

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

24 “(aa) ADDITIONAL LIMITATION ON NEWLY ELIGI-
25 BLE BENEFICIARIES.—

1 “(1) IN GENERAL.—Notwithstanding any other
2 provision of this section, on or after January 1,
3 2030, a medicare supplemental policy may not be
4 sold or issued to a targeted newly eligible Medicare
5 beneficiary.

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

12 **SEC. 414. MEDICARE PART D TAX DEDUCTION.**

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

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

22 **SEC. 415. REPEAL OF NET INVESTMENT INCOME TAX.**

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

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

4 **SEC. 416. MEDICARE COVERAGE OF BAD DEBT.**

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

7 (1) in subparagraph (T)—

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

10 (B) in clause (v)—

11 (i) by striking “during fiscal year”
12 and inserting “during fiscal years”;

13 (ii) by striking “or a subsequent fiscal
14 year” and inserting “through 2021”; and

15 (iii) by striking the period at the end
16 and inserting “, and”; and

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

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

25 (2) in subparagraph (V)—

1 (A) in clause (i)—

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

4 (ii) in subclause (IV)—

5 (I) by striking “during fiscal
6 year” and inserting “during fiscal
7 years 2015 through 2021”; and

8 (II) by striking the period at the
9 end and inserting “; and”; and

10 (iii) by adding at the end the fol-
11 lowing new subclause:

12 “(V) for cost reporting periods beginning
13 during fiscal year 2021 or a subsequent fiscal
14 year, the percent applicable for cost reporting
15 periods beginning during the previous fiscal
16 year, increased (through fiscal year 2024) by
17 10 percentage points.”; and

18 (B) in clause (ii)—

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

21 (ii) in subclause (IV)—

22 (I) by striking “a subsequent fis-
23 cal year” and inserting “fiscal years
24 2015 through 2021”;

1 (II) by striking the period at the
2 end and inserting “; and”; and

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

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

11 (3) in subparagraph (W)(i)—

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

14 (B) in subclause (III)—

15 (i) by striking “during a subsequent
16 fiscal year” and inserting “during fiscal
17 years 2015 through 2021”; and

18 (ii) by striking the period at the end
19 and inserting “; and”; and

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

22 “(IV) for cost reporting periods beginning dur-
23 ing fiscal year 2021 or a subsequent fiscal year, by
24 the percent applicable for cost reporting periods be-
25 ginning during the previous fiscal year, increased

1 (through fiscal year 2024) by 10 percentage
2 points.”.

3 **Subtitle C—Medicare Choice and**
4 **Competition**

5 **SEC. 421. COMPETITIVE BIDDING AND PREMIUMS UNDER**
6 **UNIFIED MEDICARE.**

7 (a) IN GENERAL.—Part E of title XVIII of the Social
8 Security Act, as added by section 101 and amended by
9 section 103, is further amended by adding at the end the
10 following:

11 **“Subpart 3—Competitive Bidding and Premiums**
12 **“SEC. 1860E-31. APPLICATION OF COMPETITIVE BIDDING IN**
13 **ENROLLMENT.**

14 “(a) IN GENERAL.—Notwithstanding any other pro-
15 vision of this title, the Secretary shall, beginning with plan
16 year 2021, establish a method whereby individuals enroll-
17 ing under this title so enroll through an online process
18 designed to highlight enrollment options for such individ-
19 uals and allow such individuals to compare costs of enroll-
20 ment in such options.

21 “(b) ENROLLMENT OPTIONS.—For purposes of sub-
22 section (a), the Secretary shall make the following options
23 available to individuals for enrollment under this title:

24 “(1) Traditional fee-for-service coverage.

1 “(2) provider-led risk-bearing plans (also known
2 as ACOs).

3 “(3) Medicare Advantage plans.

4 “(c) MEDICARE ADVANTAGE PLAN ACTUARIAL
5 VALUE REQUIREMENT.—Each Medicare Advantage plan
6 offered through the process described in subsection (a)
7 shall have an actuarial value equal to traditional fee-for-
8 service coverage under parts A and B.

9 “(d) MA DIRECT DEPOSIT OF CERTAIN REBATES.—
10 In the case of an Medicare Advantage plan with a bid for
11 a year that involves a premium differential between such
12 bid and the benchmark for such year and plan, such plan
13 shall provide for a direct deposit of such differential if the
14 applicable enrollee in such plan does not elect any supple-
15 mental coverage under such plan.

16 “(e) ENROLLMENT IN PRESCRIPTION DRUG COV-
17 ERAGE.—As part of the method described in subsection
18 (a), the Secretary shall establish a process to allow an in-
19 dividual to enroll in prescription drug coverage. In the
20 case of an individual who enrolls in a Medicare Advantage
21 plan, such coverage shall be provided under such plan. In
22 a case of an individual who enrolls in an ACO, such cov-
23 erage shall be provided under such network. In the case
24 of an individual who enrolls under traditional fee-for-serv-

1 ice coverage, such drug coverage shall be provided through
2 a prescription drug plan.

3 “(f) SUPPLEMENTAL BENEFITS.—

4 “(1) MA PLANS.—An MA plan is allowed to
5 offer two different packages of supplemental benefits
6 (these packages are available only to individuals who
7 select such plans).

8 “(2) ACOS.—ACOs may limit supplemental op-
9 tions for their enrollees to Medigap plans with con-
10 tractual ties.

11 “(3) FEE-FOR-SERVICE.—Fee-for-service indi-
12 viduals may select supplemental coverage from
13 Medigap policies.

14 **“SEC. 1860E-32. COMPETITION.**

15 “(a) BID AREAS.—Market areas used for bid submis-
16 sions for Medicare Advantage plans, ACOs, and for cal-
17 culation per person fee-for-services costs shall be metro-
18 politan statistical regions plus associated regions.

19 “(b) PREMIUMS.—Medicare payment benchmark by
20 market area shall be calculated based on weighted average
21 (by enrollment in previous year) of the premium bids from
22 MA plans, ACOs, and the per person costs of fee-for-serv-
23 ice, less the statutory part B premium.

24 “(c) BENEFICIARY RESPONSIBILITY.—Beneficiaries
25 shall pay the difference between Medicare payment and

1 required premium of the plan they choose, and get 100
2 percent of the savings by choosing a plan with a premium
3 below the benchmark.

4 “(d) TRANSITION.—For beneficiaries who are in fee-
5 for-service at the time of the enactment of this section,
6 there shall be a limit on the amount of a premium increase
7 allowable by year of no more than \$20 per month com-
8 pared to what such premium would have otherwise been
9 if this subpart had not been enacted for each year through
10 the fifth year.

11 “(e) MULTIYEAR CONTRACTS.—A Medicare Advan-
12 tage plan may offer to beneficiaries multiyear contracts
13 with guaranteed premiums over such years, bearing the
14 risk of any change in payments from the Secretary in sub-
15 sequent years. A beneficiary enrolling under such a con-
16 tract shall be exempt from the method described in sub-
17 section (a).”.

18 (b) CONFORMING AMENDMENTS.—

19 (1) Section 1853(a)(1)(A) of the Social Security
20 Act is amended by striking “and section 1859(e)(4)”
21 and inserting “, section 1859(e)(4), and subpart 3
22 of part E”.

23 (2) Section 1853(j) of such Act is amended by
24 inserting “and subpart 3 of part E” after “sub-
25 section (o)”.

1 (3) Section 1854 of such Act is amended—

2 (A) in subsection (a), after the heading, by
3 inserting “Subject to subpart 3 of part E.”;

4 (B) in subsection (b), after the heading, by
5 inserting “Subject to subpart 3 of part E.”;

6 (C) in subsection (d), after the heading, by
7 inserting “Subject to subpart 3 of part E.”;

8 and

9 (D) in subsection (e), after the heading, by
10 inserting “Subject to subpart 3 of part E.”.

11 **SEC. 422. NEW UNIFIED ELIGIBILITY AND ENROLLMENT**

12 **RULES.**

13 (a) IN GENERAL.—Title XVIII of the Social Security
14 Act is amended—

15 (1) by redesignating part E as part F; and

16 (2) by inserting after part D the following new
17 part:

18 **“PART E—MEDICARE WITH CHOICE AND**

19 **COMPETITION**

20 **“Subpart 1—Opt-Out and Auto-Enrollment**

21 **“SEC. 1860E-11. PART A OPT-OUT AND MA AUTO-ENROLL-**

22 **MENT.**

23 “(a) PERMITTING INDIVIDUALS TO OPT OUT OF
24 PART A COVERAGE WITHOUT LOSING SOCIAL SECURITY
25 BENEFITS.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish—

3 “(A) a process by which an individual oth-
4 erwise entitled to benefits under part A may
5 elect (at a time and in a manner specified
6 under the process) to waive such entitlement;
7 and

8 “(B) a process by which an individual who
9 elects to waive such entitlement may revoke (at
10 a time and in a manner specified under the
11 process) such waiver.

12 The process under subparagraph (B) shall be coordi-
13 nated with the enrollment process under section
14 1837 for part B.

15 “(2) APPLICATION OF LATE ENROLLMENT PEN-
16 ALTY.—An individual who revokes a waiver under
17 paragraph (1)(B) shall be subject to a late enroll-
18 ment penalty as applied under section 1860E-
19 32(c)(2)(C).

20 “(3) NO IMPACT ON TITLE II BENEFITS.—Not-
21 withstanding any other provision of law, an election
22 of an individual to waive entitlement to benefits
23 under part A under paragraph (1)(A) shall not re-
24 sult in any loss of benefits under title II.

25 “(4) DEEMED OPT-OUT.—

1 “(A) An election of an individual to waive
2 entitlement to benefits under part A under
3 paragraph (1)(A) is also deemed the filing of a
4 notice of termination of benefits under part B
5 pursuant to section 1838(b)(1).

6 “(B) The termination of benefits under
7 part B pursuant to section 1838(b) is also
8 deemed to be a waiver of any entitlement to
9 benefits under part A.

10 “(b) SPECIAL OPEN ENROLLMENT PERIOD WITH-
11 OUT LATE ENROLLMENT PENALTY FOR CURRENT PART
12 A ONLY OR PART B ONLY ENROLLEES.—Notwith-
13 standing any other provision of law, in the case of an indi-
14 vidual who as of the general effective date, is entitled to
15 benefits under part A but not enrolled under part B, or
16 who is enrolled under part B but not entitled to benefits
17 (or enrolled) under part A, beginning as of such date, such
18 individual shall be deemed to be enrolled under part B
19 or part A, respectively, unless such individual elects to be
20 enrolled (or entitled to benefits) under neither of such
21 parts during a special open enrollment period specified by
22 the Secretary. No increase in the monthly premium of an
23 individual pursuant to section 1839(b) or section 1818(c)
24 shall be effected in the case of any such individual who
25 is deemed enrolled under part B or part A pursuant to

1 the previous sentence with respect to any period prior to
2 the date of such enrollment.

3 “(c) AUTO ENROLLMENT OF DUAL ELIGIBLE INDI-
4 VIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

5 “(1) IN GENERAL.—Except in the case of a
6 State that has elected the maintenance of effort op-
7 tion described in section 1944(b)(2), in the case of
8 an individual described in subparagraph (A)(ii) of
9 section 1935(c)(6) (taking into account the applica-
10 tion of subparagraph (B) of such section), the Sec-
11 retary shall establish a process for the enrollment in
12 an MA–PD plan that is a managed care plan under
13 part C that has a monthly beneficiary premium that
14 does not exceed the premium assistance available
15 under section 1860E–41(b)(1)(A). If there is more
16 than one such plan available, the Secretary shall en-
17 roll such an individual on a random basis among all
18 such plans in the PDP region.

19 “(2) RIGHT TO DISENROLL.—Nothing in para-
20 graph (1) shall prevent such an individual from de-
21 clining enrollment in any such plan (and thereby ob-
22 taining coverage under Medicare fee-for-service) or
23 from changing enrollment in such a plan to another
24 MA–PD plan.

1 **“SEC. 1860E-12. COORDINATION WITH PART D.**

2 “(a) DEEMED ENROLLMENT UNDER PART D.—

3 “(1) IN GENERAL.—The Secretary shall estab-
4 lish a process that, beginning as of the general effec-
5 tive date, provides for the enrollment in a prescrip-
6 tion drug plan that has a monthly base beneficiary
7 premium that does not exceed the weighted average
8 of premiums for such plans that provide standard
9 prescription drug coverage (as defined in section
10 1860D-2(b)) with respect to the area involved (on
11 a random basis among all such plans in the applica-
12 ble PDP region) of each Medicare enrollee (as de-
13 fined in section 1860E-51) who—

14 “(A) failed to enroll in such a prescription
15 drug plan during the applicable enrollment or
16 coverage election period under section 1860D-
17 1(b); and

18 “(B) failed to elect not to enroll in such a
19 prescription drug plan during an applicable opt-
20 out period described in paragraph (2).

21 Nothing in the previous sentence shall prevent such
22 an individual from declining or changing such enroll-
23 ment. Such process shall be carried out in the same
24 manner as the process described in section 1860D-
25 1(b)(1)(C).

1 “(2) OPT-OUT PERIODS.—The process under
2 paragraph (1) shall provide for the opportunity to
3 make an election described in subparagraph (B) of
4 such paragraph during an opt-out period that is co-
5 ordinated with the relevant enrollment or coverage
6 election period under section 1860D–1.

7 “(3) LATE ENROLLMENT PENALTIES.—In the
8 case of an individual who makes an election de-
9 scribed in paragraph (1)(B) and then enrolls in a
10 prescription drug plan, the late enrollment penalty
11 under section 1860D–13(b) shall apply to the
12 monthly beneficiary premium of such individual, ex-
13 cept that in applying such section, any reference to
14 the initial enrollment period of such individual shall
15 be deemed to be a reference to the opt-out period
16 under paragraph (2) during which the individual
17 elected not to enroll in a prescription drug plan.

18 “(4) NO LATE ENROLLMENT PENALTY FOR
19 CURRENT FEE-FOR-SERVICE BENEFICIARIES WITH-
20 OUT DRUG COVERAGE.—In the case of an individual
21 who is a Medicare enrollee before the date of enact-
22 ment of this section and who was not enrolled under
23 a prescription drug plan before being enrolled under
24 such a plan pursuant to paragraph (1), there shall
25 be no increase in the base beneficiary premium of an

1 individual under section 1860D–13 by a late enroll-
2 ment penalty under subsection (b) of such section
3 with respect to any period prior to the date of such
4 enrollment.

5 “(b) REFERENCE TO REQUIRED PRESCRIPTION
6 DRUG COVERAGE UNDER PART C.—For provision requir-
7 ing coverage under MA plans to include prescription drug
8 coverage, see section 1860E–26.”.

9 (b) LIMITATION ON MEDICAID BENEFITS FOR FULL-
10 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Section 1902
11 of the Social Security Act (42 U.S.C. 1396a) is amended
12 by adding at the end the following new subsection:

13 “(1) LIMITATION ON BENEFITS FOR FULL-BENEFIT
14 DUAL ELIGIBLE INDIVIDUALS.—Effective as of the gen-
15 eral effective date (as specified in section 1860E–62), ex-
16 cept in the case of a State which has elected the option
17 described in section 1944(b)(2), in the case of an indi-
18 vidual described in subparagraph (A)(ii) of section
19 1935(c)(6) (taking into account the application of sub-
20 paragraph (B) of such section), notwithstanding any other
21 provision of law, medical assistance shall not be available
22 under this title for any items and services for which pay-
23 ment may be made under title XVIII.”.

24 (c) MEDICAID MAINTENANCE OF EFFORT AND AL-
25 TERNATIVES.—Title XIX of the Social Security Act is

1 amended by inserting after section 1943 the following new
2 section:

3 “MAINTENANCE OF EFFORT OPTIONS FOR FULL-BENEFIT
4 DUAL ELIGIBLE INDIVIDUALS

5 “SEC. 1944. (a) IN GENERAL.—Effective as of the
6 general effective date (as specified in section 1860E–62),
7 a State shall elect, in a form and manner specified by the
8 Secretary, a maintenance of effort option described in sub-
9 section (b). In the case of a State that fails to make such
10 an election, the State shall be deemed to have elected the
11 option described in subsection (b)(3).

12 “(b) MAINTENANCE OF EFFORT OPTIONS DE-
13 SCRIBED.—The following are maintenance of effort op-
14 tions described in this subsection for a State, which shall
15 apply to all individuals described in subparagraph (A)(ii)
16 of section 1935(c)(6) (taking into account the application
17 of subparagraph (B) of such section) for such State:

18 “(1) ENROLLMENT OF DUAL ELIGIBLES IN
19 COMPREHENSIVE MEDICAID MANAGED CARE PLAN.—

20 “(A) IN GENERAL.—The State enrolls all
21 such individuals in a comprehensive Medicaid
22 managed care plan offered by a managed care
23 entity under section 1932.

24 “(B) PAYMENT OF SUBSIDY AMOUNT TO
25 STATE.—In the case of a State that elects the
26 option under this paragraph with respect to an

1 individual, the Secretary established under sec-
2 tion 1860E–51 shall pay to the State the same
3 amount that the individual would be entitled to
4 have paid as an income-related premium sub-
5 sidy under section 1860E–41(b)(1)(A) plus the
6 amount that the Secretary estimates would
7 have been paid with respect to the individual
8 under part D (including the actuarial value of
9 subsidy payments under sections 1860D–13
10 and 1860D–14). Such payment shall be made
11 in appropriate part from the Federal Hospital
12 Insurance Trust Fund under section 1817 and
13 the Federal Supplementary Medical Insurance
14 Trust Fund under section 1841.

15 “(C) RELATION TO PART D RULES.—In
16 the case of a State that has elected the option
17 under this paragraph, notwithstanding any
18 other provision of law—

19 “(i) the coverage provided under this
20 option shall be in lieu of any coverage that
21 may otherwise be provided under part D;
22 and

23 “(ii) the payment to the State under
24 subparagraph (B) shall be in lieu of any

1 payments otherwise made with respect to
2 such individual under such part.

3 “(2) OTHER INNOVATIVE ALTERNATIVES.—

4 “(A) IN GENERAL.—The State submits to
5 the Secretary, and has approved by the Sec-
6 retary, an innovative alternative proposal relat-
7 ing to coordinating coverage of such individuals
8 under Medicare and the State plan under title
9 XIX.

10 “(B) PROCESS FOR REVIEW.—With re-
11 spect to proposals submitted to the Secretary
12 under subparagraph (A), the Secretary shall ap-
13 prove such a proposal if the State demonstrates
14 with respect to the proposal that—

15 “(i) there would be no increased cost
16 to the Federal Government if it were ap-
17 proved; and

18 “(ii) there would be no reduction in
19 the quality of care provided to such indi-
20 viduals if the proposal were approved.”.

21 (d) CONFORMING AMENDMENTS.—

22 (1) SECTION 226.—Section 226 of the Social
23 Security Act (42 U.S.C. 426) is amended—

1 (A) in subsection (a), in the matter pre-
2 ceding paragraph (1), by inserting “, subject to
3 section 1860E–11(a)” after “individual who”;

4 (B) in subsection (b), in the matter pre-
5 ceding paragraph (1), by inserting “, subject to
6 section 1860E–11(a)” after “individual who”;
7 and

8 (C) in subsection (c), in the matter pre-
9 ceding paragraph (1), by inserting “, subject to
10 section 1860E–11(a)” after “subsection (a)”.

11 (2) SECTION 226A.—Section 226A(a) of such
12 Act (42 U.S.C. 426–1(a)) is amended, in the matter
13 preceding paragraph (1), by inserting “and subject
14 to section 1860E–11(a)” after “or title XVIII”.

15 (3) SECTION 1932.—Section 1932(a)(2)(B) of
16 the Social Security Act (42 U.S.C. 1396u–
17 2(a)(2)(B)) is amended by striking “A State” and
18 inserting “Except in the case of a State that has
19 elected the maintenance of effort option described in
20 section 1944(b)(2), a State”.

21 **SEC. 423. NEW BENEFIT STRUCTURE UNDER UNIFIED**
22 **MEDICARE.**

23 (a) IN GENERAL.—Part E of title XVIII of the Social
24 Security Act, as added by section 251, is amended by add-
25 ing at the end the following:

“Subpart 2—Out-of-Pocket Limit**2 “SEC. 1860E-21. OUT-OF-POCKET LIMIT.**

3 “(a) IN GENERAL.—Beginning with 2021, in the case
4 of a Medicare enrollee, if the amount of the out-of-pocket
5 cost-sharing of such enrollee for a calendar year equals
6 or exceeds the catastrophic limit under subsection (b) for
7 that year—

8 “(1) the enrollee shall not be responsible for ad-
9 ditional out-of-pocket cost-sharing incurred during
10 that year; and

11 “(2) the Secretary shall establish procedures
12 under which the Secretary shall, in appropriate part
13 from the Part A Medicare FFS Account under sec-
14 tion 1817 and the Part B Medicare FFS Account
15 under section 1841—

16 “(A) pay on behalf of the enrollee the
17 amount of the additional out-of-pocket cost-
18 sharing described in paragraph (1) attributable
19 to deductibles and coinsurance described in sub-
20 section (c)(1); and

21 “(B) reimburse the enrollee the amount of
22 the additional out-of-pocket cost-sharing de-
23 scribed in paragraph (1) attributable to
24 deductibles and coinsurance described in sub-
25 section (c)(2).

1 “(b) CATASTROPHIC LIMIT.—The amount of the cat-
2 astrophic limit under this subsection for a year shall be
3 the dollar amount in effect under section 223(c)(2)(A)(ii)
4 of the Internal Revenue Code of 1986 for self-only cov-
5 erage for taxable years beginning in such year.

6 “(c) OUT-OF-POCKET COST-SHARING DEFINED.—In
7 this section, the term ‘out-of-pocket cost-sharing’ means,
8 with respect to an individual, the amount of costs incurred
9 by the individual that are attributable to—

10 “(1) deductibles and coinsurance imposed under
11 part A or part B; and

12 “(2) deductibles and coinsurance imposed under
13 standard prescription drug coverage pursuant to sec-
14 tion 1860D–2(b) or alternative prescription drug
15 coverage pursuant to section 1860D–2(c) offered by
16 a prescription drug plan.”.

17 (b) APPLICATION OF OUT-OF-POCKET LIMIT TO MA-
18 PD PLANS.—

19 (1) IN GENERAL.—Section 1852(a)(1)(B) of the
20 Social Security Act (42 U.S.C. 1395w–22(a)(1)(B))
21 is amended—

22 (A) in clause (i), by striking “clause (iii)”
23 and inserting “clauses (iii) and (vi)”; and

24 (B) by adding at the end the following new
25 clause:

1 “(vi) OUT-OF-POCKET LIMIT.—The
2 provisions of section 1860E–21—

3 “(I) shall apply to individuals en-
4 rolled under an MA–PD plan in the
5 same manner as such provisions apply
6 to Medicare enrollees under such sec-
7 tion, except that in lieu of the applica-
8 tion of subsection (a)(2) of such sec-
9 tion the MA–PD plan shall establish
10 procedures to provide for payment of
11 any additional out-of-pocket cost-shar-
12 ing described in subsection (a)(1) of
13 such section incurred by individuals
14 enrolled under the MA–PD plan; and

15 “(II) as applied under subclause
16 (I), may not be waived by application
17 of this subparagraph.

18 In applying subsection (b) of section
19 1860E–21 pursuant to the previous sen-
20 tence, an MA–PD plan may substitute a
21 dollar amount that is less than the dollar
22 amount specified under such subsection.”.

23 (2) EXEMPTING MA–PD PLANS OFFERING AL-
24 TERNATIVE PRESCRIPTION DRUG COVERAGE FROM
25 PART D DEDUCTIBLE AND OUT-OF-POCKET LIMIT

1 REQUIREMENTS.—Section 1860D–2(c) of the Social
2 Security Act (42 U.S.C. 1395w–102(e)) is amend-
3 ed—

4 (A) in paragraph (2), by striking “The de-
5 ductible” and inserting “In the case of a pre-
6 scription drug plan, the deductible”; and

7 (B) in paragraph (3), by striking “The
8 coverage provides” and inserting “In the case
9 of a prescription drug plan, the coverage pro-
10 vides”.

11 (c) PRESCRIPTION DRUG PLANS REQUIRED TO RE-
12 PORT ENROLLEES’ OUT-OF-POCKET COST-SHARING.—
13 Section 1860D–12(b) of the Social Security Act (42
14 U.S.C. 1395w–112(b)) is amended by adding at the end
15 the following new paragraph:

16 “(7) OUT-OF-POCKET COST-SHARING RE-
17 PORTS.—Each contract entered into with a PDP
18 sponsor under this part with respect to a prescrip-
19 tion drug plan offered by such sponsor shall require
20 that, with respect to each claim submitted for items
21 or services furnished to an individual enrolled under
22 the plan pursuant to the contract, the sponsor sub-
23 mits to the Secretary information on the amount of
24 out-of-pocket cost-sharing (as defined in section

1 1860E–23(c)) applicable to such enrollee for such
2 items or services.”.

3 (d) CONFORMING AMENDMENTS.—

4 (1) Section 1813 of the Social Security Act (42
5 U.S.C. 1395e) is amended—

6 (A) in subsection (a), by inserting “Subject
7 to subpart 2 of part E:” before paragraph (1);
8 and

9 (B) in subsection (b), by inserting “Sub-
10 ject to subpart 2 of part E:” before paragraph
11 (1).

12 (2) Section 1833 of such Act (42 U.S.C. 1395l)
13 is amended—

14 (A) in subsection (a), in the matter pre-
15 ceding paragraph (1), by inserting “and sub-
16 part 2 of part E” after “succeeding provisions
17 of this section”;

18 (B) in subsection (b), in the first sentence,
19 by striking “Before applying” and inserting
20 “Subject to subpart 2 of part E, before apply-
21 ing”;

22 (C) in subsection (c)(1), in the matter pre-
23 ceding subparagraph (A), by inserting “subject
24 to subpart 2 of part E,” after “this part,”;

1 (D) in subsection (f), by striking “In es-
2 tablishing” and inserting “Subject to subpart 2
3 of part E, in establishing”; and

4 (E) in subsection (g)(1), by inserting “and
5 subpart 2 of part E” and “paragraphs (4) and
6 (5)”.

7 (3) Section 1882(a)(2) of such Act is amended
8 by striking “No medicare” and inserting “Subject to
9 section 1860E–24(c), no medicare”.

10 **SEC. 424. LATE ENROLLMENT PENALTY NOT TO APPLY FOR**
11 **MONTHS OF ANY HEALTH COVERAGE.**

12 (a) IN GENERAL.—Section 1839(b) of the Social Se-
13 curity Act (42 U.S.C. 1395r) is amended in the second
14 sentence, by inserting before the period at the end the fol-
15 lowing: “or months during which the individual has any
16 other health coverage”.

17 (b) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply for months of coverage begin-
19 ning after the date of the enactment of this Act.

20 **SEC. 425. MEDIGAP REFORM.**

21 Notwithstanding any provision of section 1882 of the
22 Social Security Act (42 U.S.C. 1395ss), as of the date
23 of the enactment of this Act, no policy may be offered
24 under such section that does not provide guaranteed cov-
25 erage (without regard to an individual’s preexisting condi-

1 tions, if any) to all individuals eligible to enroll under such
2 policy.

3 **SEC. 426. ACO REVISION.**

4 (a) ENROLLMENT.—Enrollment in such an ACO
5 under such title shall be based on the method established
6 under part E of such title. Such a network shall bear full
7 risk in the event payments under such title do not equal
8 or exceed liabilities under such network.

9 (b) DIRECTION OF PAYMENT.—An ACO may direct
10 that any payments under such title be made to a central-
11 ized entity rather than to an individual provider or sup-
12 plier.

13 (c) BIDS.—The Secretary of Health and Human
14 Services shall establish a process whereby such networks
15 compete using a bidding process similar to that described
16 in part E of such title for Medicare Advantage plans.

17 **SEC. 427. PRIMARY CARE OPTIONS.**

18 (a) SELECTION OF PRIMARY CARE PHYSICIAN.—The
19 Secretary shall establish a mechanism under which an in-
20 dividual enrolled under part B of title XVIII of the Social
21 Security Act may select such individual's primary care
22 physician. Such an individual shall not be liable for more
23 than \$5 for each visit to such selected physician.

24 (b) PAYMENT TO PHYSICIAN.—A physician selected
25 under subsection (a) shall receive a monthly fee in lieu

1 of any other payment under such part B for evaluation
2 and monitoring of such individual. The Secretary shall
3 provide a list of standardized benefits that are included
4 in such payment, including telephone and email commu-
5 nications, office visits, preventive care, and vaccinations.

6 **SEC. 428. GENERAL PROVISIONS; EFFECTIVE DATE.**

7 Part E of title XVIII of the Social Security Act, as
8 inserted by section 101(a)(2) and as previously amended,
9 is further amended by adding at the end the following new
10 subpart:

11 **“Subpart 5.—General Provisions**

12 **“SEC. 1860E-51. APPLICABILITY; DEFINITIONS.**

13 “(a) IN GENERAL.—The provisions of this Act are
14 superseded to the extent inconsistent with the provisions
15 of this part.

16 “(b) TERMINOLOGY.—For purposes of this part:

17 “(1) MEDICARE ENROLLEE.—

18 “(A) IN GENERAL.—The term ‘Medicare
19 enrollee’ means—

20 “(i) an individual entitled to (or en-
21 rolled for benefits) under part A and en-
22 rolled under part B; and

23 “(ii) except as otherwise specified, an
24 individual described in section 1860E-
25 11(a)(3).

1 “(B) TREATMENT.—Any reference in this
2 Act (or any other Act) in effect before the date
3 of the enactment of this part, to an individual
4 entitled to benefits under part A or enrolled
5 under part B shall be deemed a reference to a
6 Medicare enrollee.

7 “(2) MEDICARE FEE-FOR-SERVICE.—The term
8 ‘Medicare fee-for-service’ means the original Medi-
9 care fee-for-service program under parts A and B,
10 as modified by this part, and does not include part
11 C or part D.

12 “(3) MEDICARE FEE-FOR-SERVICE EN-
13 ROLLEE.—The term ‘Medicare fee-for-service en-
14 rollee’ means a Medicare enrollee who is not enrolled
15 under a Medicare Advantage plan under part C.

16 **“SEC. 1860E-61. GENERAL EFFECTIVE DATE.**

17 “Except as otherwise specified, the provisions of this
18 part shall apply to items and services furnished on or after
19 January 1, 2021, and to plan years beginning on or after
20 such date (referred to in this title as the ‘general effective
21 date’).”.

1 **Subtitle D—Telehealth**
2 **Improvements and Expansion**

3 **SEC. 431. EXPANSION OF COVERAGE OF TELEHEALTH**
4 **SERVICES.**

5 (a) COVERED SERVICES.—Section 1834(m)(4)(F)(i)
6 of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)(i))
7 is amended—

8 (1) by striking “and office” and inserting “of-
9 fice”; and

10 (2) by inserting: “respiratory services, audiology
11 services (as defined in section 1861(ll)), outpatient
12 therapy services (including physical therapy, occupa-
13 tional therapy, and speech-language pathology serv-
14 ices)” after “the Secretary)),”.

15 (b) PROVIDERS.—Subsection (m) of section 1834 of
16 such Act (42 U.S.C. 1395m) is amended—

17 (1) in paragraph (1), by striking “or a practi-
18 tioner (described in section 1842(b)(18)(C))” and
19 inserting “, a practitioner (described in section
20 1842(b)(18)(C)), or an applicable professional (as
21 defined in paragraph (4)(G))”;

22 (2) by striking “physician or practitioner” each
23 time it appears in such subsection and inserting
24 “physician, practitioner, or applicable professional”;

25 (3) in paragraph (3)(A)—

1 (A) in the heading, by striking “PHYSI-
2 CIAN AND PRACTITIONER” and inserting “PHY-
3 SICIAN, PRACTITIONER, AND APPLICABLE PRO-
4 FESSIONAL”; and

5 (B) by striking “physicians or practi-
6 tioners” and inserting “physicians, practi-
7 tioners, or applicable professionals”; and

8 (4) in paragraph (4), by adding at the end the
9 following new subparagraph:

10 “(G) APPLICABLE PROFESSIONAL.—The
11 term ‘applicable professional’ means, with re-
12 spect to services furnished on or after the date
13 that is 6 months after the date of the enact-
14 ment of this subparagraph, a certified diabetes
15 educator or licensed—

16 “(i) respiratory therapist;

17 “(ii) audiologist;

18 “(iii) occupational therapist;

19 “(iv) physical therapist; or

20 “(v) speech language pathologist.”.

21 (c) HOME-BASED MONITORING SERVICES FOR CON-
22 GESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE
23 PULMONARY DISEASE.—

1 (1) COVERAGE OF REMOTE PATIENT MONI-
2 TORING SERVICES FOR CERTAIN CHRONIC HEALTH
3 CONDITIONS.—

4 (A) IN GENERAL.—Section 1861(s)(2) of
5 the Social Security Act (42 U.S.C. 1395x(s)(2))
6 is amended—

7 (i) in subparagraph (GG), by striking
8 “and” at the end;

9 (ii) in subparagraph (HH), by insert-
10 ing “and” at the end; and

11 (iii) by inserting after subparagraph
12 (HH) the following new subparagraph:

13 “(II) applicable remote patient monitoring
14 services (as defined in paragraph (1)(A) of sub-
15 section (iii));”.

16 (2) SERVICES DESCRIBED.—Section 1861 of
17 the Social Security Act (42 U.S.C. 1395x) is amend-
18 ed by adding at the end the following new sub-
19 section:

20 “(kkk) REMOTE PATIENT MONITORING SERVICES
21 FOR CHRONIC HEALTH CONDITIONS.—

22 “(1)(A) The term ‘applicable remote patient
23 monitoring services’ means remote patient moni-
24 toring services (as defined in subparagraph (B)) fur-
25 nished to provide for the monitoring, evaluation, and

1 management of an individual with a covered chronic
2 condition (as defined in paragraph (2)), insofar as
3 such services are for the management of such chron-
4 ic condition.

5 “(B) The term ‘remote patient monitoring serv-
6 ices’ means services furnished through remote pa-
7 tient monitoring technology (as defined in subpara-
8 graph (C)).

9 “(C) The term ‘remote patient monitoring tech-
10 nology’ means a coordinated system that uses one or
11 more home-based or mobile monitoring devices that
12 automatically transmit vital sign data or information
13 on activities of daily living and may include re-
14 sponses to assessment questions collected on the de-
15 vices wirelessly or through a telecommunications
16 connection to a server that complies with the Fed-
17 eral regulations (concerning the privacy of individ-
18 ually identifiable health information) promulgated
19 under section 264(c) of the Health Insurance Port-
20 ability and Accountability Act of 1996, as part of an
21 established plan of care for that patient that in-
22 cludes the review and interpretation of that data by
23 a health care professional.

24 “(2) For purposes of paragraph (1), the term
25 ‘covered chronic health condition’ means applicable

1 conditions (as defined in and applied under section
2 1886(q)(5)) when under chronic care management
3 (identified as of July 1, 2015, by HCPCS code
4 99490 (and as subsequently modified by the Sec-
5 retary)).

6 “(3)(A) Payment may be made under this part
7 for applicable remote patient monitoring services
8 provided to an individual during a period of up to
9 90 days and such additional period as provided for
10 under subparagraph (B).

11 “(B) The 90-day period described in subpara-
12 graph (A), with respect to an individual, may be re-
13 newed by the physician who provides chronic care
14 management to such individual if the individual con-
15 tinues to qualify for such management.”.

16 (3) PAYMENT UNDER THE PHYSICIAN FEE
17 SCHEDULE.—Section 1848 of the Social Security
18 Act (42 U.S.C. 1395w–4) is amended—

19 (A) in subsection (c)—

20 (i) in paragraph (2)(B)—

21 (I) in clause (ii)(II), by striking
22 “and (v)” and inserting “(v), and
23 (vii)”; and

24 (II) by adding at the end the fol-
25 lowing new clause:

1 “(vii) BUDGETARY TREATMENT OF
2 CERTAIN SERVICES.—The additional ex-
3 penditures attributable to services de-
4 scribed in section 1861(s)(2)(II) shall not
5 be taken into account in applying clause
6 (ii)(II).”; and

7 (ii) by adding at the end the following
8 new paragraph:

9 “(7) TREATMENT OF APPLICABLE REMOTE PA-
10 TIENT MONITORING SERVICES.—

11 “(A) In determining relative value units
12 for applicable remote patient monitoring serv-
13 ices (as defined in section 1861(iii)(1)(A)), the
14 Secretary, in consultation with appropriate phy-
15 sician groups, practitioner groups, and supplier
16 groups, shall take into consideration—

17 “(i) physician or practitioner re-
18 sources, including physician or practitioner
19 time and the level of intensity of services
20 provided, based on—

21 “(I) the frequency of evaluation
22 necessary to manage the individual
23 being furnished the services;

24 “(II) the complexity of the eval-
25 uation, including the information that

1 must be obtained, reviewed, and ana-
2 lyzed; and

3 “(III) the number of possible di-
4 agnoses and the number of manage-
5 ment options that must be considered;

6 “(ii) practice expense costs associated
7 with such services, including the direct
8 costs associated with installation and infor-
9 mation transmission, costs of remote pa-
10 tient monitoring technology (including
11 equipment and software), device delivery
12 costs, and resource costs necessary for pa-
13 tient monitoring and followup (but not in-
14 cluding costs of any related item or non-
15 physician service otherwise reimbursed
16 under this title); and

17 “(iii) malpractice expense resources.

18 “(B) Using the relative value units deter-
19 mined in subparagraph (A), the Secretary shall
20 provide for separate payment for such services
21 and shall not adjust the relative value units as-
22 signed to other services that might otherwise
23 have been determined to include such separately
24 paid remote patient monitoring services.”; and

1 (B) in subsection (j)(3), by inserting
2 “(2)(II),” after “health risk assessment),”.

3 **SEC. 432. EXPANDING THE USE OF TELEHEALTH THROUGH**
4 **THE WAIVER OF CERTAIN REQUIREMENTS.**

5 (a) IN GENERAL.—Section 1834(m) of the Social Se-
6 curity Act (42 U.S.C. 1395m(m)) is amended—

7 (1) in paragraph (4)(C)(i), by striking “and
8 (7)” and inserting “(7), and (8)”; and

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

10 “(8) AUTHORITY TO WAIVE REQUIREMENTS
11 AND LIMITATIONS IF CERTAIN CONDITIONS MET.—

12 “(A) IN GENERAL.—Notwithstanding the
13 preceding provisions of this subsection, in the
14 case of telehealth services furnished on or after
15 January 1, 2021, the Secretary may waive any
16 restriction applicable to payment for telehealth
17 services under this subsection that is described
18 in subparagraph (B), but only if the Secretary
19 determines that such waiver would not deny or
20 limit the coverage or provision of benefits under
21 this title, and—

22 “(i) the Secretary determines that the
23 waiver is expected to reduce spending
24 under this title without reducing the qual-

1 ity of care or improve the quality of pa-
2 tient care without increasing spending; or

3 “(ii) the waiver would apply to tele-
4 health services furnished in originating
5 sites located in a high-need health profes-
6 sional shortage area (as designated pursu-
7 ant to section 332(a)(1)(A) of the Public
8 Health Service Act (42 U.S.C.
9 254e(a)(1)(A))).

10 “(B) RESTRICTIONS DESCRIBED.—For
11 purposes of this paragraph, restrictions applica-
12 ble to payment for telehealth services under
13 paragraph (1) are—

14 “(i) requirements relating to qualifica-
15 tions for an originating site under para-
16 graph (4)(C)(ii);

17 “(ii) any geographic limitations under
18 paragraph (4)(C)(i) (other than applicable
19 State law requirements, including State li-
20 censure requirements);

21 “(iii) any limitation on the type of
22 technology used to furnish telehealth serv-
23 ices;

24 “(iv) any limitation on the type of
25 provider of services or supplier who may

1 furnish telehealth services (other than the
2 requirement that the provider of services
3 or supplier is enrolled under this title);

4 “(v) any limitation on specific services
5 designated as telehealth services pursuant
6 to this subsection (provided the Secretary
7 determines that such services are clinically
8 appropriate to furnish remotely); or

9 “(vi) any other limitation relating to
10 the furnishing of telehealth services under
11 this title identified by the Secretary.

12 “(C) PUBLIC COMMENT.—The Secretary
13 shall establish a process by which stakeholders
14 may (on at least an annual basis) provide public
15 comment for waivers under this paragraph.

16 “(D) PERIODIC REVIEW OF WAIVERS.—
17 The Secretary shall periodically, but not more
18 often than every 3 years, reassess each waiver
19 under this paragraph to determine whether the
20 waiver continues to meet the conditions applica-
21 ble under subparagraph (A).”.

22 (b) POSTING OF INFORMATION.—Not later than 2
23 years after the date on which a waiver under section
24 1834(m)(8) of the Social Security Act, as added by sub-
25 section (a), first becomes effective, and at least biennially

1 thereafter, the Secretary of Health and Human Services
2 shall post on the internet website of the Centers for Medi-
3 care & Medicaid Services—

4 (1) the number of Medicare beneficiaries receiv-
5 ing telehealth services by reason of each waiver
6 under such section;

7 (2) the impact of such waivers on expenditures
8 and utilization under title XVIII of the Social Secu-
9 rity Act (42 U.S.C. 1395 et seq.); and

10 (3) other outcomes, as determined appropriate
11 by the Secretary.

12 **SEC. 433. EXPANDING THE USE OF TELEHEALTH FOR MEN-**
13 **TAL HEALTH SERVICES.**

14 (a) IN GENERAL.—Section 1834(m) of the Social Se-
15 curity Act (42 U.S.C. 1395m(m)), as amended by the pre-
16 ceding sections, is amended—

17 (1) in paragraph (4)(C)(i), by striking “and
18 (8)” and inserting “(8), and (9)”; and

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

20 “(9) TREATMENT OF MENTAL HEALTH SERV-
21 ICES FURNISHED THROUGH TELEHEALTH.—The ge-
22 ographic requirements described in paragraph
23 (4)(C)(i) (other than applicable State law require-
24 ments, including State licensure requirements) shall
25 not apply with respect to telehealth services that are

1 mental health services (as determined by the Sec-
2 retary) furnished on or after January 1, 2021, to an
3 eligible telehealth individual at an originating site
4 described in paragraph (4)(C)(ii) (other than an
5 originating site described in subclause (IX) of such
6 paragraph).”.

7 (b) INCLUSION OF THE HOME AS AN ORIGINATING
8 SITE.—Section 1834(m)(4)(C)(ii)(X) of such Act (42
9 U.S.C. 1395m(m)(4)(C)(ii)(X)) is amended by striking
10 “paragraph (7)” and inserting “paragraphs (7) and (9)”.

11 (c) ADDITIONAL SERVICES.—As part of the imple-
12 mentation of the amendments made by this section, the
13 Secretary of Health and Human Services shall consider
14 whether additional services should be added to the services
15 specified in paragraph (4)(F)(i) of section 1834(m) of
16 such Act (42 U.S.C. 1395m) for authorized payment
17 under paragraph (1) of such section.

18 **SEC. 434. USE OF TELEHEALTH IN EMERGENCY MEDICAL**
19 **CARE.**

20 (a) IN GENERAL.—Section 1834(m) of the Social Se-
21 curity Act (42 U.S.C. 1395m(m)), as amended by the pre-
22 ceding sections, is amended—

23 (1) in paragraph (4)(C)(i), by striking “and
24 (9)” and inserting “(9), and (10)”; and

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

1 (1) implement revisions to the process so that
2 the criteria to add services prioritizes, as appro-
3 priate, improved access to care through telehealth
4 services; and

5 (2) provide clarification on what requests to
6 add telehealth services under such process should in-
7 clude.

8 **SEC. 436. RURAL HEALTH CLINICS AND FEDERALLY QUALI-**
9 **FIED HEALTH CENTERS.**

10 (a) **EXPANSION OF ORIGINATING SITES.**—Section
11 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
12 1395m(m)(4)(C)), as amended by the preceding sections,
13 is amended—

14 (1) in clause (i), by striking “and (10)” and in-
15 serting “and (10), and subject to clause (iii),”; and

16 (2) by adding at the end the following new
17 clause:

18 “(iii) **RURAL HEALTH CLINICS AND**
19 **FEDERALLY QUALIFIED HEALTH CEN-**
20 **TERS.**—The term ‘originating site’ shall
21 also include any Federally qualified health
22 center and any rural health clinic (as such
23 terms are defined in section 1861(aa)) at
24 which the eligible telehealth individual is
25 located at the time the service is furnished

1 via a telecommunications system, whether
2 or not the individual is located in an area
3 described in clause (i), insofar as such
4 sites are not otherwise included in the defi-
5 nition of originating site under such
6 clause, subject to applicable State law re-
7 quirements, including State licensure re-
8 quirements.”.

9 (b) EXPANSION OF DISTANT SITES.—Section
10 1834(m) of the Social Security Act (42 U.S.C. 1395m(m))
11 is amended—

12 (1) in the first sentence of paragraph (1)—

13 (A) by striking “or a practitioner (de-
14 scribed in section 1842(b)(18)(C))” and insert-
15 ing “, a practitioner (described in section
16 1842(b)(18)(C)), a Federally qualified health
17 center, or a rural health clinic”; and

18 (B) by striking “or practitioner” and in-
19 serting “, practitioner, Federally qualified
20 health center, or rural health clinic”;

21 (2) in paragraph (2)(A)—

22 (A) by inserting “or to a Federally quali-
23 fied health center or rural health clinic that
24 serves as a distant site” after “a distant site”;
25 and

1 (B) by striking “such physician or practi-
2 tioner” and inserting “such physician, practi-
3 tioner, Federally qualified health center, or
4 rural health clinic”; and

5 (3) in paragraph (4)—

6 (A) in subparagraph (A), by inserting
7 “and includes a Federally qualified health cen-
8 ter or rural health clinic that furnishes a tele-
9 health service to an eligible individual” before
10 the period at the end; and

11 (B) in subparagraph (F), by adding at the
12 end the following new clause:

13 “(iii) INCLUSION OF RURAL HEALTH
14 CLINIC SERVICES AND FEDERALLY QUALI-
15 FIED HEALTH CENTER SERVICES FUR-
16 NISHED USING TELEHEALTH.—For pur-
17 poses of this subparagraph, the term ‘tele-
18 health services’ includes a rural health
19 clinic service or Federally qualified health
20 center service that is furnished using tele-
21 health to the extent that payment codes
22 corresponding to services identified by the
23 Secretary under clause (i) or (ii) are listed
24 on the corresponding claim for such rural

1 health clinic service or Federally qualified
2 health center service.”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to services furnished on or after
5 January 1, 2021.

6 **SEC. 437. NATIVE AMERICAN HEALTH FACILITIES.**

7 (a) IN GENERAL.—Section 1834(m)(4)(C) of the So-
8 cial Security Act (42 U.S.C. 1395m(m)(4)(C)), as amend-
9 ed by the preceding sections, is amended—

10 (1) in clause (i), by striking “clause (iii)” and
11 inserting “clauses (iii) and (iv)”; and

12 (2) by adding at the end the following new
13 clause:

14 “(iv) NATIVE AMERICAN HEALTH FA-
15 CILITIES.—The originating site require-
16 ments described in clauses (i) and (ii) shall
17 not apply with respect to a facility of the
18 Indian Health Service, whether operated
19 by such Service, or by an Indian tribe (as
20 that term is defined in section 4 of the In-
21 dian Health Care Improvement Act (25
22 U.S.C. 1603)) or a tribal organization (as
23 that term is defined in section 4 of the In-
24 dian Self-Determination and Education
25 Assistance Act (25 U.S.C. 5304)), or a fa-

1 cility of the Native Hawaiian health care
2 systems authorized under the Native Ha-
3 waiian Health Care Improvement Act (42
4 U.S.C. 11701 et seq.).”.

5 (b) NO ORIGINATING SITE FACILITY FEE FOR NEW
6 SITES.—Section 1834(m)(2)(B)(i) of the Social Security
7 Act (42 U.S.C. 1395m(m)(2)(B)(i)) is amended, in the
8 matter preceding subclause (I), by inserting “(other than
9 an originating site that is only described in clause (iv) of
10 paragraph (4)(C), and does not meet the requirement for
11 an originating site under clause (i) of such paragraph)”
12 after “the originating site”.

13 (c) EFFECTIVE DATE.—The amendments made by
14 this section shall apply to services furnished on or after
15 January 1, 2021.

16 **SEC. 438. WAIVER OF TELEHEALTH RESTRICTIONS DURING**
17 **NATIONAL EMERGENCIES.**

18 Section 1135(b) of the Social Security Act (42 U.S.C.
19 1320b–5(b)) is amended—

20 (1) in paragraph (6), by striking “and” after
21 the semicolon;

22 (2) in paragraph (7), by striking the period at
23 the end and inserting “; and”; and

24 (3) by adding at the end the following:

1 “(8) requirements for payment for telehealth
2 services under section 1834(m).”.

3 **SEC. 439. USE OF TELEHEALTH IN RECERTIFICATION FOR**
4 **HOSPICE CARE.**

5 (a) IN GENERAL.—Section 1814(a)(7)(D)(i) of the
6 Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)) is
7 amended by inserting “(including through use of tele-
8 health, notwithstanding the requirements in section
9 1834(m)(4)(C))” after “face-to-face encounter”.

10 (b) GAO REPORT.—Not later than 3 years after the
11 date of enactment of this Act, the Comptroller General
12 of the United States shall submit a report to Congress
13 evaluating the impact of the amendment made by sub-
14 section (a) on—

15 (1) the number and percentage of beneficiaries
16 recertified for the Medicare hospice benefit at 180
17 days and for subsequent benefit periods;

18 (2) the appropriateness for hospice care of the
19 patients recertified through the use of telehealth;
20 and

21 (3) any other factors determined appropriate by
22 the Comptroller General.

1 **SEC. 440. CLARIFICATION FOR FRAUD AND ABUSE LAWS**
2 **REGARDING TECHNOLOGIES PROVIDED TO**
3 **BENEFICIARIES.**

4 Section 1128A(i)(6) of the Social Security Act (42
5 U.S.C. 1320a–7a(i)(6)) is amended—

6 (1) in subparagraph (I), by striking “; or” and
7 inserting a semicolon;

8 (2) in subparagraph (J), by striking the period
9 at the end and inserting “; or”; and

10 (3) by adding at the end the following new sub-
11 paragraph:

12 “(K) the provision of technologies (as de-
13 fined by the Secretary) on or after the date of
14 the enactment of this subparagraph, by a pro-
15 vider of services or supplier (as such terms are
16 defined for purposes of title XVIII) directly to
17 an individual who is entitled to benefits under
18 part A of title XVIII, enrolled under part B of
19 such title, or both, for the purpose of furnishing
20 telehealth services, remote patient monitoring
21 services, or other services furnished through the
22 use of technology (as defined by the Secretary),
23 if—

24 “(i) the technologies are not offered
25 as part of any advertisement or sollicita-
26 tion; and

1 “(ii) the provision of the technologies
2 meets any other requirements set forth in
3 regulations promulgated by the Sec-
4 retary.”.

5 **SEC. 441. STUDY AND REPORT ON INCREASING ACCESS TO**
6 **TELEHEALTH SERVICES IN THE HOME.**

7 (a) **MEDPAC STUDY.**—The Medicare Payment Advi-
8 sory Commission (in this section referred to as the “Com-
9 mission”) shall conduct a study on increasing access under
10 the Medicare program under title XVIII of the Social Se-
11 curity Act (42 U.S.C. 1395 et seq.) to telehealth services
12 in the home. Such study shall include an analysis of the
13 following:

14 (1) How different payers allow the home to be
15 an originating site for telehealth services.

16 (2) Particular types of telehealth services or
17 subgroups of beneficiaries with respect to which al-
18 lowing the home to be an originating site under the
19 Medicare program would be suitable.

20 (b) **REPORT.**—Not later than 24 months after the
21 date of the enactment of this Act, the Commission shall
22 submit to Congress a report containing the results of the
23 study conducted under subsection (a), together with rec-
24 ommendations for such legislation and administrative ac-
25 tion as the Commission determines appropriate.

1 **SEC. 442. ANALYSIS OF TELEHEALTH WAIVERS IN ALTER-**
2 **NATIVE PAYMENT MODELS.**

3 The second sentence of section 1115A(g) of the So-
4 cial Security Act (42 U.S.C. 1315a(g)) is amended by in-
5 serting “an analysis of waivers under section (d)(1) re-
6 lated to telehealth and the impact on quality and spending
7 under the applicable titles of such waivers,” after “sub-
8 section (c),”.

9 **SEC. 443. MODEL TO ALLOW ADDITIONAL HEALTH PROFES-**
10 **SIONALS TO FURNISH TELEHEALTH SERV-**
11 **ICES.**

12 Section 1115A(b)(2)(B) of the Social Security Act
13 (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the
14 end the following new clause:

15 “(xxviii) Allowing health professionals
16 who are not otherwise eligible under sec-
17 tion 1834(m) to furnish telehealth services
18 to furnish such services.”.

19 **SEC. 444. TESTING OF MODELS TO EXAMINE THE USE OF**
20 **TELEHEALTH UNDER THE MEDICARE PRO-**
21 **GRAM.**

22 Section 1115A(b)(2) of the Social Security Act (42
23 U.S.C. 1315a(b)(2)) is amended by adding at the end the
24 following new subparagraph:

25 “(D) TESTING MODELS TO EXAMINE USE
26 OF TELEHEALTH UNDER MEDICARE.—The Sec-

1 retary shall consider testing under this sub-
2 section models to examine the use of telehealth
3 under title XVIII.”.

○