

116TH CONGRESS  
2D SESSION

# S. 4796

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

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 5, 2020

Mr. BRAUN introduced the following bill; which was read twice and referred to the Committee on Finance

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## A BILL

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

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

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

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

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

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

“(9) DISTRIBUTION FOR MEDISAVE ACCOUNT FUNDING.—

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

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 redes-  
 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-

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

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

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



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.

14 **“SEC. 198. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES**  
15 **BASED ON HEALTH STATUS.**  
16

24 “(1) Health status.



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-

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

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

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-



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

“(i) TERMINATION OF MEDICAID OR  
CHIP COVERAGE.—The employee or de-  
pendent is covered under a Medicaid plan  
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-

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

“(D) LIMITATIONS.—

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

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

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

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

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 par-  
 2       ticipate 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(c)(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 adjudication under this section such court shall stay, and  
4 upon appointment by it of the Secretary as trustee,  
5 such court shall continue the stay of, any pending  
6 mortgage foreclosure, equity receivership, or other  
7 proceeding to reorganize, conserve, or liquidate the  
8 plan, the sponsor, or property of such plan or sponsor,  
9 and any other suit against any receiver, conservator,  
10 or trustee of the plan, the sponsor, or property of the plan or sponsor. Pending such adjudication and upon the appointment by it of the Secretary as trustee, the court may stay any proceeding  
11 to enforce a lien against property of the plan or the  
12 sponsor or any other suit against the plan or the  
13 sponsor.

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

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

1 **SEC. 212. CLARIFICATION OF TREATMENT OF SINGLE EM-**  
 2 **PLOYER ARRANGEMENTS.**

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

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

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

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.

(a) CRIMINAL PENALTIES FOR CERTAIN WILLFUL MISREPRESENTATIONS.—Section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131) is amended by adding at the end the following new subsection:

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

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

7       (c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—  
 8       Section 503 of the Employee Retirement Income Security  
 9       Act of 1974 (29 U.S.C. 1133) is amended by inserting  
 10      “(a) IN GENERAL.—” before “In accordance”, and by  
 11      adding at the end the following new subsection:

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

18      **SEC. 214. COOPERATION BETWEEN FEDERAL AND STATE**  
 19                                      **AUTHORITIES.**

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

23      “(d) CONSULTATION WITH STATES WITH RESPECT  
 24      TO ASSOCIATION HEALTH PLANS.—

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 serting 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           ment period) every 12, 24, or 36 months, as de-  
 2           termined by the State.”.

3 **SEC. 233. PROMOTING HEALTH PLANS THAT COVER INDIVIDUALS IN MORE THAN ONE STATE.**

5           There are appropriated, out of amounts in the Treas-  
 6           ury not otherwise appropriated, \$10,000,000 to be made  
 7           available by December 31, 2021, to the Center for Medi-  
 8           care & Medicaid Innovation to fund new research or pilot  
 9           programs dedicated to pursuing viable methods of enroll-  
 10          ing individuals in health insurance programs that cross  
 11          State lines.

12 **TITLE III—COMPETITION,**  
 13 **TRANSPARENCY AND AC-**  
 14 **COUNTABILITY**

15 **Subtitle A—Provider and Insurer**  
 16 **Competition**

17 **SEC. 301. HOSPITAL CONSOLIDATION.**

18           (a) AUTHORIZATION OF APPROPRIATIONS.—There is  
 19           authorized to be appropriated \$160,000,000 to the Fed-  
 20           eral Trade Commission to hire staff to investigate, as con-  
 21           sistent with the Sherman Antitrust Act and other relevant  
 22           Federal laws, anti-competitive mergers and practices  
 23           under such laws to the extent such mergers and practices  
 24           relate to providers of inpatient and outpatient health care

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 hospitals in  
 23          the 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(c) 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 or 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-

tion process described in clause (i) retain only the minimum necessary information to perform such a process, and adhere to effective security and encryption practices in data storage and transmission;

“(iii) store claims and other data collected under this subsection only in de-identified form, in accordance with section 164.514 of title 45, Code of Federal Regulations (or any successor regulations); and

“(iv) ensure that individually identifiable data is encrypted, in accordance with guidance issued by the Secretary under section 13402(h)(2) of the HITECH Act.

“(2) APPLICABLE SELF-INSURED GROUP HEALTH PLAN.—For purposes of paragraph (1), a self-insured group health plan is an applicable self-insured group health plan if such plan is self-administered, or is administered by a third-party plan administrator that meets 1 or both of the following criteria:

“(A) Administers health, medical, or pharmacy benefits for more than 50,000 enrollees.

“(B) Is one of the 5 largest administrators or issuers of self-insured group health plans in

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-



rectory is accurate as of the date of the last data update and that enrollees or prospective enrollees should consult the group health plan or issuer's electronic provider directory on its website or call a specified customer service telephone number to obtain the most current provider directory information.

“(2) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER BUSINESS PROCESSES.—Beginning on the date that is one year after the date of enactment of the Fair Care Act of 2020, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall establish business processes to—

“(A) verify and update, at least once every 90 days, the provider directory information for all providers included in the online health care provider directory search tool described in paragraph (1)(A)(iii); and

“(B) remove any provider from such online directory search tool if such provider has not verified the directory information within the previous 6 months or the plan or issuer has been unable to verify the provider's network participation.

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

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

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

“(4) REPORTS TO CONGRESS.—

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

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)”;

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

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

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

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

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

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

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.

## **Subtitle C—Prescription Drug Competition and Innovation**

### **SEC. 341. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.**

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

### **“SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.**

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

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

“(c) DESIGNATION PROCESS.—

“(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the product that is the subject of the request meets the criteria under subsection (e) to be considered a generic

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 nated—

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:



3 “(B) The summary review of each biologi-  
4 cal product licensed under subsection (a) or (k).

“(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

“(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing medical education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.”.

20 SEC. 358. CONGRESSIONAL REVIEW OF THE FOOD AND  
21 DRUG ADMINISTRATION RULEMAKING.

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

1 **“CHAPTER 10—CONGRESSIONAL REVIEW**  
 2 **OF FOOD AND DRUG ADMINISTRATION**  
 3 **RULEMAKING**

“Sec.

“920. Applicability.

“921. Congressional review.

“922. Congressional approval procedure for major rules.

“923. Congressional disapproval procedure for nonmajor rules.

“924. Definitions.

“925. Judicial review.

“926. Exemption for monetary policy.

“927. Effective date of certain rules.

“928. Regulatory cut-go requirement.

“929. Review of rules currently in effect.

4 **“§ 920. Applicability**

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

7 **“§ 921. Congressional review**

8 “(a)(1)(A) Before a rule may take effect, the Food  
 9 and Drug Administration shall satisfy the requirements  
 10 of section 928 and shall publish in the Federal Register  
 11 a list of information on which the rule is based, including  
 12 data, scientific and economic studies, and cost-benefit  
 13 analyses, and identify how the public can access such in-  
 14 formation online, and shall submit to each House of the  
 15 Congress and to the Comptroller General a report con-  
 16 taining—

17 “(i) a copy of the rule;

18 “(ii) a concise general statement relating to the  
 19 rule;

1           “(iii) a classification of the rule as a major or  
2           nonmajor rule, including an explanation of the clas-  
3           sification specifically addressing each criteria for a  
4           major rule contained within sections 924(2)(A),  
5           924(2)(B), and 924(2)(C);

6           “(iv) a list of any other related regulatory ac-  
7           tions intended to implement the same statutory pro-  
8           vision or regulatory objective as well as the indi-  
9           vidual and aggregate economic effects of those ac-  
10          tions; and

11          “(v) the proposed effective date of the rule.

12          “(B) On the date of the submission of the report  
13          under subparagraph (A), the Food and Drug Administra-  
14          tion shall submit to the Comptroller General and make  
15          available to each House of Congress—

16               “(i) a complete copy of the cost-benefit analysis  
17               of the rule, if any, including an analysis of any jobs  
18               added or lost, differentiating between public and pri-  
19               vate sector jobs;

20               “(ii) the Food and Drug Administration’s ac-  
21               tions pursuant to sections 603, 604, 605, 607, and  
22               609 of this title;

23               “(iii) the Food and Drug Administration’s ac-  
24               tions pursuant to sections 202, 203, 204, and 205  
25               of the Unfunded Mandates Reform Act of 1995; and

1           “(iv) any other relevant information or require-  
2           ments under any other Act and any relevant Execu-  
3           tive orders.

4           “(C) Upon receipt of a report submitted under sub-  
5           paragraph (A), each House shall provide copies of the re-  
6           port to the chairman and ranking member of each stand-  
7           ing committee with jurisdiction under the rules of the  
8           House of Representatives or the Senate to report a bill  
9           to amend the provision of law under which the rule is  
10          issued.

11          “(2)(A) The Comptroller General shall provide a re-  
12          port on each major rule to the committees of jurisdiction  
13          by the end of 15 calendar days after the submission or  
14          publication date. The report of the Comptroller General  
15          shall include an assessment of the Food and Drug Admin-  
16          istration’s compliance with procedural steps required by  
17          paragraph (1)(B) and an assessment of whether the major  
18          rule imposes any new limits or mandates on private-sector  
19          activity.

20          “(B) The Food and Drug Administration shall co-  
21          operate with the Comptroller General by providing infor-  
22          mation relevant to the Comptroller General’s report under  
23          subparagraph (A).

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

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

5 “(4) A nonmajor rule shall take effect as provided  
6 by section 923 after submission to Congress under para-  
7 graph (1).

8 “(5) If a joint resolution of approval relating to a  
9 major rule is not enacted within the period provided in  
10 subsection (b)(2), then a joint resolution of approval relat-  
11 ing to the same rule may not be considered under this  
12 chapter in the same Congress by either the House of Rep-  
13 resentatives or the Senate.

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

17 “(2) If a joint resolution described in subsection (a)  
18 is not enacted into law by the end of 70 session days or  
19 legislative days, as applicable, beginning on the date on  
20 which the report referred to in section 921(a)(1)(A) is re-  
21 ceived by Congress (excluding days either House of Con-  
22 gress is adjourned for more than 3 days during a session  
23 of Congress), then the rule described in that resolution  
24 shall be deemed not to be approved and such rule shall  
25 not take effect.

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

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

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

12           “(B) necessary for the enforcement of criminal  
13 laws;

14           “(C) necessary for national security; or

15           “(D) issued pursuant to any statute imple-  
16 menting an international trade agreement.

17       “(3) An exercise by the President of the authority  
18 under this subsection shall have no effect on the proce-  
19 dures under section 922.

20       “(d)(1) In addition to the opportunity for review oth-  
21 erwise provided under this chapter, in the case of any rule  
22 for which a report was submitted in accordance with sub-  
23 section (a)(1)(A) during the period beginning on the date  
24 occurring—

1           “(A) in the case of the Senate, 60 session days;

2           or

3           “(B) in the case of the House of Representa-

4           tives, 60 legislative days,

5           before the date the Congress is scheduled to adjourn a

6           session of Congress through the date on which the same

7           or succeeding Congress first convenes its next session, sec-

8           tions 922 and 923 shall apply to such rule in the suc-

9           ceeding session of Congress.

10          “(2)(A) In applying sections 922 and 923 for pur-

11          poses of such additional review, a rule described under

12          paragraph (1) shall be treated as though—

13               “(i) such rule were published in the Federal

14          Register on—

15               “(I) in the case of the Senate, the 15th

16               session day; or

17               “(II) in the case of the House of Rep-

18               resentatives, the 15th legislative day,

19               after the succeeding session of Congress first con-

20               venes; and

21               “(ii) a report on such rule were submitted to

22               Congress under subsection (a)(1) on such date.

23          “(B) Nothing in this paragraph shall be construed

24          to affect the requirement under subsection (a)(1) that a

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

3 “(3) A rule described under paragraph (1) shall take  
4 effect as otherwise provided by law (including other sub-  
5 sections of this section).

6 **“§ 922. Congressional approval procedure for major**  
7 **rules**

8 “(a)(1) For purposes of this section, the term ‘joint  
9 resolution’ means only a joint resolution addressing a re-  
10 port classifying a rule as major pursuant to section  
11 921(a)(1)(A)(iii) that—

12 “(A) bears no preamble;

13 “(B) bears the following title (with blanks filled  
14 as appropriate): ‘Approving the rule submitted by  
15 \_\_\_\_\_ relating to \_\_\_\_\_.’;

16 “(C) includes after its resolving clause only the  
17 following (with blanks filled as appropriate): ‘That  
18 Congress approves the rule submitted by \_\_\_\_\_ re-  
19 lating to \_\_\_\_\_.’; and

20 “(D) is introduced pursuant to paragraph (2).

21 “(2) After a House of Congress receives a report  
22 classifying a rule as major pursuant to section  
23 921(a)(1)(A)(iii), the majority leader of that House (or  
24 his or her respective designee) shall introduce (by request,



1 if appropriate) a joint resolution described in paragraph  
2 (1)—

3 “(A) in the case of the House of Representa-  
4 tives, within 3 legislative days; and

5 “(B) in the case of the Senate, within 3 session  
6 days.

7 “(3) A joint resolution described in paragraph (1)  
8 shall not be subject to amendment at any stage of pro-  
9 ceeding.

10 “(b) A joint resolution described in subsection (a)  
11 shall be referred in each House of Congress to the commit-  
12 tees having jurisdiction over the provision of law under  
13 which the rule is issued.

14 “(c) In the Senate, if the committee or committees  
15 to which a joint resolution described in subsection (a) has  
16 been referred have not reported it at the end of 15 session  
17 days after its introduction, such committee or committees  
18 shall be automatically discharged from further consider-  
19 ation of the resolution and it shall be placed on the cal-  
20 endar. A vote on final passage of the resolution shall be  
21 taken on or before the close of the 15th session day after  
22 the resolution is reported by the committee or committees  
23 to which it was referred, or after such committee or com-  
24 mittees have been discharged from further consideration  
25 of the resolution.

1       “(d)(1) In the Senate, when the committee or com-  
2 mittees to which a joint resolution is referred have re-  
3 ported, or when a committee or committees are discharged  
4 (under subsection (c)) from further consideration of a  
5 joint resolution described in subsection (a), it is at any  
6 time thereafter in order (even though a previous motion  
7 to the same effect has been disagreed to) for a motion  
8 to proceed to the consideration of the joint resolution, and  
9 all points of order against the joint resolution (and against  
10 consideration of the joint resolution) are waived. The mo-  
11 tion is not subject to amendment, or to a motion to post-  
12 pone, or to a motion to proceed to the consideration of  
13 other business. A motion to reconsider the vote by which  
14 the motion is agreed to or disagreed to shall not be in  
15 order. If a motion to proceed to the consideration of the  
16 joint resolution is agreed to, the joint resolution shall re-  
17 main the unfinished business of the Senate until disposed  
18 of.

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

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

3 “(3) In the Senate, immediately following the conclu-  
4 sion of the debate on a joint resolution described in sub-  
5 section (a), and a single quorum call at the conclusion of  
6 the debate if requested in accordance with the rules of the  
7 Senate, the vote on final passage of the joint resolution  
8 shall occur.

9 “(4) Appeals from the decisions of the Chair relating  
10 to the application of the rules of the Senate to the proce-  
11 dure relating to a joint resolution described in subsection  
12 (a) shall be decided without debate.

13 “(e) In the House of Representatives, if any com-  
14 mittee to which a joint resolution described in subsection  
15 (a) has been referred has not reported it to the House  
16 at the end of 15 legislative days after its introduction,  
17 such committee shall be discharged from further consider-  
18 ation of the joint resolution, and it shall be placed on the  
19 appropriate calendar. On the second and fourth Thursdays  
20 of each month it shall be in order at any time for the  
21 Speaker to recognize a Member who favors passage of a  
22 joint resolution that has appeared on the calendar for at  
23 least 5 legislative days to call up that joint resolution for  
24 immediate consideration in the House without intervention  
25 of any point of order. When so called up a joint resolution

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

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

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

15 “(B) the procedure in the receiving House shall  
16 be the same as if no joint resolution had been re-  
17 ceived from the other House until the vote on pas-  
18 sage, when the joint resolution received from the  
19 other House shall supplant the joint resolution of  
20 the receiving House.

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

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

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

3 “(h) This section and section 923 are enacted by  
 4 Congress—

5 “(1) as an exercise of the rulemaking power of  
 6 the Senate and House of Representatives, respec-  
 7 tively, and as such is deemed to be part of the rules  
 8 of each House, respectively, but applicable only with  
 9 respect to the procedure to be followed in that  
 10 House in the case of a joint resolution described in  
 11 subsection (a) and superseding other rules only  
 12 where explicitly so; and

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

18 **“§ 923. Congressional disapproval procedure for**  
 19 **nonmajor rules**

20 “(a) For purposes of this section, the term ‘joint res-  
 21 olution’ means only a joint resolution introduced in the  
 22 period beginning on the date on which the report referred  
 23 to in section 921(a)(1)(A) is received by Congress and  
 24 ending 60 days thereafter (excluding days either House  
 25 of Congress is adjourned for more than 3 days during a

1 session of Congress), the matter after the resolving clause  
2 of which is as follows: ‘That Congress disapproves the  
3 nonmajor rule submitted by the \_\_\_\_\_ relating to  
4 \_\_\_\_\_, and such rule shall have no force or effect.’ (The  
5 blank spaces being appropriately filled in).

6 “(b) A joint resolution described in subsection (a)  
7 shall be referred to the committees in each House of Con-  
8 gress with jurisdiction.

9 “(c) In the Senate, if the committee to which is re-  
10 ferred a joint resolution described in subsection (a) has  
11 not reported such joint resolution (or an identical joint  
12 resolution) at the end of 15 session days after the date  
13 of introduction of the joint resolution, such committee may  
14 be discharged from further consideration of such joint res-  
15 olution upon a petition supported in writing by 30 Mem-  
16 bers of the Senate, and such joint resolution shall be  
17 placed on the calendar.

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

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

10 “(2) In the Senate, debate on the joint resolution,  
11 and on all debatable motions and appeals in connection  
12 therewith, shall be limited to not more than 10 hours,  
13 which shall be divided equally between those favoring and  
14 those opposing the joint resolution. A motion to further  
15 limit debate is in order and not debatable. An amendment  
16 to, or a motion to postpone, or a motion to proceed to  
17 the consideration of other business, or a motion to recom-  
18 mit the joint resolution is not in order.

19 “(3) In the Senate, immediately following the conclu-  
20 sion of the debate on a joint resolution described in sub-  
21 section (a), and a single quorum call at the conclusion of  
22 the debate if requested in accordance with the rules of the  
23 Senate, the vote on final passage of the joint resolution  
24 shall occur.

1       “(4) Appeals from the decisions of the Chair relating  
2 to the application of the rules of the Senate to the proce-  
3 dure relating to a joint resolution described in subsection  
4 (a) shall be decided without debate.

5       “(e) In the Senate, the procedure specified in sub-  
6 section (c) or (d) shall not apply to the consideration of  
7 a joint resolution respecting a nonmajor rule—

8               “(1) after the expiration of the 60 session days  
9 beginning with the applicable submission or publica-  
10 tion date; or

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

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

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

23              “(2) With respect to a joint resolution described  
24 in subsection (a) of the House receiving the joint  
25 resolution—



1           “(A) the procedure in that House shall be  
 2           the same as if no joint resolution had been re-  
 3           ceived from the other House; but

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

6   **“§ 924. Definitions**

7           “For purposes of this chapter:

8           “(1) The term ‘major rule’ means any rule of  
 9           the Food and Drug Administration, including an in-  
 10          terim final rule, that the Administrator of the Office  
 11          of Information and Regulatory Affairs of the Office  
 12          of Management and Budget finds has resulted in or  
 13          is likely to result in—

14           “(A) an annual cost on the economy of  
 15          \$100,000,000 or more, adjusted annually for  
 16          inflation;

17           “(B) a major increase in costs or prices for  
 18          consumers, individual industries, Federal,  
 19          State, or local government agencies, or geo-  
 20          graphic regions; or

21           “(C) significant adverse effects on competi-  
 22          tion, employment, investment, productivity, in-  
 23          novation, or on the ability of United States-  
 24          based enterprises to compete with foreign-based  
 25          enterprises in domestic and export markets.

1           “(2) The term ‘nonmajor rule’ means any rule  
2 of the Food and Drug Administration that is not a  
3 major rule.

4           “(3) The term ‘rule’ has the meaning given  
5 such term in section 551, except that such term does  
6 not include—

7                 “(A) any rule of particular applicability;

8                 “(B) any rule relating to agency manage-  
9 ment or personnel; or

10                “(C) any rule of agency organization, pro-  
11 cedure, or practice that does not substantially  
12 affect the rights or obligations of non-agency  
13 parties.

14           “(4) The term ‘submission date or publication  
15 date’, except as otherwise provided in this chapter,  
16 means—

17                 “(A) in the case of a major rule, the date  
18 on which the Congress receives the report sub-  
19 mitted under section 921(a)(1); and

20                 “(B) in the case of a nonmajor rule, the  
21 later of—

22                         “(i) the date on which the Congress  
23 receives the report submitted under section  
24 921(a)(1); and

1 “(ii) the date on which the nonmajor  
2 rule is published in the Federal Register, if  
3 so published.

4 **“§ 925. Judicial review**

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

7 “(b) Notwithstanding subsection (a), a court may de-  
8 termine whether the Food and Drug Administration has  
9 completed the necessary requirements under this chapter  
10 for a rule to take effect.

11 “(c) The enactment of a joint resolution of approval  
12 under section 922 shall not be interpreted to serve as a  
13 grant or modification of statutory authority by Congress  
14 for the promulgation of a rule, shall not extinguish or af-  
15 fect any claim, whether substantive or procedural, against  
16 any alleged defect in a rule, and shall not form part of  
17 the record before the court in any judicial proceeding con-  
18 cerning a rule except for purposes of determining whether  
19 or not the rule is in effect.

20 **“§ 926. Exemption for monetary policy**

21 “Nothing in this chapter shall apply to rules that con-  
22 cern monetary policy proposed or implemented by the  
23 Board of Governors of the Federal Reserve System or the  
24 Federal Open Market Committee.

1   **“§ 927. Effective date of certain rules**

2           “Notwithstanding section 921, any rule other than a  
3 major rule which the Food and Drug Administration for  
4 good cause finds (and incorporates the finding and a brief  
5 statement of reasons therefore in the rule issued) that no-  
6 tice and public procedure thereon are impracticable, un-  
7 necessary, or contrary to the public interest, shall take ef-  
8 fect at such time as the Food and Drug Administration  
9 determines.

10   **“§ 928. Regulatory cut-go requirement**

11           “In making any new rule, the Food and Drug Admin-  
12 istration shall identify a rule or rules that may be amend-  
13 ed or repealed to completely offset any annual costs of  
14 the new rule to the United States economy. Before the  
15 new rule may take effect, the Food and Drug Administra-  
16 tion shall make each such repeal or amendment. In mak-  
17 ing such an amendment or repeal, the Food and Drug Ad-  
18 ministration shall comply with the requirements of sub-  
19 chapter II of chapter 5, but the Food and Drug Adminis-  
20 tration may consolidate proceedings under subchapter 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-



tion under subsection (a) or (k) shall submit to the Secretary a list that includes—

“(i) any patent not previously required to be disclosed (as described in paragraph (3)) under subparagraph (A) or (B), as applicable, within 30 days of the earlier of—

“(I) the date of issuance of such patent by the United States Patent and Trademark Office; or

“(II) the date of approval of a supplemental application for the biological product; and

“(ii) any patent, or any claim with respect to a patent, included on the list pursuant to this paragraph, that the Patent Trial and Appeal Board of the United States Patent and Trademark Office determines in a written decision to cancel as unpatentable, within 30 days of such decision.

“(2) PUBLICATION OF INFORMATION.—

“(A) IN GENERAL.—Within 1 year of the date of enactment of the Fair Care Act of 2020, the Secretary shall publish and make

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.



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

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

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

“(A) IN GENERAL.—If the PDP sponsor of a prescription drug plan (or MA organization offering an MA–PD plan) uses a standard for reimbursement (as described in subparagraph

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  
7 drugs by the health plan or health insurance  
8 coverage during the reporting period; and  
9

10 “(G) amounts paid directly or indirectly in  
11 rebates, fees, or any other type of remuneration  
12 to brokers, consultants, advisors, or any other  
13 individual or firm who referred the group health  
14 plan’s or health insurance issuer’s business to  
15 the pharmacy benefit manager.

16 “(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of  
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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           (5) The average prior authorization approval  
2           time for pharmacy benefit managers.

3           (6) Factors affecting the use of step therapy by  
4           pharmacy benefit managers.

5           (c) REPORT.—Not later than 3 years after the date  
6           of enactment of this Act, the Comptroller General shall  
7           submit to the Secretary of Health and Human Services,  
8           the Committee on Health, Education, Labor, and Pen-  
9           sions of the Senate, and the Committee on Energy and  
10          Commerce of the House of Representatives a report con-  
11          taining the results of the study conducted under sub-  
12          section (a), including policy recommendations.

## 13       **Subtitle E—Medicare and Medicaid** 14       **Prescription Drug Reforms**

### 15       **SEC. 371. MEDICARE PART B REBATE BY MANUFACTURERS** 16               **FOR DRUGS OR BIOLOGICALS WITH PRICES** 17               **INCREASING FASTER THAN INFLATION.**

18          (a) IN GENERAL.—Section 1847A of the Social Secu-  
19          rity Act (42 U.S.C. 1395w–3a) is amended by adding at  
20          the end the following new subsection:

21               “(h) REBATE BY MANUFACTURERS FOR DRUGS OR  
22          BIOLOGICALS WITH PRICES INCREASING FASTER THAN  
23          INFLATION.—

24               “(1) REQUIREMENTS.—



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     ‘rebtable 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

subparagraph for a rebatable drug for a rebate period is—

“(i) the amount determined under subsection (b)(4) for such rebatable drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

“(ii) the percentage by which the rebate period CPI-U (as defined in subparagraph (F)) for the rebate period exceeds the benchmark period CPI-U (as defined in subparagraph (E)).

“(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term ‘payment amount benchmark quarter’ means the calendar quarter beginning July 1, 2019.

“(E) BENCHMARK PERIOD CPI-U.—The term ‘benchmark period CPI-U’ means the consumer price index for all urban consumers (United States city average) for July 2019.

“(F) REBATE PERIOD CPI-U.—The term ‘rebate period CPI-U’ means, with respect to a rebate period, the consumer price index for all urban consumers (United States city average) for the last month of the calendar quarter that

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           rebatable 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

multiple source drug for a rebate period  
exceed—

“(I) for rebate periods beginning  
after December 31, 2009, and before  
September 30, 2022, 100 percent of  
the average manufacturer price of the  
drug; and

“(II) for rebate periods beginning  
on or after October 1, 2022, 125 per-  
cent of the average manufacturer  
price of the drug.

“(ii) NO MAXIMUM AMOUNT FOR  
DRUGS IF AMP INCREASES OUTPACE IN-  
FLATION.—

“(I) IN GENERAL.—If the aver-  
age manufacturer price with respect  
to each dosage form and strength of  
a single source drug or an innovator  
multiple source drug increases on or  
after October 1, 2021, and such in-  
creased average manufacturer price  
exceeds the inflation-adjusted average  
manufacturer price determined with  
respect to such drug under subclause  
(II) for the rebate period, clause (i)

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-

tion brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(9) HEALTH CARE LIABILITY CLAIM.—The term “health care liability claim” means a demand by any person, whether or not pursuant to ADR, against a health care provider, including, but not limited to, third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision or use of (or the failure to provide or use) health care services or medical products, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(10) HEALTH CARE PROVIDER.—The term “health care provider” means any person or entity required by State or Federal laws or regulations to be licensed, registered, or certified to provide health care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation, as well as any

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 accredited  
6 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 (c)(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-

based quarterly amount for a State for a category for quarters in a reform year beginning with the eleventh reform year is equal to the beneficiary-based quarterly amount under this paragraph for such State and category for the previous reform year increased by the per beneficiary percentage increase for such category and reform year.

“(E) ANNUAL PERCENTAGE INCREASE BEGINNING WITH SECOND REFORM YEAR.—For purposes of this subsection, the term ‘per beneficiary percentage increase’ means, for a reform year, the sum of—

“(i) the projected percentage change in nominal gross domestic product from the midpoint of the previous reform year to the midpoint of the reform year for which the percentage increase is being applied; and

“(ii) one percentage point.

“(2) BASE PER BENEFICIARY, PER CATEGORY AMOUNT FOR EACH STATE.—

“(A) AVERAGE PER CATEGORY.—

“(i) IN GENERAL.—The Secretary shall determine, consistent with this para-

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.

“(B) EXCLUSION OF PASS-THROUGH PAYMENTS.—In computing base per beneficiary, per category amounts under subparagraph (A)(i) the Secretary shall exclude payments described in subsection (a)(4).

“(C) STANDARDIZATION.—

“(i) IN GENERAL.—In computing each such amount, the Secretary shall standardize the amount in order to remove the variation attributable to the following:

“(I) RISK FACTORS.—Such risk factors as age, health and disability status (including high cost medical conditions), gender, institutional status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence.

“(II) GEOGRAPHIC.—Variations in costs on a county-by-county basis.

“(ii) METHOD OF STANDARDIZATION.—

“(I) CONSULTATION IN DEVELOPMENT OF RISK STANDARDIZATION.—In developing the methodology



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(c)(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            ficiary 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 (c).

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 INDIVIDUAL  
11          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(c)(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 serting “or section 1903A” after “was  
11 made under this section”; and

12 (II) in subparagraph (B), by in-  
13 serting “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-

mined based on the application of modified adjusted gross income under subparagraph (A) and who is so eligible on the basis of clause (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection (a)(10)(A), at the option of the State, the State plan may provide that the individual's eligibility shall be redetermined every 6 months (or such shorter number of months as the State may elect).”.

**SEC. 404. LOWERING SAFE HARBOR THRESHOLD WITH RESPECT TO STATE TAXES ON HEALTH CARE PROVIDERS.**

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

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

“(I) beginning”; and

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

“(II) beginning on or after January 1, 2021, and before January 1, 2030, ‘4 percent’ shall be substituted for ‘6 percent’ each place it appears;

“(III) beginning on or after January 1, 2030, and before January 1, 2035, ‘3 percent’

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 “(B) in exchange for a fee that is pub-  
 2 lished on a publicly available website of such  
 3 physician.

4 “(4) PHYSICIANS’ SERVICES.—The term ‘physi-  
 5 cians’ services’ has the meaning given such term by  
 6 section 1861(q) of the Social Security Act.

7 “(c) LIMITATION.—The amount allowed as a deduc-  
 8 tion under subsection (a) for a taxable year shall not ex-  
 9 ceed the gross receipts attributable to physicians’ services  
 10 furnished by the taxpayer during the taxable year.”.

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

“Sec. 199B. Qualified charity care.”.

## 15 **Subtitle B—Medicare Reforms**

### 16 **SEC. 411. OFF-CAMPUS PROVIDER-BASED DEPARTMENT** 17 **MEDICARE SITE NEUTRAL PAYMENT.**

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

21 “(x) OFF-CAMPUS PROVIDER-BASED DEPARTMENT  
 22 MEDICARE SITE NEUTRAL PAYMENT.—

23 “(1) IN GENERAL.—With respect to items and  
 24 services furnished in an off-campus provider-based  
 25 department, payment under this section for such

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”; and

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 INDIVIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

5 “(1) IN GENERAL.—Except in the case of a  
6 State that has elected the maintenance of effort option described in section 1944(b)(2), in the case of  
7 an individual described in subparagraph (A)(ii) of  
8 section 1935(c)(6) (taking into account the application of subparagraph (B) of such section), the Secretary shall establish a process for the enrollment in  
9 an MA–PD plan that is a managed care plan under  
10 part C that has a monthly beneficiary premium that  
11 does not exceed the premium assistance available  
12 under section 1860E–41(b)(1)(A). If there is more  
13 than one such plan available, the Secretary shall enroll such an individual on a random basis among all  
14 such plans in the PDP region.

15 “(2) RIGHT TO DISENROLL.—Nothing in paragraph (1) shall prevent such an individual from declining enrollment in any such plan (and thereby obtaining coverage under Medicare fee-for-service) or  
16 from changing enrollment in such a plan to another  
17 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 “(11) 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****“SEC. 1860E-21. OUT-OF-POCKET LIMIT.**

“(a) IN GENERAL.—Beginning with 2021, in the case of a Medicare enrollee, if the amount of the out-of-pocket cost-sharing of such enrollee for a calendar year equals or exceeds the catastrophic limit under subsection (b) for that year—

“(1) the enrollee shall not be responsible for additional out-of-pocket cost-sharing incurred during that year; and

“(2) the Secretary shall establish procedures under which the Secretary shall, in appropriate part from the Part A Medicare FFS Account under section 1817 and the Part B Medicare FFS Account under section 1841—

“(A) pay on behalf of the enrollee the amount of the additional out-of-pocket cost-sharing described in paragraph (1) attributable to deductibles and coinsurance described in subsection (c)(1); and

“(B) reimburse the enrollee the amount of the additional out-of-pocket cost-sharing described in paragraph (1) attributable to deductibles and coinsurance described in subsection (c)(2).

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(c)) 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’).”.

**Subtitle D—Telehealth**  
**Improvements and Expansion**

**SEC. 431. EXPANSION OF COVERAGE OF TELEHEALTH SERVICES.**

(a) COVERED SERVICES.—Section 1834(m)(4)(F)(i) of the Social Security Act (42 U.S.C. 1395m(m)(4)(F)(i)) is amended—

(1) by striking “and office” and inserting “office”; and

(2) by inserting: “respiratory services, audiology services (as defined in section 1861(ll)), outpatient therapy services (including physical therapy, occupational therapy, and speech-language pathology services)” after “the Secretary)),”.

(b) PROVIDERS.—Subsection (m) of section 1834 of such Act (42 U.S.C. 1395m) is amended—

(1) in paragraph (1), by striking “or a practitioner (described in section 1842(b)(18)(C))” and inserting “, a practitioner (described in section 1842(b)(18)(C)), or an applicable professional (as defined in paragraph (4)(G))”;

(2) by striking “physician or practitioner” each time it appears in such subsection and inserting “physician, practitioner, or applicable professional”;

(3) in paragraph (3)(A)—



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

conditions (as defined in and applied under section 1886(q)(5)) when under chronic care management (identified as of July 1, 2015, by HCPCS code 99490 (and as subsequently modified by the Secretary)).

“(3)(A) Payment may be made under this part for applicable remote patient monitoring services provided to an individual during a period of up to 90 days and such additional period as provided for under subparagraph (B).

“(B) The 90-day period described in subparagraph (A), with respect to an individual, may be renewed by the physician who provides chronic care management to such individual if the individual continues to qualify for such management.”.

(3) PAYMENT UNDER THE PHYSICIAN FEE SCHEDULE.—Section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended—

(A) in subsection (c)—

(i) in paragraph (2)(B)—

(I) in clause (ii)(II), by striking

“and (v)” and inserting “(v), and (vii)”; and

(II) by adding at the end the fol-

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

(c) ADDITIONAL SERVICES.—As part of the implementation of the amendments made by this section, the Secretary of Health and Human Services shall consider whether additional services should be added to the services specified in paragraph (4)(F)(i) of section 1834(m) of such Act (42 U.S.C. 1395m) for authorized payment under paragraph (1) of such section.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), as amended by the preceding sections, is amended—

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

1           “(10) TREATMENT OF EMERGENCY MEDICAL  
 2       CARE FURNISHED THROUGH TELEHEALTH.—The  
 3       geographic requirements described in paragraph  
 4       (4)(C)(i) (other than applicable State law require-  
 5       ments, including State licensure requirements) shall  
 6       not apply with respect to telehealth services that are  
 7       services for emergency medical care (as determined  
 8       by the Secretary) furnished on or after January 1,  
 9       2021, to an eligible telehealth individual at an origi-  
 10      nating site described in subclause (II), (V), or (VII)  
 11      of paragraph (4)(C)(ii).”.

12       (b) ADDITIONAL SERVICES.—As part of the imple-  
 13      mentation of the amendments made by this section, the  
 14      Secretary of Health and Human Services shall consider  
 15      whether additional services should be added to the services  
 16      specified in paragraph (4)(F)(i) of section 1834(m) of  
 17      such Act (42 U.S.C. 1395m) for authorized payment  
 18      under paragraph (1) of such section.

19      **SEC. 435. IMPROVEMENTS TO THE PROCESS FOR ADDING**  
 20                              **TELEHEALTH SERVICES.**

21       The Secretary shall undertake a review of the process  
 22      established pursuant to section 1834(m)(4)(F)(ii) of the  
 23      Social Security Act (42 U.S.C. 1395m(m)(4)(F)(ii)), and  
 24      based on the results of such review—

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

(B) by striking “such physician or practitioner” and inserting “such physician, practitioner, Federally qualified health center, or rural health clinic”; and

(3) in paragraph (4)—

(A) in subparagraph (A), by inserting “and includes a Federally qualified health center or rural health clinic that furnishes a telehealth service to an eligible individual” before the period at the end; and

(B) in subparagraph (F), by adding at the end the following new clause:

“(iii) INCLUSION OF RURAL HEALTH CLINIC SERVICES AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FURNISHED USING TELEHEALTH.—For purposes of this subparagraph, the term ‘telehealth services’ includes a rural health clinic service or Federally qualified health center service that is furnished using telehealth to the extent that payment codes corresponding to services identified by the Secretary under clause (i) or (ii) are listed on the corresponding claim for such rural

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.”.

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