

117TH CONGRESS
2D SESSION

H. R. 8588

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

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2022

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

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Fair Care Act of 2022”.

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—MODERNIZATION OF HEALTH SAVINGS ACCOUNTS

Subtitle A—Modernization of Health Savings Accounts and Contributions

- Sec. 101. Modernization of health savings accounts.
 Sec. 102. Unused premium tax credits may be deposited in health savings 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 Health Savings Accounts

- Sec. 111. One-time application of saver’s credit to contributions to health savings accounts.
 Sec. 112. Grants for health savings account assistance and outreach.
 Sec. 113. New corporations required to use health savings accounts.
 Sec. 114. Federal employee health benefits and health savings accounts.

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. Definition of “employer” under ERISA with respect to group health plans.
 Sec. 212. 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. Leveling the playing field between payers and providers.
- Sec. 304. Banning anticompetitive terms in facility and insurance contracts that limit access to higher quality, lower cost care.
- Sec. 305. Repealing eligibility of certain ACOs.
- Sec. 306. Repeal of health care reform provisions limiting Medicare exception to the prohibition on certain physician referrals for hospitals.
- Sec. 307. Alternative payment model for certain shoppable procedures.

Subtitle B—Price Transparency

- Sec. 321. Price transparency requirements.
- Sec. 322. Ensuring enrollee access to cost-sharing information.
- Sec. 323. Access of individuals to protected health information.
- Sec. 324. Timely bills for patients.
- Sec. 325. Advisory group on reducing burden of hospital administrative requirements.
- Sec. 326. Data reporting to improve the transparency regarding how 340B hospital covered entities provide care for patients.
- Sec. 327. Requiring 340B drug discount program reports by DSH hospital covered entities on low-income utilization rate of outpatient hospital services.
- Sec. 328. Employer benefits reports.
- Sec. 329. 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. Regulation of manufacturer-sponsored copay contributions.
- Sec. 350. Antitrust exemption for private health insurer issuers to negotiate wholesale acquisition prices of prescription drugs purchased from drug manufacturers.
- Sec. 351. Biological product innovation.
- Sec. 352. Prompt approval of drugs related to safety information.
- Sec. 353. Congressional review of the Food and Drug Administration rule-making.
- Sec. 354. Government Accountability Office study of rules.

Subtitle D—Prescription Drug and Pharmacy Benefit Manager Transparency

- Sec. 361. Patent disclosure requirements.
- Sec. 362. Requirements with respect to prescription drug benefits.
- Sec. 363. PBM transparency and elimination of DIR fees.

- Sec. 364. Health plan oversight of pharmacy benefit manager services.
- Sec. 365. Study by Comptroller General of United States.

Subtitle E—Medicare and Medicaid Prescription Drug Reforms

- Sec. 371. Medicare part D modernization redesign.
- Sec. 372. Maximum monthly cap on cost-sharing payments under prescription drug plans and MA–PD plans.
- Sec. 373. Medicare part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.
- Sec. 374. Market based part B pricing index.
- Sec. 375. Innovation model testing of Medicare drug payments.
- Sec. 376. 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—MODERNIZATION OF**
 2 **HEALTH SAVINGS ACCOUNTS**
 3 **Subtitle A—Modernization of**
 4 **Health Savings Accounts and**
 5 **Contributions**

6 **SEC. 101. MODERNIZATION OF HEALTH SAVINGS AC-**
 7 **COUNTS.**

8 (a) IN GENERAL.—Section 223 of the Internal Rev-
 9 enue Code of 1986 is amended to read as follows:

1 **“SEC. 223. HEALTH SAVINGS ACCOUNTS.**

2 “(a) DEDUCTION ALLOWED.—In the case of an indi-
3 vidual who is an eligible individual for any month during
4 the taxable year, there shall be allowed as a deduction for
5 the taxable year an amount equal to the aggregate amount
6 paid in cash during such taxable year by or on behalf of
7 such individual to a health savings account of such indi-
8 vidual.

9 “(b) LIMITATIONS.—

10 “(1) IN GENERAL.—The amount allowable as a
11 deduction under subsection (a) with respect to any
12 month is $\frac{1}{12}$ of the dollar amount in effect under
13 subsection (d)(2)(A) for the taxable year which in-
14 cluded such month.

15 “(2) DENIAL OF DEDUCTION TO DEPEND-
16 ENTS.—No deduction shall be allowed under this
17 section to any individual with respect to whom a de-
18 duction under section 151 is allowable to another
19 taxpayer for a taxable year beginning in the cal-
20 endar year in which such individual’s taxable year
21 begins.

22 “(3) INCREASE IN LIMIT FOR INDIVIDUALS BE-
23 COMING ELIGIBLE INDIVIDUALS AFTER THE BEGIN-
24 NING OF THE YEAR.—

25 “(A) IN GENERAL.—For purposes of com-
26 puting the limitation under paragraph (1) for

1 any taxable year, an individual who is an eligi-
2 ble individual during the last month of such
3 taxable year shall be treated—

4 “(i) as having been an eligible indi-
5 vidual during each of the months in such
6 taxable year, and

7 “(ii) as having been enrolled, during
8 each of the months such individual is
9 treated as an eligible individual solely by
10 reason of clause (i), in the same qualified
11 plan in which the individual was enrolled
12 for the last month of such taxable year.

13 “(B) FAILURE TO MAINTAIN QUALIFIED
14 PLAN COVERAGE.—

15 “(i) IN GENERAL.—If, at any time
16 during the testing period, the individual is
17 not an eligible individual, then—

18 “(I) gross income of the indi-
19 vidual for the taxable year in which
20 occurs the first month in the testing
21 period for which such individual is not
22 an eligible individual is increased by
23 the aggregate amount of all contribu-
24 tions to the health savings account of
25 the individual which could not have

1 been made but for subparagraph (A),
2 and

3 “(II) the tax imposed by this
4 chapter for any taxable year on the
5 individual shall be increased by 10
6 percent of the amount of such in-
7 crease.

8 “(ii) EXCEPTION FOR DISABILITY OR
9 DEATH.—Subclauses (I) and (II) of clause
10 (i) shall not apply if the individual ceased
11 to be an eligible individual by reason of the
12 death of the individual or the individual
13 becoming disabled (within the meaning of
14 section 72(m)(7)).

15 “(iii) TESTING PERIOD.—The term
16 ‘testing period’ means the period beginning
17 with the last month of the taxable year re-
18 ferred to in subparagraph (A) and ending
19 on the last day of the 12th month fol-
20 lowing such month.

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

23 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
24 individual’ means, with respect to any month, any

1 individual if such individual is covered under a quali-
2 fied plan as of the 1st day of such month

3 “(2) QUALIFIED PLAN.—

4 “(A) IN GENERAL.—The term ‘qualified
5 health plan’ means any health plan, including
6 employer plans, individual plans, short term
7 plans, Medicare, Medicaid, VA health care,
8 TRICARE, Indian health service, health care
9 sharing ministries, and association health plans.

10 “(B) EXCLUSION OF CERTAIN PLANS.—

11 Such term does not include a health plan if
12 substantially all of its coverage is—

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

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

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

20 “(A) insurance if substantially all of the
21 coverage provided under such insurance relates
22 to—

23 “(i) liabilities incurred under workers’
24 compensation laws,

25 “(ii) tort liabilities,

1 “(iii) liabilities relating to ownership
2 or use of property, or

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

5 “(B) insurance for a specified disease or
6 illness, and

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

9 “(4) FAMILY COVERAGE.—The term ‘family
10 coverage’ means any coverage other than self-only
11 coverage.

12 “(d) HEALTH SAVINGS ACCOUNT.—For purposes of
13 this section—

14 “(1) IN GENERAL.—The term ‘health savings
15 account’ means a trust created or organized in the
16 United States as a health savings account exclusively
17 for the purpose of paying the qualified medical ex-
18 penses of the account beneficiary, but only if the
19 written governing instrument creating the trust
20 meets the following requirements:

21 “(A) Except in the case of a rollover con-
22 tribution described in subsection (f)(5) or sec-
23 tion 220(f)(5), no contribution will be accept-
24 ed—

25 “(i) unless it is in cash, or

1 “(ii) to the extent such contribution,
2 when added to previous contributions to
3 the trust for the calendar year, exceeds the
4 limitation amount specified in paragraph
5 (2)(A), or

6 “(iii) to the extent such contribution,
7 when added to the balance of the account,
8 exceeds the limitation amount specified in
9 paragraph (2)(B).

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

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

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

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

25 “(2) LIMITATIONS.—

1 “(A) ANNUAL LIMITATION.—

2 “(i) IN GENERAL.—The limitation
3 amount specified in this subparagraph is—

4 “(I) \$5,000 in the case of a
5 qualified health plan with an actuarial
6 value of less than 40 percent,

7 “(II) \$4,300 in the case of a
8 qualified health plan with an actuarial
9 value that is 40 percent or more and
10 less than 75 percent, and

11 “(III) \$3,600 in the case of a
12 qualified health plan with an actuarial
13 value that is 75 percent or more.

14 “(ii) ACTUARIAL VALUE OF QUALI-
15 FIED HEALTH PLAN.—For purposes of
16 clause (i), the actuarial value of a qualified
17 health plan is the percentage of the total
18 average costs of covered benefits under the
19 health plan.

20 “(B) ACCOUNT ACCUMULATION LIMITA-
21 TION.—The limitation amount specified in this
22 paragraph is \$50,000.

23 “(C) INDEXING.—

24 “(i) IN GENERAL.—In the case of any
25 taxable year beginning in a calendar year

1 after 2023, each dollar amount contained
2 in subparagraphs (A)(i) and (B) shall be
3 increased by the medical care cost adjust-
4 ment of such amount for such calendar
5 year.

6 “(ii) MEDICAL CARE COST ADJUST-
7 MENT.—For purposes of clause (i), the
8 medical care cost adjustment for any cal-
9 endar year is the percentage (if any) by
10 which—

11 “(I) the medical care component
12 of the C–CPI–U (as defined in section
13 1(f)(6)) for August of the preceding
14 calendar year, exceeds

15 “(II) such component of the C–
16 CPI–U (as so defined) for August of
17 2022.

18 “(iii) ROUNDING.—

19 “(I) ANNUAL LIMITATION.—If
20 any increase in a dollar amount con-
21 tained in subparagraph (A)(i) deter-
22 mined under clause (i) is not a mul-
23 tiple of \$100, such increase shall be
24 rounded to the nearest multiple of
25 \$100.

1 “(II) ACCOUNT LIMITATION.—If
2 any increase in the dollar amount con-
3 tained in subparagraph (B) deter-
4 mined under clause (i) is not a mul-
5 tiple of \$1,000, such increase shall be
6 rounded to the nearest multiple of
7 \$1,000.

8 “(D) COORDINATION WITH OTHER CON-
9 TRIBUTIONS.—The limitation which would (but
10 for this paragraph) apply under subparagraphs
11 (A) and (B) to an individual for any taxable
12 year shall be reduced (but not below zero) by
13 the sum of—

14 “(i) the aggregate amount contributed
15 to health savings accounts of such indi-
16 vidual which is excludable from the tax-
17 payer’s gross income for such taxable year
18 under section 106(d) (and such amount
19 shall not be allowed as a deduction under
20 subsection (a)), and

21 “(ii) the aggregate amount contrib-
22 uted to health savings accounts of such in-
23 dividual for such taxable year under sec-
24 tion 408(d)(9) (and such amount shall not

1 be allowed as a deduction under subsection
2 (a).

3 “(3) QUALIFIED MEDICAL EXPENSES.—

4 “(A) IN GENERAL.—The term ‘qualified
5 medical expenses’ means, with respect to an ac-
6 count beneficiary, amounts paid by such bene-
7 ficiary for medical care (as defined in section
8 213(d)) for such individual, the spouse of such
9 individual, and any dependent (as defined in
10 section 152, determined without regard to sub-
11 sections (b)(1), (b)(2), and (d)(1)(B) thereof)
12 of such individual, but only to the extent such
13 amounts are not compensated for by insurance
14 or otherwise. For purposes of this subpara-
15 graph, amounts paid for menstrual care prod-
16 ucts shall be treated as paid for medical care.

17 “(B) HEALTH INSURANCE MAY NOT BE
18 PURCHASED FROM ACCOUNT.—

19 “(i) IN GENERAL.—Subparagraph (A)
20 shall not apply to any payment for insur-
21 ance.

22 “(ii) EXCEPTIONS.—Clause (i) shall
23 not apply to any expense for coverage
24 under—

1 “(I) a health plan during any pe-
2 riod of continuation coverage required
3 under any Federal law,

4 “(II) a qualified long-term care
5 insurance contract (as defined in sec-
6 tion 7702B(b)),

7 “(III) a health plan during a pe-
8 riod in which the individual is receiv-
9 ing unemployment compensation
10 under any Federal or State law, or

11 “(IV) in the case of an account
12 beneficiary who has attained the age
13 specified in section 1811 of the Social
14 Security Act, any health insurance
15 other than a medicare supplemental
16 policy (as defined in section 1882 of
17 the Social Security Act).

18 “(iii) EXCEPTION FOR INTEGRATED
19 HEALTH PLANS.—Clause (i) shall not
20 apply to any expense for coverage under an
21 integration eligible health plan which is in-
22 tegrated with the health savings account
23 within the meaning of section 106(d).

24 “(iv) EXCEPTION FOR DIRECT PRI-
25 MARY CARE SERVICE ARRANGEMENTS.—

1 “(I) IN GENERAL.—A direct pri-
2 mary care service arrangement shall
3 not be treated as insurance for pur-
4 poses of clause (i).

5 “(II) DIRECT PRIMARY CARE
6 SERVICE ARRANGEMENT DEFINED.—
7 For purposes of this clause, the term
8 ‘direct primary care service arrange-
9 ment’ means an arrangement under
10 which an individual is provided med-
11 ical care (as defined in section
12 213(d)(1), determined without regard
13 to subparagraph (E) thereof) con-
14 sisting solely of primary care services
15 provided by primary care practitioners
16 (as defined in section 1833(x)(2)(A)
17 of the Social Security Act, determined
18 without regard to clause (ii) thereof),
19 if the sole compensation for such care
20 is a fixed periodic fee.

21 “(C) MENSTRUAL CARE PRODUCT.—For
22 purposes of this paragraph, the term ‘menstrual
23 care product’ means a tampon, pad, liner, cup,
24 sponge, or similar product used by individuals

1 with respect to menstruation or other genital-
2 tract secretions.

3 “(4) ACCOUNT BENEFICIARY.—The term ‘ac-
4 count beneficiary’ means the individual on whose be-
5 half the health savings account was established.

6 “(5) CERTAIN RULES TO APPLY.—Rules similar
7 to the following rules shall apply for purposes of this
8 section:

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

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

13 “(C) Except as provided in section 106(d),
14 section 219(f)(5) (relating to employer pay-
15 ments).

16 “(D) Section 408(g) (relating to commu-
17 nity property laws).

18 “(E) Section 408(h) (relating to custodial
19 accounts).

20 “(e) TAX TREATMENT OF ACCOUNTS.—

21 “(1) IN GENERAL.—A health savings account is
22 exempt from taxation under this subtitle unless such
23 account has ceased to be a health savings account.
24 Notwithstanding the preceding sentence, any such
25 account is subject to the taxes imposed by section

1 511 (relating to imposition of tax on unrelated busi-
2 ness income of charitable, etc. organizations).

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

9 “(f) TAX TREATMENT OF DISTRIBUTIONS.—

10 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL
11 EXPENSES.—Any amount paid or distributed out of
12 a health savings account which is used exclusively to
13 pay qualified medical expenses of any account bene-
14 ficiary shall not be includible in gross income.

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

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

23 “(A) IN GENERAL.—If any excess con-
24 tribution is contributed for a taxable year to
25 any health savings account of an individual,

1 paragraph (2) shall not apply to distributions
2 from the health savings accounts of such indi-
3 vidual (to the extent such distributions do not
4 exceed the aggregate excess contributions to all
5 such accounts of such individual for such year)
6 if—

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

12 “(ii) such distribution is accompanied
13 by the amount of net income attributable
14 to such excess contribution.

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

18 “(B) EXCESS CONTRIBUTION.—For pur-
19 poses of subparagraph (A), the term ‘excess
20 contribution’ means any contribution (other
21 than a rollover contribution described in para-
22 graph (5) or section 220(f)(5)) which is neither
23 excludable from gross income under section
24 106(d) nor deductible under this section.

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

3 “(A) IN GENERAL.—The tax imposed by
4 this chapter on the account beneficiary for any
5 taxable year in which there is a payment or dis-
6 tribution from a health savings account of such
7 beneficiary which is includible in gross income
8 under paragraph (2) shall be increased by 20
9 percent of the amount which is so includible.

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

15 “(C) EXCEPTION FOR DISTRIBUTIONS
16 AFTER MEDICARE ELIGIBILITY.—Subparagraph
17 (A) shall not apply to any payment or distribu-
18 tion after the date on which the account bene-
19 ficiary attains the age specified in section 1811
20 of the Social Security Act.

21 “(5) ROLLOVER CONTRIBUTION.—An amount is
22 described in this paragraph as a rollover contribu-
23 tion if it meets the requirements of subparagraphs
24 (A) and (B).

1 “(A) IN GENERAL.—Paragraph (2) shall
2 not apply to any amount paid or distributed
3 from a health savings account to the account
4 beneficiary to the extent the amount received is
5 paid into a health savings account for the ben-
6 efit of such beneficiary not later than the 60th
7 day after the day on which the beneficiary re-
8 ceives the payment or distribution.

9 “(B) LIMITATION.—This paragraph shall
10 not apply to any amount described in subpara-
11 graph (A) received by an individual from a
12 health savings account if, at any time during
13 the 1-year period ending on the day of such re-
14 ceipt, such individual received any other amount
15 described in subparagraph (A) from a health
16 savings account which was not includible in the
17 individual’s gross income because of the appli-
18 cation of this paragraph.

19 “(C) ROLLOVER FROM FSA, ARCHER MSA,
20 AND HRA.—An amount is described in this sub-
21 paragraph for a calendar year as a rollover con-
22 tribution if the amount is the remaining balance
23 in a health flexible spending account, Archer
24 MSA, or health reimbursement arrangement
25 that is contributed to the health savings ac-

1 count for a taxable year ending on or before
2 one year after the date of the enactment of this
3 subparagraph.

4 “(6) COORDINATION WITH MEDICAL EXPENSE
5 DEDUCTION.—For purposes of determining the
6 amount of the deduction under section 213, any pay-
7 ment or distribution out of a health savings account
8 for qualified medical expenses shall not be treated as
9 an expense paid for medical care.

10 “(7) TRANSFER OF ACCOUNT INCIDENT TO DI-
11 VORCE.—The transfer of an individual’s interest in
12 a health savings account to an individual’s spouse or
13 former spouse under a divorce or separation instru-
14 ment described in clause (i) of section 121(d)(3)(C)
15 shall not be considered a taxable transfer made by
16 such individual notwithstanding any other provision
17 of this subtitle, and such interest shall, after such
18 transfer, be treated as a health savings account with
19 respect to which such spouse is the account bene-
20 ficiary.

21 “(8) TREATMENT AFTER DEATH OF ACCOUNT
22 BENEFICIARY.—

23 “(A) TREATMENT IF DESIGNATED BENE-
24 FICIARY IS SPOUSE.—If the account bene-
25 ficiary’s surviving spouse acquires such bene-

1 beneficiary's interest in a health savings account by
2 reason of being the designated beneficiary of
3 such account at the death of the account bene-
4 ficiary, such health savings account shall be
5 treated as if the spouse were the account bene-
6 ficiary.

7 “(B) OTHER CASES.—

8 “(i) IN GENERAL.—If, by reason of
9 the death of the account beneficiary, any
10 person acquires the account beneficiary's
11 interest in a health savings account in a
12 case to which subparagraph (A) does not
13 apply—

14 “(I) such account shall cease to
15 be a health savings account as of the
16 date of death, and

17 “(II) an amount equal to the fair
18 market value of the assets in such ac-
19 count on such date shall be includible
20 if such person is not the estate of
21 such beneficiary, in such person's
22 gross income for the taxable year
23 which includes such date, or if such
24 person is the estate of such bene-
25 ficiary, in such beneficiary's gross in-

1 come for the last taxable year of such
2 beneficiary.

3 “(ii) SPECIAL RULES.—

4 “ (I) REDUCTION OF INCLUSION
5 FOR PREDEATH EXPENSES.—The
6 amount includible in gross income
7 under clause (i) by any person (other
8 than the estate) shall be reduced by
9 the amount of qualified medical ex-
10 penses which were incurred by the de-
11 cedent before the date of the dece-
12 dent’s death and paid by such person
13 within 1 year after such date.

14 “(II) DEDUCTION FOR ESTATE
15 TAXES.—An appropriate deduction
16 shall be allowed under section 691(c)
17 to any person (other than the dece-
18 dent or the decedent’s spouse) with
19 respect to amounts included in gross
20 income under clause (i) by such per-
21 son.

22 “(g) COST-OF-LIVING ADJUSTMENT.—

23 “(1) IN GENERAL.—In the case of any taxable
24 year beginning after December 31, 2023, each dollar

1 amount in paragraphs (2) and (3) of subsection (c)
2 shall be increased by an amount equal to—

3 “(A) such dollar amount, multiplied by

4 “(B) the cost-of-living adjustment deter-
5 mined under section 1(f)(3) for the calendar
6 year in which such taxable year begins deter-
7 mined by substituting ‘2022’ for ‘2016’ in sub-
8 paragraph (A)(ii) thereof.

9 “(2) ROUNDING.—If any increase under para-
10 graph (1) is not a multiple of \$50, such increase
11 shall be rounded to the nearest multiple of \$50.

12 “(h) REPORTS.—The Secretary may require—

13 “(1) the trustee of a health savings account to
14 make such reports regarding such account to the
15 Secretary and to the account beneficiary with re-
16 spect to contributions, distributions, the return of
17 excess contributions, and such other matters as the
18 Secretary determines appropriate, and

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

24 (b) EMPLOYER CONTRIBUTIONS TO HEALTH SAV-
25 INGS ACCOUNTS.—

1 (1) IN GENERAL.—Section 106(d) is amended
2 to read as follows:

3 “(d) CONTRIBUTIONS TO HEALTH SAVINGS AC-
4 COUNTS.—

5 “(1) IN GENERAL.—In the case of an employee
6 who is an eligible individual, amounts contributed by
7 such employee’s employer to any health savings ac-
8 count of such employee shall be treated as employer-
9 provided coverage for medical expenses under an ac-
10 cident or health plan to the extent—

11 “(A) such amounts do not exceed twice the
12 limitation in effect under section 223(b)(2) (de-
13 termined without regard to this subsection)
14 which is applicable to such employee for such
15 taxable year,

16 “(B) such amounts are contributed to an
17 account which is integrated with an integration
18 eligible health plan,

19 “(C) such employer does not offer such
20 employee coverage under any other accident or
21 health plan,

22 “(D) such employer offers such amounts
23 only to members of a qualified class of employ-
24 ees and offers such amounts to all members of
25 any such qualified class,

1 “(E) such employer offers employees an
2 opportunity to elect not to receive such amounts
3 at least once per year and upon termination
4 from employment, and

5 “(F) such employee is not covered under
6 any health insurance offered by an employer of
7 such employee’s spouse.

8 “(2) INTEGRATION ELIGIBLE HEALTH PLAN.—
9 For purposes of this subsection, the term ‘integra-
10 tion eligible health plan’ means—

11 “(A) any bronze, silver, or gold plan of-
12 fered through an Exchange established under
13 the Patient Protection and Affordable Care Act,

14 “(B) entitlement to benefits under part A
15 of title XVIII of the Social Security Act and en-
16 rollment under part B of such title, including
17 enrollment under a Medicare Advantage plan
18 under part C of such title,

19 “(C) in the case of any individual who has
20 not attained age 30 or is determined by the
21 Secretary (after consultation with the Secretary
22 of Health and Human Services) to have a hard-
23 ship, coverage under a catastrophic plan, and

1 “(D) in the case of any student, coverage
2 under a health plan which is conditioned on
3 maintaining status as being such a student.

4 “(3) INTEGRATION OF PLANS AND AC-
5 COUNTS.—For purposes of this subsection, an ac-
6 count shall be treated as integrated with an integra-
7 tion eligible health plan (and such plan shall be
8 treated as integrated with such account) for any
9 month if—

10 “(A) the employee is the account bene-
11 ficiary of such account and such employee is
12 covered under an integration eligible health
13 plan for such month,

14 “(B) the employer verifies that the em-
15 ployee is so covered by requiring the submission
16 of documentation to such employer, and

17 “(C) the employer makes contributions to
18 such account for such month which are not less
19 than the excess (if any) of—

20 “(i) the adjusted monthly premiums
21 for the applicable second lowest cost silver
22 plan with respect to the taxpayer, over

23 “(ii) $\frac{1}{12}$ of 9.5 percent of the tax-
24 payer’s household income (within the
25 meaning of section 36B).

1 “(4) QUALIFIED CLASS.—For purposes of this
2 subsection—

3 “(A) IN GENERAL.—The term ‘qualified
4 class’ means only the following: All employees;
5 Full-time employees; Part-time employees; Sea-
6 sonal employees; Employees covered under a
7 collective bargaining agreement; Employees in a
8 waiting period; Foreign employees who work
9 abroad; Employees working in the same geo-
10 graphic location (same insurance rating area,
11 State, or multi-State region); Salaried workers;
12 Non-Salaried workers (such as hourly workers);
13 Temporary employees of staffing firms.

14 “(B) RULES RELATED TO CLASS SIZE.—

15 “(i) MINIMUM CLASS SIZE.—A class
16 shall not be treated as a qualified class un-
17 less in consisting of at least the following
18 number of employees:

19 “(I) In the case of an employer
20 with fewer than 100 employees, the
21 lesser of 10 employees or all employ-
22 ees of the employer.

23 “(II) In the case of an employer
24 with at least 100 and not more than
25 200 employees, 10 percent of the

1 number of such employees (if not a
2 whole number, rounded down to the
3 next lowest whole number).

4 “(III) In the case of an employer
5 with more than 200 employees, 20
6 employees.

7 “(ii) COMBINATION OF CLASSES.—
8 Two or more qualified classes described in
9 subparagraph (A) may be combined if each
10 such class separately would not satisfy the
11 requirement of clause (i).

12 “(C) PERMITTED VARIATION WITHIN
13 QUALIFIED CLASSES.—An employer shall not
14 fail to meet the requirements of paragraph
15 (1)(D) solely because the amounts offered to
16 members of a qualified class vary on the basis
17 of—

18 “(i) number of dependents,

19 “(ii) age, if such variation based on
20 age does not exceed a ratio of 3:1, and

21 “(iii) chronic health condition, if such
22 variation based on chronic health condition
23 does not exceed a ratio of 1.2:1.

1 “(5) COORDINATION WITH ACA PROVISIONS.—

2 In the case of an integration eligible health plan
3 which is integrated with a health savings account—

4 “(A) such plan shall be treated as an eligi-
5 ble employer-sponsored plan described in sec-
6 tion 5000A(f)(1)(B),

7 “(B) if an individual receives contributions
8 to such account which are excludible from the
9 gross income of such individual under this sec-
10 tion during any taxable year, no credit shall be
11 allowed under section 36B with respect to such
12 individual for such taxable year, and

13 “(C) for purposes of section
14 36B(e)(2)(C)(i)(II), the employee’s required
15 contribution with respect to such plan shall be
16 treated as being equal to the excess (if any)
17 of—

18 “(i) the adjusted monthly premiums
19 for the applicable second lowest cost silver
20 plan with respect to the taxpayer, over

21 “(ii) the contributions made the em-
22 ployer to such health savings account
23 which are excludible from the gross income
24 of the employee under this section.

1 “(6) NO CONSTRUCTIVE RECEIPT.—No amount
2 shall be included in the gross income of any em-
3 ployee solely because the employee may choose be-
4 tween the contributions referred to in paragraph (1)
5 and employer contributions to another health plan of
6 the employer.

7 “(7) SPECIAL RULE FOR DEDUCTION OF EM-
8 PLOYER CONTRIBUTIONS.—Any employer contribu-
9 tion to a health savings account, if otherwise allow-
10 able as a deduction under this chapter, shall be al-
11 lowed only for the taxable year in which paid.

12 “(8) EMPLOYER HEALTH SAVINGS ACCOUNT
13 CONTRIBUTIONS REQUIRED TO BE SHOWN ON RE-
14 TURN.—Every individual required to file a return
15 under section 6012 for the taxable year shall include
16 on such return the aggregate amount contributed by
17 employers to the health savings accounts of such in-
18 dividual or such individual’s spouse for such taxable
19 year.

20 “(9) HEALTH SAVINGS ACCOUNT CONTRIBU-
21 TIONS NOT PART OF COBRA COVERAGE.—Paragraph
22 (1) shall not apply for purposes of section 4980B.

23 “(10) DEFINITIONS.—Terms used in this sub-
24 section which are also used in section 223 shall have

1 the same respective meanings as when used in such
2 section.

3 “(11) REGULATIONS.—The Secretaries of
4 Treasury, Labor, and Health and Human Services
5 shall each issue such regulations or other guidance
6 as may be necessary or appropriate to carry out the
7 purposes of this subsection, including regulations or
8 other guidance to—

9 “(A) prevent employers from offering plans
10 integrated with health savings accounts selec-
11 tively to sicker workers, and

12 “(B) establish a safe harbor that helps em-
13 ployers determine whether contributions to
14 health savings accounts with respect to which
15 there is an integrated health plan comply with
16 affordability requirements under the Patient
17 Protection and Affordable Care Act and the
18 amendments made by such Act.

19 “(12) CROSS REFERENCE.—For penalty on fail-
20 ure by employer to make comparable contributions
21 to the health savings accounts of comparable em-
22 ployees, see section 4980G.”.

23 (2) NONAPPLICATION OF ERISA.—Contributions
24 by an employer to a health savings account (as de-
25 fined in section 223 of the Internal Revenue Code of

1 1986), and an integration eligible health plan which
2 is integrated with such account (within the meaning
3 of such section), shall not be treated as a plan for
4 purposes of the Employee Retirement Income Secu-
5 rity Act of 1974 if—

6 (A) receipt of such contributions by the
7 employee is voluntary,

8 (B) the employer does not select or en-
9 dorse the integration eligible health plan which
10 is integrated with such account,

11 (C) no premiums, other than premiums for
12 the integration eligible health plan which is in-
13 tegrated with such account, are paid from the
14 account,

15 (D) the employer receives no consideration
16 (money or other benefit) in connection with the
17 employee selecting or renewing a plan, and

18 (E) each participant is notified annually
19 that such contributions and such plan are not
20 subject to the requirements of such Act.

21 (c) TERMINATION OF CERTAIN OTHER HEALTH
22 CARE RELATED TAX BENEFITS.—

23 (1) EXCLUSION LIMITED TO SELF-FUNDED
24 MAJOR MEDICAL PLAN OF EMPLOYERS.—Section
25 105(b) of such Code is amended by striking “paid,”

1 and inserting “paid under a self-funded major med-
2 ical plan of the employer”.

3 (2) EXCLUSION NOT APPLICABLE TO HEALTH
4 REIMBURSEMENT ARRANGEMENTS.—Section 105(h)
5 of such Code is amended to read as follows:

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

9 (3) REPEAL OF EXCLUSIONS FROM INCOME FOR
10 ARCHER MSAS AND FSAS.—Section 106 of such Code
11 is amended by striking subsections (b), (e), and (g).

12 (4) TERMINATION OF DEDUCTION FOR CON-
13 TRIBUTIONS TO ARCHER MSAS.—Section 220(a) of
14 such Code is amended by adding at the end the fol-
15 lowing: “No amount shall be allowed as a deduction
16 under the preceding sentence for any taxable year
17 beginning after one year after the date of the enact-
18 ment of this sentence.”.

19 (d) BANKRUPTCY PROTECTIONS.—Section 522 of
20 title 11, United States Code, is amended by adding at the
21 end the following new subsection:

22 “(r) For purposes of this section, any health savings
23 account (as described in section 223 of the Internal Rev-
24 enue Code of 1986) shall be treated in the same manner

1 as an individual retirement account described in section
2 408 of such Code.”.

3 (e) ROLLOVER OF FSA, ARCHER MSA, HRA TO
4 HEALTH SAVINGS ACCOUNT.—Notwithstanding any other
5 provision of law, if the remaining balance in a health flexi-
6 ble spending arrangement, Archer MSA, or health reim-
7 bursement arrangement is transferred to a health savings
8 account before the end of any taxable year ending on or
9 before one year after the date of the enactment of this
10 Act, such transfer shall be treated as a rollover to the
11 health savings account under section 223(f)(5) of the In-
12 ternal Revenue Code of 1986 and the distribution from
13 the health flexible spending arrangement, Archer MSA, or
14 health reimbursement arrangement shall not be includible
15 in gross income.

16 (f) EFFECTIVE DATES.—

17 (1) IN GENERAL.—The amendments made by
18 subsections (a) and (b) shall apply to taxable years
19 beginning after the date of the enactment of this
20 Act.

21 (2) TERMINATION OF CERTAIN OTHER HEALTH
22 CARE RELATED TAX BENEFITS.—The amendments
23 made by subsection (c) shall apply to taxable years
24 beginning after the date which is 1 year after the
25 date of the enactment of this Act.

1 (3) BANKRUPTCY PROTECTIONS.—The amend-
2 ment made by subsection (d) shall apply to cases
3 commencing under title 11, United States Code,
4 after the date of the enactment of this Act.

5 **SEC. 102. UNUSED PREMIUM TAX CREDITS MAY BE DEPOS-**
6 **ITED IN HEALTH SAVINGS ACCOUNTS.**

7 (a) IN GENERAL.—Section 36B is amended by redес-
8 ignating subsection (h) as subsection (i) and by inserting
9 after subsection (g) the following new subsection:

10 “(h) EXCESS CREDIT MAY BE DEPOSITED INTO A
11 HEALTH SAVINGS ACCOUNT.—

12 “(1) IN GENERAL.—If the amount described in
13 subparagraph (B) of subsection (b)(2) exceeds the
14 amount described in subparagraph (A) of such sub-
15 section with respect to any coverage month and an
16 election under paragraph (2) is in effect with respect
17 to the applicable taxpayer, the Secretary shall de-
18 posit such excess into a health savings account of
19 such taxpayer.

20 “(2) ELECTION TO DEPOSIT EXCESS CREDIT
21 INTO A HEALTH SAVINGS ACCOUNT.—A taxpayer
22 may elect (at such time and in such manner as the
23 Secretary may provide) to have the Secretary deposit
24 the excess described in paragraph (1) into a health
25 savings account of the taxpayer. Any such election

1 shall only be treated as being in effect if the tax-
2 payer provides the Secretary with such information
3 as the Secretary may require to allow the Secretary
4 to make such deposit.

5 “(3) COORDINATION WITH HEALTH SAVINGS
6 ACCOUNT RULES.—Any amount deposited in a
7 health savings account by the Secretary under this
8 subsection shall—

9 “(A) be includible in the gross income of
10 the applicable taxpayer, and

11 “(B) be taken into account as an amount
12 paid to such account for purposes of this sec-
13 tion.

14 “(4) TREATMENT OF DEPOSITS.—For purposes
15 of section 1324 of title 31, United States Code, any
16 deposit made under this subsection shall be treated
17 as a credit allowed under this section.”.

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

21 **SEC. 103. HEALTH REIMBURSEMENT ARRANGEMENTS AND**
22 **OTHER ACCOUNT-BASED GROUP HEALTH**
23 **PLANS.**

24 The rule published by the Internal Revenue Service,
25 the Employee Benefits Security Administration, and the

1 Health and Human Services Department relating to
2 “Health Reimbursement Arrangements and Other Ac-
3 count-Based Group Health Plans” (June 20, 2019) shall
4 have the force and effect of law. Health Reimbursement
5 Arrangements as described in this rule are subject to all
6 sections in this title.

7 **SEC. 104. COST-SHARING REDUCTION PAYMENTS AS ELIGI-**
8 **BLE CONTRIBUTIONS.**

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

13 “(f) ALTERNATIVE WAIVER FOR STATE INNOVA-
14 TION.—

15 “(1) IN GENERAL.—Notwithstanding any pre-
16 ceding provision of this section, a State may apply
17 to the Secretary for the waiver of any requirement
18 of subsection (a)(2) with respect to health insurance
19 coverage within that State for plan years beginning
20 on or after January 1, 2023, if instead of complying
21 with section 1402 the State provides for the dis-
22 tribution of funding received under paragraph (2) to
23 health savings accounts of qualifying individuals
24 with respect to such State. Such application shall be
25 filed at such time and in such manner as the Sec-

1 retary may require, and shall include such informa-
2 tion as the Secretary may require (including a 10-
3 year budget plan for such plan that is budget neu-
4 tral for the Federal Government).

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

16 “(A) had the State not received such waiv-
17 er;

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

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

24 “(i) the percentages specified in sub-
25 clauses (I), (II), and (III) of section

1 1402(c)(1)(B) were references to 84 per-
2 cent, 77 percent, and 63 percent, respec-
3 tively; and

4 “(ii) the references in subparagraphs
5 (A), (B), and (C) of section 1402(c)(2) to
6 94 percent, 87 percent, and 73 percent, re-
7 spectively, were references to 84 percent,
8 77 percent, and 63 percent, respectively;
9 and

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

13 “(i) the percentages specified in sub-
14 clauses (I), (II), and (III) of section
15 1402(c)(1)(B) were references to 74 per-
16 cent, 67 percent, and 53 percent, respec-
17 tively; and

18 “(ii) the references in subparagraphs
19 (A), (B), and (C) of section 1402(c)(2) to
20 94 percent, 87 percent, and 73 percent, re-
21 spectively, were references to 74 percent,
22 67 percent, and 53 percent, respectively.

23 The amount transferred pursuant to the previous
24 sentence shall be determined annually by the Sec-
25 retary, taking into consideration the experience of

1 other States with respect to participation in an Ex-
2 change and reductions provided under such provi-
3 sions to residents of the other States, and shall be
4 paid to the State for purposes of implementing such
5 waiver.

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

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

23 “(5) DEFINITIONS.—For purposes of this sub-
24 section:

1 “(A) HEALTH SAVINGS ACCOUNT.—The
2 term ‘health savings account’ has the meaning
3 given such term in section 223 of the Internal
4 Revenue Code of 1986.

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

8 “(i) who is enrolled in a health sav-
9 ings account;

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

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

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

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

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

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

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

11 “(g) FUNDING.—

12 “(1) APPROPRIATIONS.—Out of any funds in
13 the Treasury not otherwise appropriated, there is
14 appropriated such sums as may be necessary to,
15 subject to paragraph (2), provide health benefits
16 coverage through payment to issuers (under this sec-
17 tion or through advance payment by the Secretary
18 of the Treasury under section 1412(c)(3)) of the
19 amounts computed under this section for each of
20 plan years 2023 through 2027.

21 “(2) ADJUSTMENTS.—Notwithstanding any
22 other provision of law, payments and other actions
23 for adjustments to obligations incurred prior to De-
24 cember 31, 2023, may be made through December
25 31, 2023.

1 “(3) LIMITATION.—Amounts appropriated
2 under paragraph (1) for each of plan years 2023
3 through 2027 are subject to the requirements and
4 limitations under sections 506 and 507 of division H
5 of Public Law 115–31 in the same manner and to
6 the same extent as if such amounts for each such
7 year were appropriated under such division.”.

8 **SEC. 105. DIRECT PRIMARY CARE.**

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

12 “(D) TREATMENT OF DIRECT PRIMARY
13 CARE SERVICE ARRANGEMENTS.—

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

18 “(ii) DIRECT PRIMARY CARE SERVICE
19 ARRANGEMENT.—For purposes of this
20 paragraph—

21 “(I) IN GENERAL.—The term ‘di-
22 rect primary care service arrange-
23 ment’ means, with respect to any indi-
24 vidual, an arrangement under which
25 such individual is provided medical

1 care (as defined in section 213(d))
2 consisting solely of primary care serv-
3 ices provided by primary care practi-
4 tioners (as defined in section
5 1833(x)(2)(A) of the Social Security
6 Act, determined without regard to
7 clause (ii) thereof), if the sole com-
8 pensation for such care is a fixed peri-
9 odic fee.

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

23 “(iii) CERTAIN SERVICES SPECIFI-
24 CALLY EXCLUDED FROM TREATMENT AS
25 PRIMARY CARE SERVICES.—For purposes

1 of this paragraph, the term ‘primary care
2 services’ shall not include—

3 “(I) procedures that require the
4 use of general anesthesia, and

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

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

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

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

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

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

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

1 at the end of clause (ii) and inserting “, and”, and
2 by inserting after clause (ii) the following new
3 clause:

4 “(iii) in the case of the dollar amount
5 in subsection (c)(1)(D)(ii)(II) for taxable
6 years beginning in calendar years after
7 2020, calendar year 2019.”.

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

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

19 (e) EFFECTIVE DATE.—The amendments made by
20 this section shall apply to months beginning after Decem-
21 ber 31, 2022, in taxable years ending after such date.

1 **Subtitle B—Assistance to Health**
2 **Savings Accounts**

3 **SEC. 111. ONE-TIME APPLICATION OF SAVER'S CREDIT TO**
4 **CONTRIBUTIONS TO HEALTH SAVINGS AC-**
5 **COUNTS.**

6 (a) **IN GENERAL.**—In the case of an applicable tax-
7 able year, contributions to any health savings account of
8 the taxpayer during such taxable year shall be treated as
9 a qualified retirement savings contribution for purposes
10 of section 25B of the Internal Revenue Code of 1986.

11 (b) **APPLICABLE TAXABLE YEAR.**—For purposes of
12 this section, the term “applicable taxable year” means any
13 taxable year elected by the taxpayer (at such time and
14 in such manner as the Secretary of the Treasury may pro-
15 vide) which begins after during the 3-year period begin-
16 ning 1 year after the date of the enactment of this Act.
17 A taxpayer may not elect not more than 1 applicable tax-
18 able year under this subsection.

19 **SEC. 112. GRANTS FOR HEALTH SAVINGS ACCOUNT ASSIST-**
20 **ANCE AND OUTREACH.**

21 (a) **IN GENERAL.**—The Administrator shall establish
22 a grant program to provide assistance to eligible entities
23 to carry out the activities described in subsection (c).

24 (b) **APPLICATION.**—An eligible entity shall submit an
25 application to the Administrator in such time and in such

1 manner as the Administrator may require, providing that
2 such application requires a demonstration of the existence
3 of a relationship with, or the ability to establish a relation-
4 ship with, an employer, employee, self-employed indi-
5 vidual, or consumer eligible to enroll in a health savings
6 account.

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

9 (1) distribute fair and impartial information to
10 consumers about health savings accounts, including
11 the availability of such accounts and how such ac-
12 counts may be utilized;

13 (2) conduct activities to raise public awareness
14 of health savings accounts;

15 (3) facilitate enrollment in health savings ac-
16 counts; and

17 (4) refer individuals enrolled in a health savings
18 account to the appropriate official, organization, or
19 State agency for the purpose of addressing a com-
20 plaint, grievance, or other question with respect to
21 such health savings account.

22 (d) AMOUNT.—The Administrator may distribute up
23 to \$5,000,000 annually to be divided among grant recipi-
24 ents under this section.

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

6 (f) DEFINITIONS.—In this section:

7 (1) ADMINISTRATOR.—The term “Adminis-
8 trator” means the Administrator of the Centers for
9 Medicare & Medicaid Services.

10 (2) CONSUMER.—The term “consumer” means
11 an individual enrolled in, or seeking to enroll in, a
12 health savings account.

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

15 (A) A State.

16 (B) Trade.

17 (C) Industry.

18 (D) Professional associations.

19 (E) Commercial fishing industry organiza-
20 tions.

21 (F) Ranching and farming organizations.

22 (G) Community and consumer-focused
23 nonprofit groups.

24 (H) Chambers of commerce.

25 (I) Unions.

1 (J) Small business development centers (as
2 defined in section 21 of the Small Business Act
3 (15 U.S.C. 648)).

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

6 (4) HEALTH SAVINGS ACCOUNT.—The term
7 “health savings account” has the meaning given
8 such term in section 223 of the Internal Revenue
9 Code of 1986.

10 (5) STATE.—The term “State” means each of
11 the several States, the District of Columbia, each
12 territory and possession of the United States, and
13 each federally recognized Indian Tribe.

14 **SEC. 113. NEW CORPORATIONS REQUIRED TO USE HEALTH**
15 **SAVINGS ACCOUNTS.**

16 Notwithstanding any other provision of law, a cor-
17 poration incorporated after December 31, 2022, may not
18 receive tax benefits for offering employees health insur-
19 ance. The previous sentence shall not apply to health sav-
20 ings account contributions offered by such a corporation.

21 **SEC. 114. FEDERAL EMPLOYEE HEALTH BENEFITS AND**
22 **HEALTH SAVINGS ACCOUNTS.**

23 (a) IN GENERAL.—Section 1312(d)(3)(D) of the Pa-
24 tient Protection and Affordable Care Act (42 U.S.C.
25 18032(d)(3)(D)) is amended—

1 (1) in the subparagraph heading, by striking
2 “MEMBERS OF CONGRESS” and inserting “PRESI-
3 DENT, VICE PRESIDENT, MEMBERS OF CONGRESS,
4 AND FEDERAL EMPLOYEES”;

5 (2) in clause (i), in the matter preceding sub-
6 clause (I)—

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

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

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

17 “(II) FEDERAL EMPLOYEE.—The
18 term ‘Federal employee’ means—

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

22 “(bb) includes an individual
23 to whom subsection (c) or (f) of
24 such section 2105 pertains

1 (whether or not such individual
2 satisfies item (aa)).”.

3 (b) CONVERSION TO HEALTH SAVINGS ACCOUNTS.—
4 Each plan offered under chapter 89 of title 5, United
5 States Code, shall be converted into a health savings ac-
6 count deposit and funded at the level of the second-least
7 expensive silver plan available through the Exchange
8 where the applicable individual resides.

9 **TITLE II—IMPROVING PRIVATE**
10 **HEALTH INSURANCE**
11 **Subtitle A—Maintaining Protec-**
12 **tions for Patients With Pre-**
13 **existing Conditions**

14 **SEC. 201. GUARANTEED AVAILABILITY OF COVERAGE; PRO-**
15 **HIBITING DISCRIMINATION.**

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

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

21 **“(a) GUARANTEED ISSUANCE OF COVERAGE IN THE**
22 **INDIVIDUAL AND GROUP MARKET.—**Subject to sub-
23 sections (b) through (d), each health insurance issuer that
24 offers health insurance coverage in the individual or group

1 market in a State must accept every employer and indi-
2 vidual in the State that applies for such coverage.

3 “(b) ENROLLMENT.—

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

8 “(2) ESTABLISHMENT.—A health insurance
9 issuer described in subsection (a) shall, in accord-
10 ance with the regulations promulgated under para-
11 graph (3), establish special enrollment periods for
12 qualifying events (under section 603 of the Em-
13 ployee Retirement Income Security Act of 1974).

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

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

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

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

1 “(B) within the service area of such plan,
2 deny such coverage to such employers and indi-
3 viduals if the issuer has demonstrated, if re-
4 quired, to the applicable State authority that—

5 “(i) it will not have the capacity to de-
6 liver services adequately to enrollees of any
7 additional groups or any additional individ-
8 uals because of its obligations to existing
9 group contract holders and enrollees; and

10 “(ii) it is applying this paragraph uni-
11 formly to all employers and individuals
12 without regard to the claims experience of
13 those individuals, employers and their em-
14 ployees (and their dependents), or any
15 health status-related factor relating to
16 such individuals, employees, and depend-
17 ents.

18 “(2) 180-DAY SUSPENSION UPON DENIAL OF
19 COVERAGE.—An issuer, upon denying health insur-
20 ance coverage in any service area in accordance with
21 paragraph (1)(B), may not offer coverage in the
22 group or individual market within such service area
23 for a period of 180 days after the date such cov-
24 erage is denied.

1 “(d) APPLICATION OF FINANCIAL CAPACITY LIM-
2 ITS.—

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

7 “(A) it does not have the financial reserves
8 necessary to underwrite additional coverage;
9 and

10 “(B) it is applying this paragraph uni-
11 formly to all employers and individuals in the
12 group or individual market in the State con-
13 sistent with applicable State law and without
14 regard to the claims experience of those individ-
15 uals, employers and their employees (and their
16 dependents) or any health status-related factor
17 relating to such individuals, employees, and de-
18 pendents.

19 “(2) 180-DAY SUSPENSION UPON DENIAL OF
20 COVERAGES.—A health insurance issuer upon denying
21 health insurance coverage in connection with group
22 health plans in accordance with paragraph (1) in a
23 State may not offer coverage in connection with
24 group health plans in the group or individual market
25 in the State for a period of 180 days after the date

1 such coverage is denied or until the issuer has dem-
2 onstrated to the applicable State authority, if re-
3 quired under applicable State law, that the issuer
4 has sufficient financial reserves to underwrite addi-
5 tional coverage, whichever is later. An applicable
6 State authority may provide for the application of
7 this subsection on a service-area-specific basis.

8 “(e) DEFINITIONS.—In this section and in sections
9 197 through 199A:

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

12 “(2) The terms ‘genetic information’, ‘genetic
13 test’, ‘group health plan’, ‘group market’, ‘health in-
14 surance coverage’, ‘health insurance issuer’, ‘group
15 health insurance coverage’, ‘individual health insur-
16 ance coverage’, ‘individual market’, and ‘under-
17 writing purpose’ have the meanings given such terms
18 in section 2791 of the Public Health Service Act.

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

20 “(a) PROHIBITING DISCRIMINATORY PREMIUM
21 RATES.—

22 “(1) IN GENERAL.—With respect to the pre-
23 mium rate charged by a health insurance issuer for
24 health insurance coverage offered in the individual
25 or small group market—

1 “(A) such rate shall vary with respect to
2 the particular plan or coverage involved only
3 by—

4 “(i) whether such plan or coverage
5 covers an individual or family;

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

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

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

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

18 “(2) RATING AREA.—

19 “(A) IN GENERAL.—Each State shall es-
20 tablish 1 or more rating areas within that State
21 for purposes of applying the requirements of
22 this title.

23 “(B) SECRETARIAL REVIEW.—The Sec-
24 retary shall review the rating areas established
25 by each State under subparagraph (A) to en-

1 sure the adequacy of such areas for purposes of
2 carrying out the requirements of this title. If
3 the Secretary determines a State’s rating areas
4 are not adequate, or that a State does not es-
5 tablish such areas, the Secretary may establish
6 rating areas for that State.

7 “(3) PERMISSIBLE AGE BANDS.—The Sec-
8 retary, in consultation with the National Association
9 of Insurance Commissioners, shall define the permis-
10 sible age bands for rating purposes under paragraph
11 (1)(A)(iii).

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

20 **“SEC. 198. PROHIBITING DISCRIMINATION AGAINST INDI-**
21 **VIDUAL PARTICIPANTS AND BENEFICIARIES**
22 **BASED ON HEALTH STATUS.**

23 “(a) IN GENERAL.—A group health plan and a health
24 insurance issuer offering group or individual health insur-
25 ance coverage may not establish rules for eligibility (in-

1 cluding continued eligibility) of any individual to enroll
2 under the terms of the plan or coverage based on any of
3 the following health status-related factors in relation to
4 the individual or a dependent of the individual:

5 “(1) Health status.

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

8 “(3) Claims experience.

9 “(4) Receipt of health care.

10 “(5) Medical history.

11 “(6) Genetic information.

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

14 “(8) Disability.

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

17 “(b) IN PREMIUM CONTRIBUTIONS.—

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

1 related factor in relation to the individual or to an
2 individual enrolled under the plan as a dependent of
3 the individual.

4 “(2) CONSTRUCTION.—Nothing in paragraph
5 (1) shall be construed—

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

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

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

20 “(A) IN GENERAL.—For purposes of this
21 section, a group health plan, and health insur-
22 ance issuer offering group health insurance cov-
23 erage in connection with a group health plan,
24 may not adjust premium or contribution

1 amounts for the group covered under such plan
2 on the basis of genetic information.

3 “(B) RULE OF CONSTRUCTION.—Nothing
4 in subparagraph (A) or in paragraphs (1) and
5 (2) of subsection (d) shall be construed to limit
6 the ability of a health insurance issuer offering
7 group or individual health insurance coverage to
8 increase the premium for an employer based on
9 the manifestation of a disease or disorder of an
10 individual who is enrolled in the plan. In such
11 case, the manifestation of a disease or disorder
12 in one individual cannot also be used as genetic
13 information about other group members and to
14 further increase the premium for the employer.

15 “(c) GENETIC TESTING.—

16 “(1) LIMITATION ON REQUESTING OR REQUIR-
17 ING GENETIC TESTING.—A group health plan, and a
18 health insurance issuer offering health insurance
19 coverage in connection with a group health plan,
20 shall not request or require an individual or a family
21 member of such individual to undergo a genetic test.

22 “(2) RULE OF CONSTRUCTION.—Paragraph (1)
23 shall not be construed to limit the authority of a
24 health care professional who is providing health care

1 services to an individual to request that such indi-
2 vidual undergo a genetic test.

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

5 “(A) IN GENERAL.—Nothing in paragraph
6 (1) shall be construed to preclude a group
7 health plan, or a health insurance issuer offer-
8 ing health insurance coverage in connection
9 with a group health plan, from obtaining and
10 using the results of a genetic test in making a
11 determination regarding payment (as such term
12 is defined for the purposes of applying the regu-
13 lations promulgated by the Secretary under
14 part C of title XI of the Social Security Act and
15 section 264 of this Act, as may be revised from
16 time to time) consistent with subsection (a).

17 “(B) LIMITATION.—For purposes of sub-
18 paragraph (A), a group health plan, or a health
19 insurance issuer offering health insurance cov-
20 erage in connection with a group health plan,
21 may request only the minimum amount of in-
22 formation necessary to accomplish the intended
23 purpose.

24 “(4) RESEARCH EXCEPTION.—Notwithstanding
25 paragraph (1), a group health plan, or a health in-

1 surance issuer offering health insurance coverage in
2 connection with a group health plan, may request,
3 but not require, that a participant or beneficiary un-
4 dergo a genetic test if each of the following condi-
5 tions is met:

6 “(A) The request is made pursuant to re-
7 search that complies with part 46 of title 45,
8 Code of Federal Regulations, or equivalent Fed-
9 eral regulations, and any applicable State or
10 local law or regulations for the protection of
11 human subjects in research.

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

16 “(i) compliance with the request is
17 voluntary; and

18 “(ii) noncompliance will have no effect
19 on enrollment status or premium or con-
20 tribution amounts.

21 “(C) No genetic information collected or
22 acquired under this paragraph shall be used for
23 underwriting purposes.

24 “(D) The plan or issuer notifies the Sec-
25 retary in writing that the plan or issuer is con-

1 ducting activities pursuant to the exception pro-
2 vided for under this paragraph, including a de-
3 scription of the activities conducted.

4 “(E) The plan or issuer complies with such
5 other conditions as the Secretary may by regu-
6 lation require for activities conducted under this
7 paragraph.

8 “(d) PROHIBITION ON COLLECTION OF GENETIC IN-
9 FORMATION.—

10 “(1) IN GENERAL.—A group health plan, and a
11 health insurance issuer offering health insurance
12 coverage in connection with a group health plan,
13 shall not request, require, or purchase genetic infor-
14 mation for underwriting purposes.

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

24 “(3) INCIDENTAL COLLECTION.—If a group
25 health plan, or a health insurance issuer offering

1 health insurance coverage in connection with a group
2 health plan, obtains genetic information incidental to
3 the requesting, requiring, or purchasing of other in-
4 formation concerning any individual, such request,
5 requirement, or purchase shall not be considered a
6 violation of paragraph (2) if such request, require-
7 ment, or purchase is not in violation of paragraph
8 (1).

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

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

17 “(2) with respect to an individual or family
18 member utilizing an assisted reproductive tech-
19 nology, include genetic information of any embryo le-
20 gally held by the individual or family member.

21 “(f) PROGRAMS OF HEALTH PROMOTION OR DIS-
22 EASE PREVENTION.—

23 “(1) GENERAL PROVISIONS.—

24 “(A) GENERAL RULE.—For purposes of
25 subsection (b)(2)(B), a program of health pro-

1 motion or disease prevention (referred to in this
2 subsection as a ‘wellness program’) shall be a
3 program offered by an employer that is de-
4 signed to promote health or prevent disease
5 that meets the applicable requirements of this
6 subsection.

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

18 “(C) CONDITIONS BASED ON HEALTH STA-
19 TUS FACTOR.—If any of the conditions for ob-
20 taining a premium discount or rebate or other
21 reward for participation in a wellness program
22 is based on an individual satisfying a standard
23 that is related to a health status factor, such
24 wellness program shall not violate this section if

1 the requirements of paragraph (3) are complied
2 with.

3 “(2) WELLNESS PROGRAMS NOT SUBJECT TO
4 REQUIREMENTS.—If none of the conditions for ob-
5 taining a premium discount or rebate or other re-
6 ward under a wellness program as described in para-
7 graph (1)(B) are based on an individual satisfying
8 a standard that is related to a health status factor
9 (or if such a wellness program does not provide such
10 a reward), the wellness program shall not violate
11 this section if participation in the program is made
12 available to all similarly situated individuals. The
13 following programs shall not have to comply with the
14 requirements of paragraph (3) if participation in the
15 program is made available to all similarly situated
16 individuals:

17 “(A) A program that reimburses all or
18 part of the cost for memberships in a fitness
19 center.

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

23 “(C) A program that encourages preven-
24 tive care related to a health condition through
25 the waiver of the copayment or deductible re-

1 requirement under group health plan for the costs
2 of certain items or services related to a health
3 condition (such as prenatal care or well-baby
4 visits).

5 “(D) A program that reimburses individ-
6 uals for the costs of smoking cessation pro-
7 grams without regard to whether the individual
8 quits smoking.

9 “(E) A program that provides a reward to
10 individuals for attending a periodic health edu-
11 cation seminar.

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

20 “(A) The reward for the wellness program,
21 together with the reward for other wellness pro-
22 grams with respect to the plan that requires
23 satisfaction of a standard related to a health
24 status factor, shall not exceed 30 percent of the
25 cost of employee-only coverage under the plan.

1 If, in addition to employees or individuals, any
2 class of dependents (such as spouses or spouses
3 and dependent children) may participate fully
4 in the wellness program, such reward shall not
5 exceed 30 percent of the cost of the coverage in
6 which an employee or individual and any de-
7 pendents are enrolled. For purposes of this
8 paragraph, the cost of coverage shall be deter-
9 mined based on the total amount of employer
10 and employee contributions for the benefit
11 package under which the employee is (or the
12 employee and any dependents are) receiving
13 coverage. A reward may be in the form of a dis-
14 count or rebate of a premium or contribution,
15 a waiver of all or part of a cost-sharing mecha-
16 nism (such as deductibles, copayments, or coin-
17 surance), the absence of a surcharge, or the
18 value of a benefit that would otherwise not be
19 provided under the plan. The Secretaries of
20 Labor, Health and Human Services, and the
21 Treasury may increase the reward available
22 under this subparagraph to up to 50 percent of
23 the cost of coverage if the Secretaries determine
24 that such an increase is appropriate.

1 “(B) The wellness program shall be rea-
2 sonably designed to promote health or prevent
3 disease. A program complies with the preceding
4 sentence if the program has a reasonable
5 chance of improving the health of, or preventing
6 disease in, participating individuals and it is
7 not overly burdensome, is not a subterfuge for
8 discriminating based on a health status factor,
9 and is not highly suspect in the method chosen
10 to promote health or prevent disease.

11 “(C) The plan shall give individuals eligible
12 for the program the opportunity to qualify for
13 the reward under the program at least once
14 each year.

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

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

22 “(I) for a reasonable alternative
23 standard (or waiver of the otherwise
24 applicable standard) for obtaining the
25 reward for any individual for whom,

1 for that period, it is unreasonably dif-
2 ficult due to a medical condition to
3 satisfy the otherwise applicable stand-
4 ard; and

5 “(II) for a reasonable alternative
6 standard (or waiver of the otherwise
7 applicable standard) for obtaining the
8 reward for any individual for whom,
9 for that period, it is medically inadvis-
10 able to attempt to satisfy the other-
11 wise applicable standard.

12 “(ii) If reasonable under the cir-
13 cumstances, the plan or issuer may seek
14 verification, such as a statement from an
15 individual’s physician, that a health status
16 factor makes it unreasonably difficult or
17 medically inadvisable for the individual to
18 satisfy or attempt to satisfy the otherwise
19 applicable standard.

20 “(E) The plan or issuer involved shall dis-
21 close in all plan materials describing the terms
22 of the wellness program the availability of a
23 reasonable alternative standard (or the possi-
24 bility of waiver of the otherwise applicable
25 standard) required under subparagraph (D). If

1 plan materials disclose that such a program is
2 available, without describing its terms, the dis-
3 closure under this subparagraph shall not be re-
4 quired.

5 **“SEC. 199. PROHIBITION OF PREEXISTING CONDITION EX-**
6 **CLUSIONS OR OTHER DISCRIMINATION**
7 **BASED ON HEALTH STATUS.**

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

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

13 “(1) PREEXISTING CONDITION EXCLUSION.—

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

22 “(B) TREATMENT OF GENETIC INFORMA-
23 TION.—Genetic information shall not be treated
24 as a condition described in subsection (a)(1) in

1 the absence of a diagnosis of the condition re-
2 lated to such information.

3 “(2) ENROLLMENT DATE.—The term ‘enroll-
4 ment date’ means, with respect to an individual cov-
5 ered under a group health plan or health insurance
6 coverage, the date of enrollment of the individual in
7 the plan or coverage or, if earlier, the first day of
8 the waiting period for such enrollment.

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

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

15 “(B) a special enrollment period under
16 subsection (f).

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

24 “(c) RULES RELATING TO CREDITING PREVIOUS
25 COVERAGE.—

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

5 “(A) A group health plan.

6 “(B) Health insurance coverage.

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

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

12 “(E) Chapter 55 of title 10, United States
13 Code.

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

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

17 “(H) A health plan offered under chapter
18 89 of title 5, United States Code.

19 “(I) A public health plan (as defined in
20 regulations).

21 “(J) A health benefit plan under section
22 5(e) of the Peace Corps Act (22 U.S.C.
23 2504(e)).

1 Such term does not include coverage consisting sole-
2 ly of coverage of excepted benefits (as defined in sec-
3 tion 2791(c)).

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

6 “(A) IN GENERAL.—A period of creditable
7 coverage shall not be counted, with respect to
8 enrollment of an individual under a group or in-
9 dividual health plan, if, after such period and
10 before the enrollment date, there was a 63-day
11 period during all of which the individual was
12 not covered under any creditable coverage.

13 “(B) WAITING PERIOD NOT TREATED AS A
14 BREAK IN COVERAGE.—For purposes of sub-
15 paragraph (A) and subsection (d)(4), any pe-
16 riod that an individual is in a waiting period for
17 any coverage under a group or individual health
18 plan (or for group health insurance coverage) or
19 is in an affiliation period (as defined in sub-
20 section (g)(2)) shall not be taken into account
21 in determining the continuous period under
22 subparagraph (A).

23 “(C) TAA-ELIGIBLE INDIVIDUALS.—In the
24 case of plan years beginning before January 1,
25 2014—

1 “(i) TAA PRE-CERTIFICATION PERIOD
2 RULE.—In the case of a TAA-eligible indi-
3 vidual, the period beginning on the date
4 the individual has a TAA-related loss of
5 coverage and ending on the date that is 7
6 days after the date of the issuance by the
7 Secretary (or by any person or entity des-
8 ignated by the Secretary) of a qualified
9 health insurance costs credit eligibility cer-
10 tificate for such individual for purposes of
11 section 7527 of the Internal Revenue Code
12 of 1986 shall not be taken into account in
13 determining the continuous period under
14 subparagraph (A).

15 “(ii) DEFINITIONS.—The terms ‘TAA-
16 eligible individual’ and ‘TAA-related loss of
17 coverage’ have the meanings given such
18 terms in section 2205(b)(4).

19 “(3) METHOD OF CREDITING COVERAGE.—

20 “(A) STANDARD METHOD.—Except as oth-
21 erwise provided under subparagraph (B), for
22 purposes of applying subsection (a)(3), a group
23 health plan, and a health insurance issuer offer-
24 ing group or individual health insurance cov-
25 erage, shall count a period of creditable cov-

1 erage without regard to the specific benefits
2 covered during the period.

3 “(B) ELECTION OF ALTERNATIVE METH-
4 OD.—A group health plan, or a health insur-
5 ance issuer offering group or individual health
6 insurance, may elect to apply subsection (a)(3)
7 based on coverage of benefits within each of
8 several classes or categories of benefits specified
9 in regulations rather than as provided under
10 subparagraph (A). Such election shall be made
11 on a uniform basis for all participants and
12 beneficiaries. Under such election a group or in-
13 dividual health plan or issuer shall count a pe-
14 riod of creditable coverage with respect to any
15 class or category of benefits if any level of bene-
16 fits is covered within such class or category.

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

22 “(i) prominently state in any disclo-
23 sure statements concerning the plan, and
24 state to each enrollee at the time of enroll-

1 ment under the plan, that the plan has
2 made such election; and

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

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

9 “(i) shall prominently state in any dis-
10 closure statements concerning the cov-
11 erage, and to each employer at the time of
12 the offer or sale of the coverage, that the
13 issuer has made such election; and

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

16 “(4) ESTABLISHMENT OF PERIOD.—Periods of
17 creditable coverage with respect to an individual
18 shall be established through presentation of certifi-
19 cations described in subsection (e) or in such other
20 manner as may be specified in regulations.

21 “(d) EXCEPTIONS.—

22 “(1) EXCLUSION NOT APPLICABLE TO CERTAIN
23 NEWBORNS.—Subject to paragraph (4), a group
24 health plan, and a health insurance issuer offering
25 group or individual health insurance coverage, may

1 not impose any preexisting condition exclusion in the
2 case of an individual who, as of the last day of the
3 30-day period beginning with the date of birth, is
4 covered under creditable coverage.

5 “(2) EXCLUSION NOT APPLICABLE TO CERTAIN
6 ADOPTED CHILDREN.—Subject to paragraph (4), a
7 group health plan, and a health insurance issuer of-
8 fering group or individual health insurance coverage,
9 may not impose any preexisting condition exclusion
10 in the case of a child who is adopted or placed for
11 adoption before attaining 18 years of age and who,
12 as of the last day of the 30-day period beginning on
13 the date of the adoption or placement for adoption,
14 is covered under creditable coverage. The previous
15 sentence shall not apply to coverage before the date
16 of such adoption or placement for adoption.

17 “(3) EXCLUSION NOT APPLICABLE TO PREG-
18 NANCY.—A group health plan, and health insurance
19 issuer offering group or individual health insurance
20 coverage, may not impose any preexisting condition
21 exclusion relating to pregnancy as a preexisting con-
22 dition.

23 “(4) LOSS IF BREAK IN COVERAGE.—Para-
24 graphs (1) and (2) shall no longer apply to an indi-
25 vidual after the end of the first 63-day period during

1 all of which the individual was not covered under
2 any creditable coverage.

3 “(e) CERTIFICATIONS AND DISCLOSURE OF COV-
4 ERAGE.—

5 “(1) REQUIREMENT FOR CERTIFICATION OF
6 PERIOD OF CREDITABLE COVERAGE.—

7 “(A) IN GENERAL.—A group health plan,
8 and a health insurance issuer offering group or
9 individual health insurance coverage, shall pro-
10 vide the certification described in subparagraph
11 (B)—

12 “(i) at the time an individual ceases
13 to be covered under the plan or otherwise
14 becomes covered under a COBRA continu-
15 ation provision;

16 “(ii) in the case of an individual be-
17 coming covered under such a provision, at
18 the time the individual ceases to be covered
19 under such provision; and

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

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

5 “(B) CERTIFICATION.—The certification
6 described in this subparagraph is a written cer-
7 tification of—

8 “(i) the period of creditable coverage
9 of the individual under such plan and the
10 coverage (if any) under such COBRA con-
11 tinuation provision; and

12 “(ii) the waiting period (if any) (and
13 affiliation period, if applicable) imposed
14 with respect to the individual for any cov-
15 erage under such plan.

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

24 “(2) DISCLOSURE OF INFORMATION ON PRE-
25 VIOUS BENEFITS.—In the case of an election de-

1 scribed in subsection (c)(3)(B) by a group health
2 plan or health insurance issuer, if the plan or issuer
3 enrolls an individual for coverage under the plan and
4 the individual provides a certification of coverage of
5 the individual under paragraph (1)—

6 “(A) upon request of such plan or issuer,
7 the entity which issued the certification pro-
8 vided by the individual shall promptly disclose
9 to such requesting plan or issuer information
10 on coverage of classes and categories of health
11 benefits available under such entity’s plan or
12 coverage; and

13 “(B) such entity may charge the request-
14 ing plan or issuer for the reasonable cost of dis-
15 closing such information.

16 “(3) REGULATIONS.—The Secretary shall es-
17 tablish rules to prevent an entity’s failure to provide
18 information under paragraph (1) or (2) with respect
19 to previous coverage of an individual from adversely
20 affecting any subsequent coverage of the individual
21 under another group health plan or health insurance
22 coverage.

23 “(f) SPECIAL ENROLLMENT PERIODS.—

24 “(1) INDIVIDUALS LOSING OTHER COVERAGE.—

25 A group health plan, and a health insurance issuer

1 offering group health insurance coverage in connec-
2 tion with a group health plan, shall permit an em-
3 ployee who is eligible, but not enrolled, for coverage
4 under the terms of the plan (or a dependent of such
5 an employee if the dependent is eligible, but not en-
6 rolled, for coverage under such terms) to enroll for
7 coverage under the terms of the plan if each of the
8 following conditions is met:

9 “(A) The employee or dependent was cov-
10 ered under a group health plan or had health
11 insurance coverage at the time coverage was
12 previously offered to the employee or dependent.

13 “(B) The employee stated in writing at
14 such time that coverage under a group health
15 plan or health insurance coverage was the rea-
16 son for declining enrollment, but only if the
17 plan sponsor or issuer (if applicable) required
18 such a statement at such time and provided the
19 employee with notice of such requirement (and
20 the consequences of such requirement) at such
21 time.

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

1 “(i) was under a COBRA continu-
2 ation provision and the coverage under
3 such provision was exhausted; or

4 “(ii) was not under such a provision
5 and either the coverage was terminated as
6 a result of loss of eligibility for the cov-
7 erage (including as a result of legal separa-
8 tion, divorce, death, termination of employ-
9 ment, or reduction in the number of hours
10 of employment) or employer contributions
11 toward such coverage were terminated.

12 “(D) Under the terms of the plan, the em-
13 ployee requests such enrollment not later than
14 30 days after the date of exhaustion of coverage
15 described in subparagraph (C)(i) or termination
16 of coverage or employer contribution described
17 in subparagraph (C)(ii).

18 “(2) FOR DEPENDENT BENEFICIARIES.—

19 “(A) IN GENERAL.—If—

20 “(i) a group health plan makes cov-
21 erage available with respect to a dependent
22 of an individual;

23 “(ii) the individual is a participant
24 under the plan (or has met any waiting pe-
25 riod applicable to becoming a participant

1 under the plan and is eligible to be enrolled
2 under the plan but for a failure to enroll
3 during a previous enrollment period); and

4 “(iii) a person becomes such a de-
5 pendent of the individual through mar-
6 riage, birth, or adoption or placement for
7 adoption,

8 the group health plan shall provide for a de-
9 pendent special enrollment period described in
10 subparagraph (B) during which the person (or,
11 if not otherwise enrolled, the individual) may be
12 enrolled under the plan as a dependent of the
13 individual, and in the case of the birth or adop-
14 tion of a child, the spouse of the individual may
15 be enrolled as a dependent of the individual if
16 such spouse is otherwise eligible for coverage.

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

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

24 “(ii) the date of the marriage, birth,
25 or adoption or placement for adoption (as

1 the case may be) described in subpara-
2 graph (A)(iii).

3 “(C) NO WAITING PERIOD.—If an indi-
4 vidual seeks to enroll a dependent during the
5 first 30 days of such a dependent special enroll-
6 ment period, the coverage of the dependent
7 shall become effective—

8 “(i) in the case of marriage, not later
9 than the first day of the first month begin-
10 ning after the date the completed request
11 for enrollment is received;

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

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

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

20 “(A) IN GENERAL.—A group health plan,
21 and a health insurance issuer offering group
22 health insurance coverage in connection with a
23 group health plan, shall permit an employee
24 who is eligible, but not enrolled, for coverage
25 under the terms of the plan (or a dependent of

1 such an employee if the dependent is eligible,
2 but not enrolled, for coverage under such
3 terms) to enroll for coverage under the terms of
4 the plan if either of the following conditions is
5 met:

6 “(i) TERMINATION OF MEDICAID OR
7 CHIP COVERAGE.—The employee or de-
8 pendent is covered under a Medicaid plan
9 under title XIX of the Social Security Act
10 or under a State child health plan under
11 title XXI of such Act and coverage of the
12 employee or dependent under such a plan
13 is terminated as a result of loss of eligi-
14 bility for such coverage and the employee
15 requests coverage under the group health
16 plan (or health insurance coverage) not
17 later than 60 days after the date of termi-
18 nation of such coverage.

19 “(ii) ELIGIBILITY FOR EMPLOYMENT
20 ASSISTANCE UNDER MEDICAID OR CHIP.—
21 The employee or dependent becomes eligi-
22 ble for assistance, with respect to coverage
23 under the group health plan or health in-
24 surance coverage, under such Medicaid
25 plan or State child health plan (including

1 under any waiver or demonstration project
2 conducted under or in relation to such a
3 plan), if the employee requests coverage
4 under the group health plan or health in-
5 surance coverage not later than 60 days
6 after the date the employee or dependent is
7 determined to be eligible for such assist-
8 ance.

9 “(B) COORDINATION WITH MEDICAID AND
10 CHIP.—

11 “(i) OUTREACH TO EMPLOYEES RE-
12 GARDING AVAILABILITY OF MEDICAID AND
13 CHIP COVERAGE.—

14 “(I) IN GENERAL.—Each em-
15 ployer that maintains a group health
16 plan in a State that provides medical
17 assistance under a State Medicaid
18 plan under title XIX of the Social Se-
19 curity Act, or child health assistance
20 under a State child health plan under
21 title XXI of such Act, in the form of
22 premium assistance for the purchase
23 of coverage under a group health
24 plan, shall provide to each employee a
25 written notice informing the employee

1 of potential opportunities then cur-
2 rently available in the State in which
3 the employee resides for premium as-
4 sistance under such plans for health
5 coverage of the employee or the em-
6 ployee’s dependents. For purposes of
7 compliance with this subclause, the
8 employer may use any State-specific
9 model notice developed in accordance
10 with section 701(f)(3)(B)(i)(II) of the
11 Employee Retirement Income Security
12 Act of 1974 (29 U.S.C.
13 1181(f)(3)(B)(i)(II)).

14 “(II) OPTION TO PROVIDE CON-
15 CURRENT WITH PROVISION OF PLAN
16 MATERIALS TO EMPLOYEE.—An em-
17 ployer may provide the model notice
18 applicable to the State in which an
19 employee resides concurrent with the
20 furnishing of materials notifying the
21 employee of health plan eligibility,
22 concurrent with materials provided to
23 the employee in connection with an
24 open season or election process con-
25 ducted under the plan, or concurrent

1 with the furnishing of the summary
2 plan description as provided in section
3 104(b) of the Employee Retirement
4 Income Security Act of 1974.

5 “(ii) DISCLOSURE ABOUT GROUP
6 HEALTH PLAN BENEFITS TO STATES FOR
7 MEDICAID AND CHIP ELIGIBLE INDIVID-
8 UALS.—In the case of an enrollee in a
9 group health plan who is covered under a
10 Medicaid plan of a State under title XIX
11 of the Social Security Act or under a State
12 child health plan under title XXI of such
13 Act, the plan administrator of the group
14 health plan shall disclose to the State,
15 upon request, information about the bene-
16 fits available under the group health plan
17 in sufficient specificity, as determined
18 under regulations of the Secretary of
19 Health and Human Services in consulta-
20 tion with the Secretary that require use of
21 the model coverage coordination disclosure
22 form developed under section 311(b)(1)(C)
23 of the Children’s Health Insurance Reau-
24 thorization Act of 2009, so as to permit
25 the State to make a determination (under

1 paragraph (2)(B), (3), or (10) of section
2 2105(c) of the Social Security Act or oth-
3 erwise) concerning the cost-effectiveness of
4 the State providing medical or child health
5 assistance through premium assistance for
6 the purchase of coverage under such group
7 health plan and in order for the State to
8 provide supplemental benefits required
9 under paragraph (10)(E) of such section
10 or other authority.

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

13 “(1) IN GENERAL.—A health maintenance orga-
14 nization which offers health insurance coverage in
15 connection with a group health plan and which does
16 not impose any preexisting condition exclusion al-
17 lowed under subsection (a) with respect to any par-
18 ticular coverage option may impose an affiliation pe-
19 riod for such coverage option, but only if—

20 “(A) such period is applied uniformly with-
21 out regard to any health status-related factors;
22 and

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

25 “(2) AFFILIATION PERIOD.—

1 “(A) DEFINED.—For purposes of this
2 title, the term ‘affiliation period’ means a pe-
3 riod which, under the terms of the health insur-
4 ance coverage offered by the health mainte-
5 nance organization, must expire before the
6 health insurance coverage becomes effective.
7 The organization is not required to provide
8 health care services or benefits during such pe-
9 riod and no premium shall be charged to the
10 participant or beneficiary for any coverage dur-
11 ing the period.

12 “(B) BEGINNING.—Such period shall begin
13 on the enrollment date.

14 “(C) RUNS CONCURRENTLY WITH WAITING
15 PERIODS.—An affiliation period under a plan
16 shall run concurrently with any waiting period
17 under the plan.

18 “(3) ALTERNATIVE METHODS.—A health main-
19 tenance organization described in paragraph (1) may
20 use alternative methods, from those described in
21 such paragraph, to address adverse selection as ap-
22 proved by the State insurance commissioner or offi-
23 cial or officials designated by the State to enforce
24 the requirements of this part for the State involved
25 with respect to such issuer.

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

2 “(a) IN GENERAL.—A group health plan and a health
3 insurance issuer offering group or individual health insur-
4 ance coverage that provides dependent coverage of chil-
5 dren shall continue to make such coverage available for
6 an adult child (who is not married) until the child turns
7 26 years of age. Nothing in this section shall require a
8 health plan or a health insurance issuer described in the
9 preceding sentence to make coverage available for a child
10 of a child receiving dependent coverage.

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

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

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

19 “(a) IN GENERAL.—

20 “(1) 2014.—The cost-sharing incurred under a
21 group health plan or group or individual health in-
22 surance coverage with respect to self-only coverage
23 or coverage other than self-only coverage for a plan
24 year beginning in 2014 shall not exceed the dollar
25 amounts in effect under section 223(c)(2)(A)(ii) of
26 the Internal Revenue Code of 1986 for self-only and

1 family coverage, respectively, for taxable years begin-
2 ning in 2014.

3 “(2) 2015 AND LATER.—In the case of any
4 plan year beginning in a calendar year after 2014,
5 the limitation under this paragraph shall—

6 “(A) in the case of self-only coverage, be
7 equal to the dollar amount under paragraph (1)
8 for self-only coverage for plan years beginning
9 in 2014, increased by an amount equal to the
10 product of that amount and the premium ad-
11 justment percentage under subsection (c) for
12 the calendar year; and

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

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

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

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

21 “(A) deductibles, coinsurance, copayments,
22 or similar charges; and

23 “(B) any other expenditure required of an
24 insured individual which is a qualified medical
25 expense (within the meaning of section

1 State has failed to substantially enforce a provision
2 (or provisions) of sections 196 through 199A with
3 respect to health insurance issuers in the State, the
4 Secretary shall enforce such provision (or provisions)
5 under subsection (b) insofar as they relate to the
6 issuance, sale, renewal, and offering of health insur-
7 ance coverage in connection with group health plans
8 or individual health insurance coverage in such
9 State.

10 “(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

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

14 “(A) as provided under such subsection;

15 and

16 “(B) with respect to individual health in-
17 surance coverage or group health plans that are
18 non-Federal governmental plans.

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

21 “(A) IN GENERAL.—Subject to the suc-
22 ceeding provisions of this subsection, any non-
23 Federal governmental plan that is a group
24 health plan and any health insurance issuer
25 that fails to meet a provision of this part appli-

1 cable to such plan or issuer is subject to a civil
2 money penalty under this subsection.

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

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

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

9 “(I) sponsored by 2 or more em-
10 ployers, the plan is liable for such
11 penalty; or

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

14 “(C) AMOUNT OF PENALTY.—

15 “(i) IN GENERAL.—The maximum
16 amount of penalty imposed under this
17 paragraph is \$100 for each day for each
18 individual with respect to which such a
19 failure occurs.

20 “(ii) CONSIDERATIONS IN IMPOSI-
21 TION.—In determining the amount of any
22 penalty to be assessed under this para-
23 graph, the Secretary shall take into ac-
24 count the previous record of compliance of
25 the entity being assessed with the applica-

1 ble provisions of this part and the gravity
2 of the violation.

3 “(iii) LIMITATIONS.—

4 “(I) PENALTY NOT TO APPLY
5 WHERE FAILURE NOT DISCOVERED
6 EXERCISING REASONABLE DILI-
7 GENCE.—No civil money penalty shall
8 be imposed under this paragraph on
9 any failure during any period for
10 which it is established to the satisfac-
11 tion of the Secretary that none of the
12 entities against whom the penalty
13 would be imposed knew, or exercising
14 reasonable diligence would have
15 known, that such failure existed.

16 “(II) PENALTY NOT TO APPLY
17 TO FAILURES CORRECTED WITHIN 30
18 DAYS.—No civil money penalty shall
19 be imposed under this paragraph on
20 any failure if such failure was due to
21 reasonable cause and not to willful ne-
22 glect, and such failure is corrected
23 during the 30-day period beginning on
24 the first day any of the entities
25 against whom the penalty would be

1 imposed knew, or exercising reason-
2 able diligence would have known, that
3 such failure existed.

4 “(D) ADMINISTRATIVE REVIEW.—

5 “(i) OPPORTUNITY FOR HEARING.—

6 The entity assessed shall be afforded an
7 opportunity for hearing by the Secretary
8 upon request made within 30 days after
9 the date of the issuance of a notice of as-
10 sessment. In such hearing the decision
11 shall be made on the record pursuant to
12 section 554 of title 5, United States Code.
13 If no hearing is requested, the assessment
14 shall constitute a final and unappealable
15 order.

16 “(ii) HEARING PROCEDURE.—If a
17 hearing is requested, the initial agency de-
18 cision shall be made by an administrative
19 law judge, and such decision shall become
20 the final order unless the Secretary modi-
21 fies or vacates the decision. Notice of in-
22 tent to modify or vacate the decision of the
23 administrative law judge shall be issued to
24 the parties within 30 days after the date of
25 the decision of the judge. A final order

1 which takes effect under this paragraph
2 shall be subject to review only as provided
3 under subparagraph (E).

4 “(E) JUDICIAL REVIEW.—

5 “(i) FILING OF ACTION FOR RE-
6 VIEW.—Any entity against whom an order
7 imposing a civil money penalty has been
8 entered after an agency hearing under this
9 paragraph may obtain review by the
10 United States district court for any district
11 in which such entity is located or the
12 United States District Court for the Dis-
13 trict of Columbia by filing a notice of ap-
14 peal in such court within 30 days from the
15 date of such order, and simultaneously
16 sending a copy of such notice by registered
17 mail to the Secretary.

18 “(ii) CERTIFICATION OF ADMINISTRA-
19 TIVE RECORD.—The Secretary shall
20 promptly certify and file in such court the
21 record upon which the penalty was im-
22 posed.

23 “(iii) STANDARD FOR REVIEW.—The
24 findings of the Secretary shall be set aside
25 only if found to be unsupported by sub-

1 stantial evidence as provided by section
2 706(2)(E) of title 5, United States Code.

3 “(iv) APPEAL.—Any final decision,
4 order, or judgment of the district court
5 concerning such review shall be subject to
6 appeal as provided in chapter 83 of title 28
7 of such Code.

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

10 “(i) FAILURE TO PAY ASSESSMENT.—
11 If any entity fails to pay an assessment
12 after it has become a final and
13 unappealable order, or after the court has
14 entered final judgment in favor of the Sec-
15 retary, the Secretary shall refer the matter
16 to the Attorney General who shall recover
17 the amount assessed by action in the ap-
18 propriate United States district court.

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

23 “(G) PAYMENT OF PENALTIES.—Except as
24 otherwise provided, penalties collected under
25 this paragraph shall be paid to the Secretary

1 (or other officer) imposing the penalty and shall
2 be available without appropriation and until ex-
3 pended for the purpose of enforcing the provi-
4 sions with respect to which the penalty was im-
5 posed.

6 “(3) ENFORCEMENT AUTHORITY RELATING TO
7 GENETIC DISCRIMINATION.—

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

20 “(B) AMOUNT.—

21 “(i) IN GENERAL.—The amount of
22 the penalty imposed under this paragraph
23 shall be \$100 for each day in the non-
24 compliance period with respect to each par-

1 participant or beneficiary to whom such fail-
2 ure relates.

3 “(ii) NONCOMPLIANCE PERIOD.—For
4 purposes of this paragraph, the term ‘non-
5 compliance period’ means, with respect to
6 any failure, the period—

7 “(I) beginning on the date such
8 failure first occurs; and

9 “(II) ending on the date the fail-
10 ure is corrected.

11 “(C) MINIMUM PENALTIES WHERE FAIL-
12 URE DISCOVERED.—Notwithstanding clauses (i)
13 and (ii) of subparagraph (D):

14 “(i) IN GENERAL.—In the case of 1 or
15 more failures with respect to an indi-
16 vidual—

17 “(I) which are not corrected be-
18 fore the date on which the plan re-
19 ceives a notice from the Secretary of
20 such violation; and

21 “(II) which occurred or continued
22 during the period involved,

23 the amount of penalty imposed by subpara-
24 graph (A) by reason of such failures with

1 respect to such individual shall not be less
2 than \$2,500.

3 “(ii) HIGHER MINIMUM PENALTY
4 WHERE VIOLATIONS ARE MORE THAN DE
5 MINIMIS.—To the extent violations for
6 which any person is liable under this para-
7 graph for any year are more than de mini-
8 mis, clause (i) shall be applied by sub-
9 stituting ‘\$15,000’ for ‘\$2,500’ with re-
10 spect to such person.

11 “(D) LIMITATIONS.—

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

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

1 “(I) such failure was due to rea-
2 sonable cause and not to willful ne-
3 glect; and

4 “(II) such failure is corrected
5 during the 30-day period beginning on
6 the first date the person otherwise lia-
7 ble for such penalty knew, or exer-
8 cising reasonable diligence would have
9 known, that such failure existed.

10 “(iii) OVERALL LIMITATION FOR UN-
11 INTENTIONAL FAILURES.—In the case of
12 failures which are due to reasonable cause
13 and not to willful neglect, the penalty im-
14 posed by subparagraph (A) for failures
15 shall not exceed the amount equal to the
16 lesser of—

17 “(I) 10 percent of the aggregate
18 amount paid or incurred by the em-
19 ployer (or predecessor employer) dur-
20 ing the preceding taxable year for
21 group health plans; or

22 “(II) \$500,000.

23 “(E) WAIVER BY SECRETARY.—In the case
24 of a failure which is due to reasonable cause
25 and not to willful neglect, the Secretary may

1 waive part or all of the penalty imposed by sub-
2 paragraph (A) to the extent that the payment
3 of such penalty would be excessive relative to
4 the failure involved.

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

6 “(1) GOVERNMENTAL PLAN.—The term ‘gov-
7 ernmental plan’ has the meaning given such term
8 under section 3(32) of the Employee Retirement In-
9 come Security Act of 1974 and any Federal govern-
10 mental plan.

11 “(2) FEDERAL GOVERNMENTAL PLAN.—The
12 term “Federal governmental plan” means a govern-
13 mental plan established or maintained for its em-
14 ployees by the Government of the United States or
15 by any agency or instrumentality of such Govern-
16 ment.

17 “(3) NON-FEDERAL GOVERNMENTAL PLAN.—
18 The term ‘non-Federal governmental plan’ means a
19 governmental plan that is not a Federal govern-
20 mental plan.”.

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

“Sec. 196. Guaranteed availability of coverage.

“Sec. 197. Fair health insurance premiums.

“Sec. 198. Prohibiting discrimination against individual participants and beneficiaries based on health status.

“Sec. 199. Prohibition of preexisting condition exclusions or other discrimination based on health status.

“Sec. 199A. Extension of dependent coverage.

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

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

1 (c) ERISA AND IRC ENFORCEMENT.—

2 (1) ERISA.—Subpart B of part 7 of title I of
3 the Employee Retirement Income Security Act of
4 1974 (29 U.S.C. 1185 et seq.) is amended by adding
5 at the end the following new section:

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

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

1 with group health plans, the provisions of such sections
2 196 through 199B shall apply.”.

3 (2) IRC.—Subchapter B of chapter 100 of sub-
4 title K of title 26 of the Internal Revenue Code of
5 1986 is amended by adding at the end the following
6 new section:

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

8 “Sections 196 and 197 of the Health Insurance Port-
9 ability and Accountability Act of 1996 shall apply to
10 health insurance issuers providing health insurance cov-
11 erage in connection with group health plans, and sections
12 198 through 199B of such Act shall apply to group health
13 plans and health insurance issuers providing health insur-
14 ance coverage in connection with group health plans, as
15 if included in this subchapter, and to the extent that any
16 provision of this chapter conflicts with a provision of such
17 section 196 or 197 with respect to health insurance issuers
18 providing health insurance coverage in connection with
19 group health plans or of such section 198, 199, 199A, or
20 199B with respect to group health plans or health insur-
21 ance issuers providing health insurance coverage in con-
22 nection with group health plans, the provisions of such
23 sections 196 through 199B shall apply.”.

24 (d) EFFECTIVE DATE.—The amendments made by
25 this section shall take effect on the date on which the Su-

1 preme Court of the United States issues a decision strik-
2 ing down the Patient Protection and Affordable Care Act
3 (Public Law 111–148) in its entirety.

4 **Subtitle B—Expanding Coverage** 5 **Options**

6 **SEC. 211. DEFINITION OF “EMPLOYER” UNDER ERISA WITH** 7 **RESPECT TO GROUP HEALTH PLANS.**

8 (a) DEFINITION OF EMPLOYER.—Section 3(5) of the
9 Employee Retirement Income Security Act of 1974 (29
10 U.S.C. 1002(5)) is amended by striking the period and
11 inserting “(which, with respect to a group health plan,
12 shall be determined in accordance with criteria that in-
13 cludes the criteria under section 735).”.

14 (b) GROUP HEALTH PLANS.—Part 7 of subtitle B
15 of title I of the Employee Retirement Income Security Act
16 of 1974 (29 U.S.C. 1181 et seq.) is amended by adding
17 at the end the following:

18 **“SEC. 735. DEFINITION OF ‘EMPLOYER’ WITH RESPECT TO** 19 **GROUP HEALTH PLANS.**

20 “(a) IN GENERAL.—A group or association of em-
21 ployers that meets the criteria under subsection (b) shall
22 be considered an employer under section 3(5) for purposes
23 of sponsoring a group health plan.

24 “(b) REQUIREMENTS.—The requirements under this
25 subsection are each of the following:

1 “(1) The primary purpose of the group or asso-
2 ciation may be to offer and provide health coverage
3 to its employer members and their employees, if
4 such group or association has at least 1 substantial
5 business purpose, as described in subsection (c), un-
6 related to offering and providing health coverage or
7 other employee benefits to its employer members and
8 their employees.

9 “(2) Each employer member of the group or as-
10 sociation participating in the group health plan is a
11 person acting directly as an employer of at least 1
12 employee who is a participant covered under the
13 plan.

14 “(3) The group or association has—

15 “(A) a formal organizational structure
16 with a governing body; and

17 “(B) by-laws or other similar indications of
18 formality.

19 “(4) The functions and activities of the group
20 or association shall be controlled by the employer
21 members of the group or association, and the em-
22 ployer members of the group or association that par-
23 ticipate in the group health plan shall control the
24 plan. Control under this paragraph shall be in form
25 and substance.

1 “(5) The employer members shall have a com-
2 monality of interest as described in subsection (d).

3 “(6)(A) The group or association shall not
4 make health coverage through the group health plan
5 available other than to—

6 “(i) an employee of a current employer
7 member of the group or association;

8 “(ii) a former employee of a current em-
9 ployer member of the group or association who
10 became eligible for coverage under the group
11 health plan when the former employee was an
12 employee of the employer; and

13 “(iii) a beneficiary of an individual de-
14 scribed in clause (i) or (ii), such as a spouse or
15 dependent child.

16 “(B) Notwithstanding subparagraph (A), the
17 group or association shall not make health coverage
18 through the group health plan available to any indi-
19 vidual (or beneficiaries of the individual) for any
20 plan year following the plan year in which the plan
21 determines pursuant to reasonable monitoring proce-
22 dures described in subsection (f)(2)(C) that the indi-
23 vidual ceases to meet the conditions described in
24 subsection (f)(2) for being a working owner (unless

1 the individual again meets those conditions), except
2 as may be required by section 601.

3 “(7) The group or association, and any health
4 coverage offered by the group or association, shall
5 comply with the nondiscrimination provisions under
6 subsection (e).

7 “(8) The group or association shall not be a
8 health insurance issuer, or owned or controlled by
9 such a health insurance issuer or by a subsidiary or
10 affiliate of such a health insurance issuer, other
11 than to the extent such entities participate in the
12 group or association in their capacity as employer
13 members of the group or association.

14 “(c) SUBSTANTIAL BUSINESS PURPOSE.—

15 “(1) IN GENERAL.—For purposes of subsection
16 (b)(1), a substantial business purpose shall exist if
17 the group or association would be a viable entity in
18 the absence of sponsoring an employee benefit plan.

19 “(2) BUSINESS PURPOSE.—For purposes of
20 subsection (b)(1) and paragraph (1), a business pur-
21 pose shall—

22 “(A) include promoting common business
23 interests of the members of the group or asso-
24 ciation or the common economic interests in a
25 given trade or employer community; and

1 “(B) not be required to be a for-profit ac-
2 tivity.

3 “(d) COMMONALITY OF INTEREST.—

4 “(1) IN GENERAL.—Subject to paragraph (3),
5 employer members of the group or association shall
6 be treated as having a commonality of interest for
7 purposes of subsection (b)(5) if—

8 “(A) the employers are in the same trade,
9 industry, line of business, or profession; or

10 “(B) each employer has a principal place
11 of business in the same region that does not ex-
12 ceed the boundaries of a single State or a met-
13 ropolitan area (even if the metropolitan area in-
14 cludes more than 1 State).

15 “(2) SAME TRADE, INDUSTRY, OR LINE OF
16 BUSINESS.—In the case of a group or association
17 that is sponsoring a group health plan under this
18 section and that is itself an employer member of the
19 group or association, the group or association shall
20 be deemed for purposes of paragraph (1)(A) to be
21 in the same trade, industry, line of business, or pro-
22 fession, as applicable, as the other employer mem-
23 bers of the group or association.

24 “(3) NONDISCRIMINATION.—The standards
25 under paragraph (1) shall not be implemented in a

1 manner that is subterfuge for discrimination as is
2 prohibited under subsection (e).

3 “(e) NONDISCRIMINATION.—

4 “(1) IN GENERAL.—A group or association of
5 employers sponsoring a group health plan under this
6 section, and any health coverage sponsored by such
7 group or association, shall comply with each of the
8 following:

9 “(A) The group or association shall not
10 condition employer membership in the group or
11 association on any health factor of any indi-
12 vidual who is or may become eligible to partici-
13 pate in the group health plan sponsored by the
14 group or association.

15 “(B) The group health plan sponsored by
16 the group or association shall comply with the
17 rules under section 2590.702(b) of title 29,
18 Code of Federal Regulations (as in effect on
19 June 21, 2018), with respect to nondiscrimina-
20 tion in rules for eligibility for benefits, subject
21 to subparagraph (D).

22 “(C) The group health plan sponsored by
23 the group or association shall comply with the
24 rules under section 2590.702(c) of title 29,
25 Code of Federal Regulations (as in effect on

1 June 21, 2018), with respect to nondiscrimina-
2 tion in premiums or contributions required by
3 any participant or beneficiary for coverage
4 under the plan, subject to subparagraph (D).

5 “(D) In applying subparagraphs (B) and
6 (C), the group or association may not treat the
7 employees of different employer members of the
8 group or association as distinct groups of simi-
9 larly-situated individuals based on a health fac-
10 tor of 1 or more individuals.

11 “(2) DEFINITION OF HEALTH FACTOR.—For
12 purposes of this subsection, the term ‘health factor’
13 has the meaning given such term in section
14 2590.702(a) of title 29, Code of Federal Regulations
15 (as in effect on June 21, 2018).

16 “(f) DUAL TREATMENT OF WORKING OWNERS AS
17 EMPLOYERS AND EMPLOYEES.—

18 “(1) IN GENERAL.—A person determined in ac-
19 cordance with paragraph (2) to be a working owner
20 of a trade or business may qualify as both an em-
21 ployer and as an employee of the trade or business
22 for purposes of the requirements under subsection
23 (b), including the requirements under paragraphs
24 (2) and (6) of such subsection.

25 “(2) WORKING OWNER.—

1 “(A) ELIGIBILITY.—A person shall qualify
2 as a ‘working owner’ if a responsible fiduciary
3 of the group health plan reasonably determines
4 that the person—

5 “(i) does not have any common law
6 employees;

7 “(ii) has an ownership right of any
8 nature in a trade or business, whether in-
9 corporated or unincorporated, including a
10 partner and other self-employed individual;

11 “(iii) is earning wages or self-employ-
12 ment income from the trade or business
13 for providing personal services to the trade
14 or business; and

15 “(iv) either—

16 “(I) works on average at least 20
17 hours per week, or at least 80 hours
18 per month, providing personal services
19 to the person’s trade or business; or

20 “(II) has wages or self-employ-
21 ment income from such trade or busi-
22 ness that at least equals the person’s
23 cost of coverage for participation by
24 the person, and any covered bene-
25 ficiaries, in the group health plan

1 sponsored by the group or association
2 in which the person is participating.

3 “(B) DETERMINATION.—The determina-
4 tion under subparagraph (A) shall be made
5 when the person first becomes eligible for cov-
6 erage under the group health plan.

7 “(C) REASONABLE MONITORING PROCE-
8 DURES.—A responsible fiduciary of the group
9 health plan shall, through reasonable moni-
10 toring procedures, periodically confirm the con-
11 tinued eligibility of a person to qualify as a
12 working owner under subparagraph (A) for pur-
13 poses of meeting the requirements under sub-
14 section (b) for the group health plan sponsored
15 under this section.

16 “(g) APPLICABILITY.—

17 “(1) FULLY INSURED.—This section shall apply
18 beginning on September 1, 2018, with respect to a
19 group or association of employers sponsoring a
20 group health plan that is fully insured.

21 “(2) PLANS EXPANDING TO INCLUDE BROADER
22 GROUP.—This section shall apply beginning on Jan-
23 uary 1, 2019, with respect to a group or association
24 of employers sponsoring a group health plan that—

25 “(A) is not fully insured;

1 “(B) is in existence on June 21, 2018;

2 “(C) meets the requirements that applied
3 with respect to such plan before June 21, 2018;
4 and

5 “(D) chooses to be a plan sponsored under
6 this section (and subject to the requirements
7 under subsections (b) through (f)).

8 “(3) OTHER ASSOCIATION HEALTH PLANS.—
9 This section shall apply beginning on April 1, 2019,
10 with respect to any other group or association of em-
11 ployers sponsoring a group health plan.

12 “(4) OTHER CRITERIA IN ADVISORY OPIN-
13 IONS.—The criteria under this section shall not in-
14 validate any criteria provided in an advisory opinion,
15 in effect on or after the date of enactment of the
16 Fair Care Act of 2022, that the Secretary may use
17 to determine if a group or association of employers
18 is an employer under section 3(5) for purposes of
19 sponsoring a group health plan.

20 “(h) DETERMINATION OF EMPLOYER OR JOINT EM-
21 PLOYER STATUS.—

22 “(1) IN GENERAL.—Participating in or facili-
23 tating a group health plan sponsored by a bona fide
24 group or association of employers pursuant to sub-
25 section (a) shall not be construed as establishing an

1 employer or joint employer relationship under any
2 Federal or State law.

3 “(2) APPLICATION OF PROVISION.—Paragraph
4 (1) shall apply to a group health plan sponsored or
5 facilitated by a franchisor and any franchisee, by
6 multiple franchisors for the benefit of the employees
7 of such franchisors and their franchisees, by mul-
8 tiple franchisees for the benefit of the employees of
9 such franchisees, by a franchisor whose franchisee or
10 franchisees participate or participates in the plan, or
11 by a person or entity that contracts with any indi-
12 vidual as an independent contractor for whom the
13 plan benefits.

14 “(i) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed as repealing or otherwise limiting
16 the application of this Act (including section 712 relating
17 to mental health parity) to group health plans and em-
18 ployee welfare benefit plans.”.

19 **SEC. 212. SHORT-TERM LIMITED DURATION INSURANCE.**

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

23 “(6) SHORT-TERM LIMITED DURATION INSUR-
24 ANCE.—The term ‘short-term limited duration insur-
25 ance’ means health insurance coverage provided pur-

1 suant to a contract with a health insurance issuer
2 that has an expiration date specified in the contract
3 (not taking into account any extensions that may be
4 elected by the policyholder with or without the
5 issuer’s consent) that is less than 12 months after
6 the original effective date of the contract.”.

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

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

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

14 “(f) APPLICATION TO SHORT-TERM LIMITED DURA-
15 TION INSURANCE.—

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

18 “(A) a reference to ‘health insurance cov-
19 erage’ with respect to such coverage offered in
20 the individual market shall be deemed to in-
21 clude short-term limited duration insurance;
22 and

23 “(B) a reference to ‘health insurance
24 issuer’ with respect to health insurance cov-
25 erage offered in the individual market shall be

1 deemed to include an issuer of short-term lim-
2 ited duration insurance.

3 “(2) SPECIAL RULE FOR SHORT-TERM LIMITED
4 DURATION INSURANCE.—In the case of short-term
5 limited duration insurance, at the time of application
6 for enrollment in such insurance coverage, an issuer
7 of such insurance may offer renewability of such
8 coverage, and an individual may decline renewability
9 of such coverage in accordance with this section, and
10 the contract between such individual and the health
11 insurance issuer shall specify whether the individual
12 opted for renewability or no renewability.”.

13 (c) APPLICABILITY.—The amendments made by sub-
14 sections (a) and (b) shall apply with respect to contracts
15 for short-term limited duration insurance that take effect
16 on or after January 1, 2023.

17 **Subtitle C—Improving Commercial** 18 **Health Insurance**

19 **SEC. 221. INVISIBLE GUARANTEED COVERAGE POOL REIN-** 20 **SURANCE PROGRAM; TAX ON EXCHANGE** 21 **PLANS.**

22 (a) ESTABLISHMENT.—Not later than 2 years after
23 the date of enactment of this Act, the Secretary of Health
24 and Human Services shall establish the Invisible Guarant-

1 teed Coverage Pool Reinsurance Program (in this section
2 referred to as the “IGCPR program”).

3 (b) STATE GRANTS.—Under the IGCPR program,
4 the Secretary shall, from amounts appropriated under
5 subsection (f) for a fiscal year, award grants to States for
6 such fiscal year, in amounts determined in accordance
7 with the allocation methodology specified under subsection
8 (d). Such grants shall be used for the purpose of estab-
9 lishing or maintaining a qualifying Invisible Guaranteed
10 Coverage Pool for the State.

11 (c) FEDERAL DEFAULT.—

12 (1) IN GENERAL.—In the case of a State that
13 does not, by a date and in a manner specified by the
14 Secretary, choose to be awarded a grant under sub-
15 section (b) for a fiscal year to operate a qualifying
16 Invisible Guaranteed Coverage Pool for the State,
17 the Secretary shall, from amounts appropriated
18 under subsection (f) for such fiscal year, use the al-
19 location determined for the State under subsection
20 (d) for participation of such State in the Federal de-
21 fault qualifying Invisible Guaranteed Coverage Pool
22 described in paragraph (2).

23 (2) FEDERAL DEFAULT QUALIFYING INVISIBLE
24 GUARANTEED COVERAGE POOL.—The Federal de-
25 fault qualifying high risk pool is, with respect to

1 each State that chooses not to be awarded a grant
2 under subsection (b) with respect to a fiscal year for
3 which funds are appropriated under subsection (f),
4 an Invisible Guaranteed Coverage Pool under which
5 health insurance issuers participating in the Ex-
6 change of such a State, with respect to designated
7 individuals who are enrolled in health insurance cov-
8 erage and are expected to experience higher than av-
9 erage health costs as determined by the insurer, cede
10 risk to the pool, without affecting the premium paid
11 by the designated individuals or their terms of cov-
12 erage. With respect to such pool—

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

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

20 (C) the ceding issuer shall retain the same
21 risk under the ceded policies as under any other
22 policy of the issuer with respect to the first
23 \$10,000 of benefits for each ceded policy in-
24 volved and will not retain any risk under ceded
25 policies after such first \$10,000 of benefits; and

1 (D) after a ceding issuer, with respect to
2 a ceded policy, no longer retains risk under
3 such policy pursuant to subparagraph (C), the
4 negotiated rate under such policy for items and
5 services shall be payable at the reimbursement
6 rate under the Medicare program under title
7 XVIII of the Social Security Act for such items
8 and services, or in the case of items and serv-
9 ices for which payment is available under the
10 policy but not the Medicare program, at a rate
11 determined by the Secretary.

12 (d) ALLOCATION METHODOLOGY.—Not later than six
13 months after the establishment of the IG CPR program,
14 the Secretary shall specify an allocation methodology for
15 determining the amount of funds appropriated under sub-
16 section (f) for a fiscal year to be allocated for each State
17 for purposes of subsections (b) and (c). Such methodology
18 shall be based on the number of residents of each State
19 and the general health status of such residents.

20 (e) QUALIFYING INVISIBLE GUARANTEED COVERAGE
21 POOL.—For purposes of this section, the term “qualifying
22 Invisible Guaranteed Coverage Pool” means, with respect
23 to a State, a method of designation under which health
24 insurance issuers identify individuals who experience high-
25 er than average health costs as determined by the State

1 and are enrolled in health insurance coverage offered in
2 the individual market, and cede the risk of spending more
3 than \$10,000 on health care services for a single indi-
4 vidual to the pool without affecting the premium paid by
5 the designated individuals or their terms of coverage. With
6 respect to such pool, the State, or an entity operating the
7 pool on behalf of the State, shall establish—

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

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

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

21 (f) APPROPRIATIONS.—There is appropriated to the
22 Secretary of Health and Human Services
23 \$200,000,000,000 to carry out this section for the period
24 of the first 10 years after the establishment of the IGCP
25 program.

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

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

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

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

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

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

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

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

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

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

4 (h) REPORT.—The Secretary of Health and Human
5 Services, in collaboration with the Comptroller General of
6 the United States, shall submit to Congress, not later than
7 5 years after the date of enactment of this Act, and again
8 5 years thereafter, a report on the status of reinsurance
9 pool funding, along with any recommendations with re-
10 spect to future allocations or funding methods for such
11 pool.

12 **SEC. 222. EMPLOYER HEALTH INSURANCE MANDATE RE-**
13 **PEAL.**

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

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

19 (c) CONFORMING AMENDMENTS.—

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

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

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

7 (4) The table of sections for subpart D of part
8 III of subchapter A of chapter 61 of such Code is
9 amended by striking the item relating to section
10 6056.

11 (5) Section 1513 of the Patient Protection and
12 Affordable Care Act is amended by striking sub-
13 section (c).

14 (d) EFFECTIVE DATE.—

15 (1) IN GENERAL.—Except as otherwise pro-
16 vided in this subsection, the amendments made by
17 this section shall apply to months and other periods
18 beginning after December 31, 2023.

19 (2) REPEAL OF STUDY AND REPORT.—The
20 amendment made by subsection (c)(5) shall take ef-
21 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 2023, 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 2023’ for ‘calendar year 2018’ 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 2023 and before
16 2033 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, 2023.

6 **SEC. 225. CHANGE IN PERMISSIBLE AGE VARIATION IN**
7 **HEALTH INSURANCE PREMIUM RATES.**

8 Section 2701(a)(1)(A)(iii) of the Public Health Serv-
9 ice Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by in-
10 sserting after “(consistent with section 2707(c))” the fol-
11 lowing: “or, for plan years beginning on or after January
12 1, 2023, 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	8.3	6.7	8.3	6.7	8.3
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 2023, 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 2023,
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 2023, over
14 the rate of growth in the consumer
15 price index for calendar year 2023.

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, 2023.

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, 2023.

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 2023, 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 2023, 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 years of 1 year after the date of enactment
26 of this Act, the Exchange may provide for open

1 enrollment periods (after the initial enrollment
 2 period) every 12, 24, or 36 months, as deter-
 3 mined by the State.”.

4 **SEC. 233. PROMOTING HEALTH PLANS THAT COVER INDI-**
 5 **VIDUALS IN MORE THAN ONE STATE.**

6 There are appropriated, out of amounts in the Treas-
 7 ury not otherwise appropriated, \$10,000,000 to be made
 8 available by no later than 1 year after the date of enact-
 9 ment of this Act, to the Center for Medicare & Medicaid
 10 Innovation to fund new research or pilot programs dedi-
 11 cated to pursuing viable methods of enrolling individuals
 12 in health insurance programs that cross State lines.

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

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

18 **SEC. 301. HOSPITAL CONSOLIDATION.**

19 (a) AUTHORIZATION OF APPROPRIATIONS.—There is
 20 authorized to be appropriated \$160,000,000 to the Fed-
 21 eral Trade Commission to hire staff to investigate, as con-
 22 sistent with the Sherman Antitrust Act and other relevant
 23 Federal laws, anti-competitive mergers and practices
 24 under such laws to the extent such mergers and practices
 25 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 hospital in the
23 hospital referral region.”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by this subsection shall apply with respect to items
3 and services furnished on or after January 1, 2023.

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 2022
20 through 2031. 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 2023, 102, plus 1 percentage
2 point for each subsequent year through 2031, 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 2023, 102, plus 1 percentage point for each
8 subsequent year through 2031, 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. 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. 304. BANNING ANTICOMPETITIVE TERMS IN FACILITY**
19 **AND INSURANCE CONTRACTS THAT LIMIT AC-**
20 **CESS TO HIGHER QUALITY, LOWER COST**
21 **CARE.**

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

1 “(b) PROTECTING HEALTH PLANS NETWORK DE-
2 SIGN FLEXIBILITY.—

3 “(1) IN GENERAL.—A group health plan or a
4 health insurance issuer offering group or individual
5 health insurance coverage shall not enter into an
6 agreement with a provider, network or association of
7 providers, or other service provider offering access to
8 a network of service providers if such agreement, di-
9 rectly or indirectly—

10 “(A) restricts the group health plan or
11 health insurance issuer from—

12 “(i) directing or steering enrollees to
13 other health care providers; or

14 “(ii) offering incentives to encourage
15 enrollees to utilize specific health care pro-
16 viders;

17 “(B) requires the group health plan or
18 health insurance issuer to enter into any addi-
19 tional contract with an affiliate of the provider,
20 such as an affiliate of the provider, as a condi-
21 tion of entering into a contract with such pro-
22 vider;

23 “(C) requires the group health plan or
24 health insurance issuer to agree to payment

1 rates or other terms for any affiliate not party
2 to the contract of the provider involved; or

3 “(D) restricts other group health plans or
4 health insurance issuers not party to the con-
5 tract from paying a lower rate for items or
6 services than the contracting plan or issuer
7 pays for such items or services.

8 “(2) ADDITIONAL REQUIREMENT FOR SELF-IN-
9 SURED PLANS.—A self-insured group health plan
10 shall not enter into an agreement with a provider,
11 network or association of providers, third-party ad-
12 ministrator, or other service provider offering access
13 to a network of providers if such agreement directly
14 or indirectly requires the group health plan to cer-
15 tify, attest, or otherwise confirm in writing that the
16 group health plan is bound by restrictive contracting
17 terms between the service provider and a third-party
18 administrator that the group health plan is not
19 party to, without a disclosure that such terms exist.

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

1 “(A) a health maintenance organization
2 (as defined in section 2791(b)(3)), if such
3 health maintenance organization operates pri-
4 marily through exclusive contracts with multi-
5 specialty physician groups, nor to any arrange-
6 ment between such a health maintenance orga-
7 nization and its affiliates; or

8 “(B) a value-based network arrangement,
9 such as an exclusive provider network, account-
10 able care organization, center of excellence, a
11 provider sponsored health insurance issuer that
12 operates primarily through aligned multi-spe-
13 cialty physician group practices or integrated
14 health systems, or such other similar network
15 arrangements as determined by the Secretary
16 through rulemaking.

17 “(4) ATTESTATION.—A group health plan or
18 health insurance issuer offering group or individual
19 health insurance coverage shall annually submit to,
20 as applicable, the applicable authority described in
21 section 2723 or the Secretary of Labor, an attesta-
22 tion that such plan or issuer is in compliance with
23 the requirements of this subsection.

24 “(c) MAINTENANCE OF EXISTING HIPAA, GINA,
25 AND ADA PROTECTIONS.—Nothing in this section shall

1 modify, reduce, or eliminate the existing privacy protec-
2 tions and standards provided by reason of State and Fed-
3 eral law, including the requirements of parts 160 and 164
4 of title 45, Code of Federal Regulations (or any successor
5 regulations).

6 “(d) REGULATIONS.—The Secretary, not later than
7 1 year after the date of enactment of the Fair Care Act
8 of 2022, shall promulgate regulations to carry out this sec-
9 tion.

10 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
11 tion shall be construed to limit network design or cost or
12 quality initiatives by a group health plan or health insur-
13 ance issuer, including accountable care organizations, ex-
14 clusive provider organizations, networks that tier providers
15 by cost or quality or steer enrollees to centers of excel-
16 lence, or other pay-for-performance programs.

17 “(f) CLARIFICATION WITH RESPECT TO ANTITRUST
18 LAWS.—Compliance with this section does not constitute
19 compliance with the antitrust laws, as defined in sub-
20 section (a) of the first section of the Clayton Act (15
21 U.S.C. 12(a)).”.

22 (b) EFFECTIVE DATE.—Section 2729B of the Public
23 Health Service Act (as added by section 301 and amended
24 by subsection (a)) shall apply with respect to any contract
25 entered into on or after the date that is 18 months after

1 the date of enactment of this Act. With respect to an ap-
2 plicable contract that is in effect on the date of enactment
3 of this Act, such section 2729B shall apply on the earlier
4 of the date of renewal of such contract or 3 years after
5 such date of enactment.

6 **SEC. 305. REPEALING ELIGIBILITY OF CERTAIN ACOS.**

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

10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall take effect on January 1, 2023.

12 **SEC. 306. REPEAL OF HEALTH CARE REFORM PROVISIONS**
13 **LIMITING MEDICARE EXCEPTION TO THE**
14 **PROHIBITION ON CERTAIN PHYSICIAN RE-**
15 **FERRALS FOR HOSPITALS.**

16 Sections 6001 and 10601 of the Patient Protection
17 and Affordable Care Act (Public Law 111–148; 124 Stat.
18 684, 1005) and section 1106 of the Health Care and Edu-
19 cation Reconciliation Act of 2010 (Public Law 111–152;
20 124 Stat. 1049) are repealed and the provisions of law
21 amended by such sections are restored as if such sections
22 had never been enacted.

1 **SEC. 307. ALTERNATIVE PAYMENT MODEL FOR CERTAIN**
2 **SHOPPABLE PROCEDURES.**

3 (a) **IN GENERAL.**—A group health plan and a health
4 insurance issuer offering group or individual health insur-
5 ance coverage (as such terms are defined in section 2791
6 of the Public Health Service Act (42 U.S.C. 300gg–91))
7 may elect, with respect to a plan year, to provide a set
8 payment amount to an enrollee under such plan or cov-
9 erage for certain shoppable procedures (as defined in sub-
10 section (b)) in accordance with the provisions of this sec-
11 tion in lieu of otherwise providing coverage for such a pro-
12 cedure under such plan or coverage, but only if the en-
13 rollee so agrees to such set payment amount.

14 (b) **DEFINITION.**—For purposes of this section, the
15 term “shoppable procedure” means a procedure specified
16 by the Secretary of Health and Human Services (in this
17 section referred to as the “Secretary”) with respect to
18 which individuals may be expected to compare prices for
19 such procedure of health care providers and facilities, in-
20 cluding primary and preventive services, prenatal care and
21 childbirth, common surgeries that can be scheduled, and
22 other similar services.

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

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

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

7 (3) not be less than the median negotiated rate
8 for all group health plans and health insurance cov-
9 erage offered in such area for such procedure;

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

13 (5) represent the entirety of the payment obli-
14 gation of such plan or such issuer with respect to
15 such procedure; and

16 (6) may be retained by such enrollee to the ex-
17 tent that the amount of such payment exceeds the
18 amount charged by such provider or facility for such
19 procedure.

20 (d) PROVISION OF PRICE INFORMATION.—Each
21 health care provider and facility that may furnish a
22 shoppable procedure during a year shall post in a public
23 area a notice containing the prices that will be charged
24 by such provider of facility with respect to each such pro-
25 cedure to individuals making payment for such services

1 pursuant to a set payment amount described in subsection
2 (a).

3 (e) EHB WAIVER AUTHORITY.—The Secretary may
4 waive such provisions of section 1302(b) of the Patient
5 Protection and Affordable Care Act (42 U.S.C. 18022(b))
6 with respect to a group health plan, health insurance
7 issuer offering group or individual health insurance cov-
8 erage, and a plan year as the Secretary determines nec-
9 essary to allow for the provision of set payment amounts
10 described in subsection (a).

11 **Subtitle B—Price Transparency**

12 **SEC. 321. PRICE TRANSPARENCY REQUIREMENTS.**

13 (a) HOSPITALS.—Section 2718(e) of the Public
14 Health Service Act (42 U.S.C. 300gg–18(e)) is amend-
15 ed—

16 (1) by striking “Each hospital” and inserting
17 the following:

18 “(1) IN GENERAL.—Each hospital”;

19 (2) by inserting “, in a machine-readable for-
20 mat, via open application program interfaces
21 (APIs)” after “a list”;

22 (3) by inserting “, along with such additional
23 information as the Secretary may require with re-
24 spect to such charges for purposes of promoting
25 public awareness of hospital pricing in advance of

1 receiving a hospital item or service” before the pe-
2 riod; and

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

4 “(2) DEFINITION OF STANDARD CHARGES.—

5 Notwithstanding any other provision of law, for pur-
6 poses of paragraph (1), the term ‘standard charges’
7 means the rates hospitals, including providers or en-
8 tities that contract with or practice at a hospital,
9 charge for all items and services at a minimum,
10 chargemaster rates, rates that hospitals negotiate
11 with third party payers across all plans, including
12 those related to a patient’s specific plan, discounted
13 cash prices, and other rates determined by the Sec-
14 retary.

15 “(3) ENFORCEMENT.—In addition to any other
16 enforcement actions or penalties that may apply
17 under subsection (b)(3) or another provision of law,
18 a hospital that fails to provide the information re-
19 quired by this subsection and has not completed a
20 corrective action plan to comply with the require-
21 ments of such subsection shall be subject to a civil
22 monetary penalty of an amount not to exceed \$300
23 per day that the violation is ongoing as determined
24 by the Secretary. Such penalty shall be imposed and
25 collected in the same manner as civil money pen-

1 alties under subsection (a) of section 1128A of the
2 Social Security Act are imposed and collected.”.

3 (b) TRANSPARENCY IN COVERAGE.—Section
4 1311(e)(3) of the Patient Protection and Affordable Care
5 Act (42 U.S.C. 18031(e)(3)) is amended—

6 (1) in subparagraph (A)—

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

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

15 (C) by inserting after clause (viii), the fol-
16 lowing:

17 “(ix) Information on the specific nego-
18 tiated payment rates between the plan and
19 health care providers for all items and
20 services covered under the plan.”;

21 (2) in subparagraph (B)—

22 (A) in the heading, by striking “USE” and
23 inserting “DELIVERY METHODS AND USE”;

24 (B) by inserting “, as applicable,” after
25 “English proficiency”; and

1 (C) by inserting after the second sentence,
2 the following: “The Secretary shall establish
3 standards for electronic delivery and access to
4 such information by individuals, free of charge,
5 in machine readable format, through an Inter-
6 net website and via open APIs.”;

7 (3) in subparagraph (C)—

8 (A) in the first sentence, by inserting “or
9 out-of-network provider” after “item or service
10 by a participating provider”;

11 (B) in the second sentence, by striking
12 “through an Internet website” and inserting
13 “free of charge, in machine readable format,
14 through an Internet website, and via open
15 APIs, in accordance with standards established
16 by the Secretary,”; and

17 (C) by adding at the end the following:
18 “Such information shall include specific nego-
19 tiated rates that allow for comparison between
20 providers and across plans, and related to a pa-
21 tient’s specific plan, including after an enrollee
22 has exceeded their deductible responsibility.”;
23 and

1 (4) in subparagraph (D) by striking “subpara-
2 graph (A)” and inserting “subparagraphs (A), (B),
3 and (C)”.

4 **SEC. 322. ENSURING ENROLLEE ACCESS TO COST-SHARING**
5 **INFORMATION.**

6 (a) IN GENERAL.—Subpart II of part A of title
7 XXVII of the Public Health Service Act (42 U.S.C.
8 300gg–11 et seq.), as amended by the preceding sections,
9 is further amended by adding at the end the following:

10 **“SEC. 2729F. PROVISION OF COST-SHARING INFORMATION.**

11 “(a) PROVIDER DISCLOSURES.—A provider that is
12 in-network with respect to a group health plan or a health
13 insurance issuer offering group or individual health insur-
14 ance coverage shall provide to an enrollee in the plan or
15 coverage who submits a request for the information de-
16 scribed in paragraph (1) or (2), together with accurate
17 and complete information about the enrollee’s coverage
18 under the applicable plan or coverage—

19 “(1) as soon as practicable and not later than
20 2 business days after the enrollee requests such in-
21 formation, a good faith estimate of the expected en-
22 rollee cost-sharing for the provision of a particular
23 health care service (including any service that is rea-
24 sonably expected to be provided in conjunction with
25 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. 323. 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. 324. 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. 325. ADVISORY GROUP ON REDUCING BURDEN OF**
7 **HOSPITAL ADMINISTRATIVE REQUIREMENTS.**

8 (a) IN GENERAL.—Not later than January 1, 2023,
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 2024, 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 nonprofit health
16 insurance issuers and health plans operating in
17 at least 5 States; and

18 (C) one representative of nonprofit 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. 326. DATA REPORTING TO IMPROVE THE TRANS-**
2 **PARENCY REGARDING HOW 340B HOSPITAL**
3 **COVERED ENTITIES PROVIDE CARE FOR PA-**
4 **TIENTS.**

5 Section 340B of the Public Health Service Act (42
6 U.S.C. 256b) is amended by adding at the end the fol-
7 lowing new subsection:

8 “(f) DATA REPORTING TO IMPROVE THE TRANS-
9 PARENCY REGARDING HOW HOSPITAL COVERED ENTI-
10 TIES PROVIDE CARE FOR PATIENTS.—

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

19 “(A) The following information:

20 “(i) With respect to such covered enti-
21 ty and with respect to each child site of
22 such entity (as referenced in paragraph
23 (11)), the number and percentage of indi-
24 viduals who are dispensed or administered
25 drugs that are subject to an agreement
26 under this section, organized by form of

1 health insurance coverage of such individ-
2 uals (including at least by the Medicare
3 program under title XVIII of the Social
4 Security Act, the Medicaid program under
5 title XIX of such Act, health insurance
6 coverage offered in the individual or group
7 market or a group health plan (as such
8 terms are defined in section 2791), and
9 uninsured).

10 “(ii) With respect to each such child
11 site of such entity, the total costs incurred
12 at each such site and the cost incurred at
13 each such site for charity care as defined
14 in line 23 of worksheet S-10 to the Medi-
15 care cost report or in any successor form.

16 “(B) The aggregate amount of gross reim-
17 bursement received by each such covered entity
18 (including child sites of such entity) described
19 in such subparagraph (L) or (M) for all drugs
20 purchased that are subject to an agreement
21 under this section and the entity’s aggregate
22 acquisition cost for such drugs.

23 “(C) In the case of covered entity de-
24 scribed in subparagraph (L) of subsection
25 (a)(4), at the time of application and recertifi-

1 cation (and at least annually thereafter), the
2 contract that is the basis for eligibility under
3 the requirement under clause (i) of such sub-
4 paragraph and any modifications to such con-
5 tract for purposes of review by the Secretary.

6 “(D) With respect to such covered entity
7 and with respect to each child site of such enti-
8 ty, the name of all third-party vendors or other
9 similar entities that the covered entity contracts
10 with to provide services associated with the pro-
11 gram under this section.

12 “(2) AVAILABILITY OF INFORMATION.—

13 “(A) IN GENERAL.—The Secretary shall
14 make data reported by covered entities under
15 subparagraphs (A), (C), and (D) of paragraph
16 (1) available on the public website of the De-
17 partment of Health and Human Services in an
18 electronic and searchable format, which may in-
19 clude the 340B Office of Pharmacy Affairs In-
20 formation System or a successor to such sys-
21 tem.

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

1 covered entities described in subparagraphs (L)
2 and (M) of subsection (a)(4) and child sites of
3 such covered entities. In carrying out this para-
4 graph, with respect to data reported pursuant
5 to paragraph (1)(C), the Secretary shall ensure
6 that any proprietary information shall be re-
7 dacted from contracts submitted pursuant to
8 such paragraph (1)(C) before posting such
9 data.

10 “(3) INTERIM FINAL REGULATIONS.—The Sec-
11 retary shall issue interim final regulations no later
12 than the date that is 6 months after the date of the
13 enactment of this subsection, to carry out this sub-
14 section and shall finalize such regulations prior to
15 the end of the moratorium period to which sub-
16 section (a)(11) applies.

17 “(4) REPORTS TO CONGRESS.—

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

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

3 “(B) GAO REPORTS.—

4 “(i) INITIAL REPORT.—Not later than
5 1 year after the date of the enactment of
6 this subsection, the Comptroller General of
7 the United States shall submit to Congress
8 a report—

9 “(I) analyzing the State and local
10 government contracts intended to sat-
11 isfy the requirement under subsection
12 (a)(4)(L)(i) for a covered entity to
13 qualify as an entity described in sub-
14 paragraph (L) of subsection (a)(4);

15 “(II) assessing the amount of
16 care such contracts obligate such enti-
17 ty to provide to low-income individuals
18 ineligible for Medicare under title
19 XVIII of the Social Security Act and
20 Medicaid under title XIX of such Act;
21 and

22 “(III) analyzing how these con-
23 tracts define low-income individuals
24 and whether the Secretary reviews
25 such determinations.

1 “(ii) SUBSEQUENT REPORT.—Not
2 later than 2 years after the date of the en-
3 actment of this subsection, the Comptroller
4 General of the United States shall submit
5 to Congress a final report on the informa-
6 tion collected under paragraph (1)(B) re-
7 garding the difference between the aggre-
8 gate gross reimbursement and aggregate
9 acquisition costs received by each such cov-
10 ered entity (including child sites of such
11 entity) for drugs subject to an agreement
12 under this section.”.

13 **SEC. 327. 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 one
22 year after the date of enactment of the Act, by re-
23 quiring covered entities described in subsection
24 (a)(4)(L) to submit (and to so regularly update) in-
25 formation described in subparagraph (C)”;

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

3 “(C) INFORMATION ON LOW-INCOME UTI-
4 LIZATION RATE OF OUTPATIENT HOSPITAL
5 SERVICES.—

6 “(i) IN GENERAL.—For purposes of
7 subparagraph (B)(i), the information de-
8 scribed in this subparagraph, with respect
9 to a covered entity described in subsection
10 (a)(4)(L) and an update under such sub-
11 paragraph (B)(i), is—

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

15 “(II) the low-income outpatient
16 utilization rate of off-site outpatient
17 facilities, clinics, eligible off-site loca-
18 tions, and associated sites of such en-
19 tity identified as child sites of such
20 entity pursuant to the identification
21 system under subparagraph (B)(iv)
22 for the most recent fiscal year.

23 “(ii) LOW-INCOME OUTPATIENT UTI-
24 LIZATION RATE DEFINED.—In this sub-
25 paragraph, the term ‘low-income outpatient

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

5 “(I) clauses (i) and (ii) of sub-
6 paragraph (A) of such paragraph
7 shall be applied as if—

8 “(aa) each reference to ‘pa-
9 tient services’ were a reference to
10 ‘patient services furnished on an
11 outpatient basis’; and

12 “(bb) for purposes of clause
13 (i)(II) of this subparagraph, each
14 reference to ‘hospital’ were a ref-
15 erence to ‘off-site outpatient fa-
16 cilities, clinics, eligible off-site lo-
17 cations, and associated sites of
18 the hospital that are identified as
19 child sites of the hospital pursu-
20 ant to the identification system
21 under section 340B(d)(2)(B)(iv)
22 of the Public Health Service Act’;
23 and

1 “(II) clauses (i) and (ii) of sub-
2 paragraph (B) of such paragraph
3 shall be applied as if—

4 “(aa) each reference to ‘in-
5 patient hospital services’ were a
6 reference to ‘outpatient hospital
7 services’; and

8 “(bb) for purposes of clause
9 (i)(II) each reference to ‘hos-
10 pital’s charges’ were a reference
11 to ‘charges of the off-site out-
12 patient facilities, clinics, eligible
13 off-site locations, and associated
14 sites of the hospital that are
15 identified as child sites of the
16 hospital pursuant to the identi-
17 fication system under section
18 340B(d)(2)(B)(iv) of the Public
19 Health Service Act’.”.

20 (b) ANNUAL REPORTS.—Not later than 1 year after
21 the date of enactment of this Act, and annually thereafter,
22 the Administrator of the Health Resources and Services
23 Administration shall submit to Congress a report on infor-
24 mation submitted by covered entities for the previous year
25 pursuant to the amendments made by subsection (a).

1 **SEC. 328. EMPLOYER BENEFITS REPORTS.**

2 (a) IN GENERAL.—Subject to subsection (b), for each
3 plan year beginning on or after 1 year after the date of
4 enactment of this Act, a group health plan and a health
5 insurance issuer offering group health insurance coverage
6 shall provide to each individual enrolled in such plan or
7 such coverage for such plan year a notification containing
8 the following:

9 (1) The amount the sponsor of such group
10 health plan expended with respect to such individual
11 under such plan for such plan year (or, in the case
12 of a health insurance issuer offering group health in-
13 surance coverage, the amount the employer of such
14 individual contributed for such coverage for such in-
15 dividual for such plan year).

16 (2) The amount the sponsor of such group
17 health plan expended with respect to such individual
18 under such plan for each previous plan year (or, in
19 the case of a health insurance issuer offering group
20 health insurance coverage, the amount the employer
21 of such individual contributed for such coverage for
22 such individual for each previous plan year), if appli-
23 cable.

24 (b) LIMITATION.—Subsection (a) shall not apply to
25 a group health plan, or a health insurance issuer offering
26 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. 329. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**
19 **ON PROFIT- AND REVENUE-SHARING IN**
20 **HEALTH CARE.**

21 (a) STUDY.—Not later than 1 year after the date of
22 enactment of this Act, the Comptroller General of the
23 United States shall conduct a study to—

24 (1) describe what is known about profit- and
25 revenue-sharing relationships in the commercial

1 health care markets, including those relationships
2 that—

3 (A) involve one or more—

4 (i) physician groups that practice
5 within a hospital included in the profit- or
6 revenue-sharing relationship, or refer pa-
7 tients to such hospital;

8 (ii) laboratory, radiology, or pharmacy
9 services that are delivered to privately in-
10 sured patients of such hospital;

11 (iii) surgical services;

12 (iv) hospitals or group purchasing or-
13 ganizations; or

14 (v) rehabilitation or physical therapy
15 facilities or services; and

16 (B) include revenue- or profit-sharing
17 whether through a joint venture, management
18 or professional services agreement, or other
19 form of gain-sharing contract;

20 (2) describe Federal oversight of such relation-
21 ships, including authorities of the Department of
22 Health and Human Services and the Federal Trade
23 Commission to review such relationships and their
24 potential to increase costs for patients, and identify
25 limitations in such oversight; and

1 (3) as appropriate, make recommendations to
2 improve Federal oversight of such relationships.

3 (b) REPORT.—Not later than 1 year after the date
4 of enactment of this Act, the Comptroller General of the
5 United States shall prepare and submit a report on the
6 study conducted under subsection (a) to the Committee
7 on Health, Education, Labor, and Pensions of the Senate
8 and the Committee on Education and Labor and Com-
9 mittee on Energy and Commerce of the House of Rep-
10 resentatives.

11 **Subtitle C—Prescription Drug**
12 **Competition and Innovation**

13 **SEC. 341. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
14 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
15 **UCTS.**

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

19 **“SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
20 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
21 **UCTS.**

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

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

5 “(c) DESIGNATION PROCESS.—

6 “(1) IN GENERAL.—Not later than 60 calendar
7 days after the receipt of a request under subsection
8 (c), the Secretary shall determine whether the prod-
9 uct that is the subject of the request meets the cri-
10 teria under subsection (e) to be considered a generic
11 complex drug product. If the Secretary determines
12 that the product meets the criteria, the Secretary
13 shall designate the product for expedited develop-
14 ment and priority review.

15 “(2) REVIEW.—Review of a request under sub-
16 section (b) shall be undertaken by a team that is
17 composed of experienced staff and senior managers
18 of the Food and Drug Administration.

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

24 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
25 VIEW GUIDANCE.—

1 “(1) CONTENT.—Not later than 1 year after
2 the date of enactment of this Act, the Secretary
3 shall issue guidance on the implementation of this
4 section. Such guidance shall—

5 “(A) set forth the process by which a per-
6 son may seek a designation under subsection
7 (c);

8 “(B) provide a template for requests under
9 subsection (b);

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

13 “(D) identify the criteria and processes the
14 Secretary will use to expedite the development
15 and review of products designated under this
16 section.

17 “(2) PROCESS.—Prior to finalizing the guid-
18 ance under paragraph (1), the Secretary shall seek
19 public comment on a draft version of that guidance.

20 “(e) GENERIC COMPLEX DRUG PRODUCT DE-
21 FINED.—In this section, the term ‘generic complex drug
22 product’ means a product that represents a complex ther-
23 apy that consists of or includes a drug for approval under
24 section 505(j) and that—

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

5 “(B) is composed of complex formulations (such
6 as liposomes or colloids);

7 “(C) requires a complex route of delivery (such
8 as locally acting drugs such as dermatological prod-
9 ucts and complex ophthalmological products and otic
10 dosage forms that are formulated as suspensions,
11 emulsions, or gels); or

12 “(D) involves a complex dosage form (such as
13 transdermals, metered dose inhalers, or extended re-
14 lease injectables);

15 “(2) presents as a complex drug-device com-
16 bination product (such as auto injectors or metered
17 dose inhalers); or

18 “(3) is a product that would benefit from early
19 scientific engagement due to complexity or uncer-
20 tainty concerning the approval pathway under sec-
21 tion 505(j).”.

22 **SEC. 342. PREVENTING BLOCKING OF GENERIC DRUGS.**

23 (a) IN GENERAL.—Section 505(j)(5)(B)(iv)(I) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 355(j)(5)(B)(iv)(I)) is amended—

1 (1) by striking “180 days after the date” and
2 inserting “180 days after the earlier of the fol-
3 lowing:

4 “(aa) The date”; and

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

6 “(bb) The date on which all of the fol-
7 lowing conditions are first met, provided
8 no application submitted by any first appli-
9 cant is approved on or before such date:

10 “(AA) An application for the
11 drug submitted by an applicant other
12 than a first applicant has received
13 tentative approval and could receive
14 approval, if no first applicant were eli-
15 gible for 180-day exclusivity under
16 this clause, and such applicant has
17 not entered into an agreement that
18 would prevent commercial marketing
19 upon approval and has submitted a
20 notification to the Secretary docu-
21 menting that it has not entered into
22 an agreement that would prevent com-
23 mercial marketing.

24 “(BB) Thirty-three months have
25 passed since the date of submission of

1 an application for the drug by one
2 first applicant, if there is only one
3 first applicant, or, in the case of more
4 than one first applicant, 33 months
5 have passed since the date of submis-
6 sion of all such applications.

7 “(CC) Approval of an application
8 for the drug submitted by at least one
9 first applicant would not be precluded
10 under clause (iii).”.

11 (b) INFORMATION.—Not later than 60 days of the
12 date of enactment of this Act, the Secretary of Health and
13 Human Services (referred to in this subsection as the
14 “Secretary”) shall publish, as appropriate and available,
15 information sufficient to allow applicants to assess wheth-
16 er the conditions described in subitems (AA) through (CC)
17 of section 505(j)(5)(B)(iv)(I)(bb) of the Federal Food,
18 Drug, and Cosmetic Act (as amended by subsection (a))
19 have been or will be satisfied for all applications where
20 the exclusivity period under (iv)(I) of section 505(j)(5)(B)
21 of the Federal Food, Drug, and Cosmetic Act (as so
22 amended) has not expired, and shall provide updates to
23 reflect the most recent information available to the Sec-
24 retary.

1 **SEC. 343. ENSURING TIMELY ACCESS TO GENERICS.**

2 Section 505(q) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 355(q)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)(i), by inserting “,
6 10.31,” after “10.30”;

7 (B) in subparagraph (E)—

8 (i) by striking “application and” and
9 inserting “application or”;

10 (ii) by striking “If the Secretary” and
11 inserting the following:

12 “(i) IN GENERAL.—If the Secretary”;

13 and

14 (iii) by striking the second sentence
15 and inserting the following:

16 “(ii) PRIMARY PURPOSE OF DELAY-
17 ING.—

18 “(I) IN GENERAL.—In deter-
19 mining whether a petition was sub-
20 mitted with the primary purpose of
21 delaying an application, the Secretary
22 may consider the following factors:

23 “(aa) Whether the petition
24 was submitted in accordance with
25 paragraph (2)(B), based on when
26 the petitioner knew or reasonably

1 should have known the relevant
2 information relied upon to form
3 the basis of such petition.

4 “(bb) Whether the petitioner
5 has submitted multiple or serial
6 petitions or supplements to peti-
7 tions raising issues that reason-
8 ably could have been known to
9 the petitioner at the time of sub-
10 mission of the earlier petition or
11 petitions.

12 “(cc) Whether the petition
13 was submitted close in time to a
14 known, first date upon which an
15 application under subsection
16 (b)(2) or (j) of this section or
17 section 351(k) of the Public
18 Health Service Act could be ap-
19 proved.

20 “(dd) Whether the petition
21 was submitted without relevant
22 data or information in support of
23 the scientific positions forming
24 the basis of such petition.

1 “(ee) Whether the petition
2 raises the same or substantially
3 similar issues as a prior petition
4 to which the Secretary has re-
5 sponded substantively already, in-
6 cluding if the subsequent submis-
7 sion follows such response from
8 the Secretary closely in time.

9 “(ff) Whether the petition
10 requests changing the applicable
11 standards that other applicants
12 are required to meet, including
13 requesting testing, data, or label-
14 ing standards that are more on-
15 erous or rigorous than the stand-
16 ards the Secretary has deter-
17 mined to be applicable to the list-
18 ed drug, reference product, or pe-
19 titioner’s version of the same
20 drug.

21 “(gg) The petitioner’s record
22 of submitting petitions to the
23 Food and Drug Administration
24 that have been determined by the
25 Secretary to have been submitted

1 with the primary purpose of
2 delay.

3 “(hh) Other relevant and
4 appropriate factors, which the
5 Secretary shall describe in guid-
6 ance.

7 “(II) GUIDANCE.—The Secretary
8 may issue or update guidance, as ap-
9 propriate, to describe factors the Sec-
10 retary considers in accordance with
11 subclause (II).”;

12 (C) by adding at the end the following:

13 “(iii) REFERRAL TO THE FEDERAL
14 TRADE COMMISSION.—The Secretary shall
15 establish procedures for referring to the
16 Federal Trade Commission any petition or
17 supplement to a petition that the Secretary
18 determines was submitted with the primary
19 purpose of delaying approval of an applica-
20 tion. Such procedures shall include notifi-
21 cation to the petitioner by the Secretary.”;

22 (D) by striking subparagraph (F);

23 (E) by redesignating subparagraphs (G)
24 through (I) as subparagraphs (F) through (H),
25 respectively; and

1 (F) in subparagraph (H), as so redesignated,
2 nated, by striking “submission of this petition”
3 and inserting “submission of this document”;
4 (2) in paragraph (2)—

5 (A) by redesignating subparagraphs (A)
6 through (C) as subparagraphs (C) through (E),
7 respectively;

8 (B) by inserting before subparagraph (C),
9 as so redesignated, the following:

10 “(A) IN GENERAL.—A person shall submit
11 a petition to the Secretary under paragraph (1)
12 before filing a civil action in which the person
13 seeks to set aside, delay, rescind, withdraw, or
14 prevent submission, review, or approval of an
15 application submitted under subsection (b)(2)
16 or (j) of this section or section 351(k) of the
17 Public Health Service Act. Such petition and
18 any supplement to such a petition shall describe
19 all information and arguments that form the
20 basis of the relief requested in any civil action
21 described in the previous sentence.

22 “(B) TIMELY SUBMISSION OF CITIZEN PE-
23 TITION.—A petition and any supplement to a
24 petition shall be submitted within 60 days after
25 the person knew, or reasonably should have

1 known, the information that forms the basis of
2 the request made in the petition or supple-
3 ment.”;

4 (C) in subparagraph (C), as so redesignig-
5 nated—

6 (i) in the heading, by striking “WITH-
7 IN 150 DAYS”;

8 (ii) in clause (i), by striking “during
9 the 150-day period referred to in para-
10 graph (1)(F),”; and

11 (iii) by amending clause (ii) to read as
12 follows:

13 “(ii) on or after the date that is 151
14 days after the date of submission of the
15 petition, the Secretary approves or has ap-
16 proved the application that is the subject
17 of the petition without having made such a
18 final decision.”;

19 (D) by amending subparagraph (D), as so
20 redesignated, to read as follows:

21 “(D) DISMISSAL OF CERTAIN CIVIL AC-
22 TIONS.—

23 “(i) PETITION.—If a person files a
24 civil action against the Secretary in which
25 a person seeks to set aside, delay, rescind,

1 withdraw, or prevent submission, review, or
2 approval of an application submitted under
3 subsection (b)(2) or (j) of this section or
4 section 351(k) of the Public Health Service
5 Act without complying with the require-
6 ments of subparagraph (A), the court shall
7 dismiss without prejudice the action for
8 failure to exhaust administrative remedies.

9 “(ii) TIMELINESS.—If a person files a
10 civil action against the Secretary in which
11 a person seeks to set aside, delay, rescind,
12 withdraw, or prevent submission, review, or
13 approval of an application submitted under
14 subsection (b)(2) or (j) of this section or
15 section 351(k) of the Public Health Service
16 Act without complying with the require-
17 ments of subparagraph (B), the court shall
18 dismiss with prejudice the action for fail-
19 ure to timely file a petition.

20 “(iii) FINAL RESPONSE.—If a civil ac-
21 tion is filed against the Secretary with re-
22 spect to any issue raised in a petition time-
23 ly filed under paragraph (1) in which the
24 petitioner requests that the Secretary take
25 any form of action that could, if taken, set

1 aside, delay, rescind, withdraw, or prevent
2 submission, review, or approval of an appli-
3 cation submitted under subsection (b)(2)
4 or (j) of this section or section 351(k) of
5 the Public Health Service Act before the
6 Secretary has taken final agency action on
7 the petition within the meaning of sub-
8 paragraph (C), the court shall dismiss
9 without prejudice the action for failure to
10 exhaust administrative remedies.”; and

11 (E) in clause (iii) of subparagraph (E), as
12 so redesignated, by striking “as defined under
13 subparagraph (2)(A)” and inserting “within the
14 meaning of subparagraph (C)”;

15 (3) in paragraph (4)—

16 (A) by striking “EXCEPTIONS” and all that
17 follows through “This subsection does” and in-
18 serting “EXCEPTIONS.—This subsection does”;

19 (B) by striking subparagraph (B); and

20 (C) by redesignating clauses (i) and (ii) as
21 subparagraphs (A) and (B), respectively, and
22 adjusting the margins accordingly.

1 **SEC. 344. PREEMPTION OF STATE BARRIERS TO THE SUB-**
2 **STITUTION OF BIOSIMILAR PRODUCTS.**

3 No State, or any political subdivision thereof, may,
4 under any circumstances, prohibit a pharmacy or phar-
5 macist from dispensing, in place of a biological reference
6 product, any biosimilar that the Food and Drug Adminis-
7 tration has designated as an interchangeable product for
8 that biological reference product.

9 **SEC. 345. INCREASING PHARMACEUTICAL OPTIONS TO**
10 **TREAT AN UNMET MEDICAL NEED.**

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

14 “(4) UNMET MEDICAL NEED.—For purposes of
15 paragraph (1), a drug shall be deemed to address an
16 unmet medical need for a disease or condition if
17 fewer than 3 available drugs exist for the treatment
18 of such disease or condition.”.

19 **SEC. 346. PROVISIONAL APPROVAL OF NEW HUMAN DRUGS.**

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

23 **“SEC. 524B. PROVISIONAL APPROVAL OF NEW HUMAN**
24 **DRUGS.**

25 “(a) PRIORITY REVIEW AND EVALUATION OF APPLI-
26 CATIONS.—

1 “(1) IN GENERAL.—The Secretary shall estab-
2 lish a priority review system to evaluate applications
3 submitted under this pathway for provisional ap-
4 proval within 90 days of receipt of a completed ap-
5 plication.

6 “(2) REVIEW OF APPLICATIONS DURING
7 EPIDEMICS AND PANDEMICS.—In the case of an epi-
8 demic or pandemic, including with respect to
9 COVID–19, the Secretary shall accept and review
10 various portions of an application submitted under
11 the pathway under this section for provisional ap-
12 proval on a rolling basis, and the review of any part
13 of an application so submitted shall be completed
14 not later than 3 weeks after submission.

15 “(3) OTHER DESIGNATIONS.—If a drug sub-
16 mitted for review under the pathway under this sec-
17 tion is eligible for a special designation by the Sec-
18 retary under this Act, including as a drug for a rare
19 disease or condition under section 526, all benefits
20 of such other designation shall be available for use
21 under provisional approval, including any tax credits
22 and waiving of fees under chapter VII.

23 “(b) ELIGIBILITY.—A drug may be eligible for provi-
24 sional approval under this section if the Secretary deter-

1 mines that the drug is intended for the treatment, preven-
2 tion, or medical diagnosis of—

3 “(1) a serious or life-threatening disease or con-
4 dition for which there is a reasonable likelihood that
5 premature death will occur without early medical
6 intervention for an individual contracting or being
7 diagnosed with such disease or condition;

8 “(2) a disease or condition that poses a threat
9 of epidemic or pandemic; or

10 “(3) a disease or condition associated with mor-
11 bidity that has a substantial impact on day-to-day
12 functioning.

13 “(c) STANDARD OF REVIEW FOR APPROVAL.—

14 “(1) REQUIREMENTS.—An application for pro-
15 visional approval under this section may be approved
16 only if the Secretary determines that—

17 “(A) there is substantial evidence of safety
18 for the drug, such that there is evidence con-
19 sisting of adequate and well-controlled inves-
20 tigations, including clinical investigations, by
21 experts qualified by scientific training and expe-
22 rience to evaluate the safety of the drug in-
23 volved, on the basis of which it could fairly and
24 responsibly be concluded that the drug will have
25 the effect it purports or is represented to have

1 under the conditions of use prescribed, rec-
2 ommended, or suggested in the labeling or pro-
3 posed labeling; and

4 “(B) there is relevant early evidence based
5 on adequate and well-controlled investigations,
6 including early-stage clinical investigations, to
7 establish that—

8 “(i) the drug provides a positive
9 therapeutic outcome; and

10 “(ii) the outcome of the drug is con-
11 sistent with or greater than currently mar-
12 keted on-label therapies, with equal or
13 fewer side effects, if there are currently
14 marketed on-label therapies.

15 “(2) PROTOCOLS.—The Secretary shall promul-
16 gate rules that establish the appropriate protocols
17 for a sponsor of an application for provisional ap-
18 proval under this section and the Commissioner to
19 follow to enable rolling, real-time, mid-trial submis-
20 sion while preserving the integrity of the ongoing
21 trial and without penalizing the sponsor for making
22 use of this pathway.

23 “(3) REAL WORLD EVIDENCE.—The Secretary
24 shall allow the use of real world evidence (as defined
25 in section 505F(b)), including real world data used

1 to generate real world evidence, to support an appli-
2 cation for provisional approval under this section,
3 and to fulfill the follow-up requirements and support
4 applications for full approval as described under sec-
5 tion 505 or section 351 of the Public Health Service
6 Act, as applicable.

7 “(4) USE OF SCIENTIFICALLY SUBSTANTIATED
8 SURROGATES.—

9 “(A) IN GENERAL.—The sponsor of an ap-
10 plication for provisional approval under this sec-
11 tion may use scientifically substantiated surro-
12 gates to support such application.

13 “(B) DEFINITION.—In subparagraph (A),
14 the term ‘scientifically substantiated surrogates’
15 means surrogate endpoints to predict clinical
16 benefit other than such endpoints previously
17 validated by the Secretary, based on—

18 “(i) epidemiologic, therapeutic, patho-
19 physiologic, or other evidence; or

20 “(ii) an effect on a clinical endpoint
21 other than survival or irreversible mor-
22 bidity of interest.

23 “(d) TRANSPARENCY AND PATIENT MONITORING
24 REQUIREMENTS.—

25 “(1) REGISTRIES.—

1 “(A) IN GENERAL.—The sponsor of a drug
2 provisionally approved under this section shall
3 require that all patients who use such drug par-
4 ticipate in an observational registry and consent
5 to the sponsor’s collection, and submission to
6 the registry, of data related to the patient’s use
7 of such drug until such drug receives full ap-
8 proval under section 505 or section 351 of the
9 Public Health Service Act, or the provisional
10 approval is rescinded.

11 “(B) REQUIREMENTS FOR REGISTRIES.—
12 An observational registry described in subpara-
13 graph (A) may be run by a third party, such as
14 a government, for profit, or non-profit organiza-
15 tion, and shall track all patients who use the
16 provisionally approved drug.

17 “(C) ACCESSIBILITY.—An observational
18 registry described in subparagraph (A) shall be
19 easily accessible for—

20 “(i) all patients who are participating
21 in any registry related to a provisionally
22 approved drug that allows for easy, unre-
23 stricted (or transparent) access for such
24 patients to their patient data and related

1 information regarding their usage of the
2 provisionally approved drug; and

3 “(ii) approved researchers and med-
4 ical professionals who may access data
5 maintained in the registry, which access
6 shall be for public health research and only
7 in a de-identified, aggregated manner.

8 “(2) FUNDING.—An observational registry
9 under this subsection shall be maintained, as appli-
10 cable—

11 “(A) by the sponsor of the drug provision-
12 ally approved under this section that is the sub-
13 ject of the registry;

14 “(B) by a third party, such as a govern-
15 ment, for profit, or nonprofit organization; or

16 “(C) the Federal Government, in the case
17 of any drug so approved that is intended to
18 treat a disease or condition associated with an
19 epidemic or pandemic.

20 “(3) SPONSOR REQUIREMENTS.—

21 “(A) IN GENERAL.—For any drug applica-
22 tion provisionally approved under this section,
23 the Secretary shall notify the sponsor of the
24 exact data such sponsor is required to submit
25 to an observational registry.

1 “(B) ANNUAL REVIEW OF THE REGISTRY;
2 PENALTIES.—The Secretary shall conduct an
3 annual review of observational registries estab-
4 lished under this subsection. If, at such an an-
5 nual review, less than 90 percent of patients are
6 participating in an observational registry with
7 respect to a drug approved under this section,
8 the Secretary shall issue to the sponsor of such
9 drug a civil monetary penalty of not more than
10 \$100,000. If a violation of this section is not
11 corrected within the 30-day period following no-
12 tification, the sponsor shall, in addition to any
13 penalty under this subparagraph be subject to
14 a civil monetary penalty of not more than
15 \$10,000 for each day of the violation after such
16 period until the violation is corrected. If appli-
17 cation patient participation in an observational
18 registry is not at or above 90 percent within 6
19 months of issuance of such penalty, the provi-
20 sional approval shall be withdrawn.

21 “(4) ANNUAL REPORT TO CONGRESS.—The
22 Secretary shall submit an annual report to Congress
23 on all drugs granted provisional approval under this
24 section. Such report shall include—

1 “(A) the number of patients treated with
2 each such drug, and the number of patients
3 tracked in an observational registry with re-
4 spect to each such drug;

5 “(B) a discussion of the minimum amount
6 of data required in the registries, including pa-
7 tient treatments and uses, length of use, side
8 effects encountered, relevant biomarkers or sci-
9 entifically substantiated surrogates, scan re-
10 sults, cause of death and how long the patient
11 lived, and adverse drug effects;

12 “(C) a list of all such drugs for which an
13 application for full approval under section 505
14 of this Act or section 351 of the Public Health
15 Service Act, or an application for an extension
16 of provisional approval under this section, has
17 been submitted; and

18 “(D) a list of all applications denied provi-
19 sional approval under this section, together with
20 an explanation for the decisions to deny each
21 such application.

22 “(e) WITHDRAWAL OF PROVISIONAL APPROVAL.—

23 “(1) IN GENERAL.—The Secretary shall with-
24 draw provisional approval under this section if there
25 are a significant number of patients who experience

1 serious adverse effects, compared to the other cur-
2 rently marketed on-label therapies that are available
3 for the applicable disease or condition.

4 “(2) EFFECT OF WITHDRAWAL.—If a provi-
5 sional approval is withdrawn under this subsection,
6 the sponsor may not make the drug available to any
7 new patients, but may be allowed to continue to
8 make such drug available to patients who started
9 taking the drug prior to the date of withdrawal, for
10 as long a period as dictated by patient need, as de-
11 termined by the Secretary.

12 “(f) TRANSPARENCY.—Any scientific, medical, aca-
13 demic, or health care journal publishing an article explain-
14 ing, releasing, conveying or announcing research findings
15 which were funded by the Department of Health and
16 Human Services shall be prohibited from publishing such
17 research unless—

18 “(1) such article conveying research findings is
19 made publicly available on the journal’s internet
20 website without a paywall or charge not later than
21 3 months after the date on which such article was
22 first provided to subscribers of such journal (or first
23 made available for purchase); and

24 “(2) the article’s author or researcher or au-
25 thor’s institution (or, in the case of multiple authors,

1 researchers, or institutions, all such authors, re-
2 searchers, or institutions) received less than 30 per-
3 cent of funding for such research from the Depart-
4 ment of Health and Human Services throughout the
5 period of time the research was conducted.

6 “(g) INFORMED CONSENT.—Prior to receiving a drug
7 provisionally approved under this section, the sponsor of
8 the drug shall receive from each patient, or the patient’s
9 representative, informed consent, through a signed in-
10 formed consent form, acknowledging that such patient un-
11 derstands that the drug did not undergo the usual process
12 for full approval of a drug by the Food and Drug Adminis-
13 tration, and that such patient is willing to accept the risks
14 involved in taking such drug.

15 “(h) POSTMARKET CONTROLS AND LABELING.—

16 “(1) FDA ANNUAL REVIEW OF REGISTRY
17 DATA.—The Secretary shall annually review the data
18 made available through the observational registries
19 under subsection (d) and make a determination re-
20 garding whether the side effect profile of any drug
21 approved under this pathway does not support the
22 benefit provided, or the data shows the benefit is
23 less than the benefits offered through other, fully
24 approved drugs.

1 “(2) LABELING.—The sponsor of the provision-
2 ally approved drug shall ensure that all labeling and
3 promotional materials for the drug bear the state-
4 ment ‘provisionally approved by the FDA pending a
5 full demonstration of effectiveness under application
6 number _____’ (specifying the application
7 number assigned by the Secretary in place of the
8 blank). All promotional, educational and marketing
9 materials for provisionally approved products shall
10 be reviewed and approved by the Secretary before
11 such materials are distributed.

12 “(3) RESCISSION OF PROVISIONAL AP-
13 PROVAL.—If the Secretary determines that the side
14 effect profile of any drug included in such observa-
15 tional registries does not support the benefit pro-
16 vided by such drug, or that the data shows that the
17 benefit is less than the benefits offered through
18 other, fully approved drugs, the Secretary shall re-
19 scind such provisional approval.

20 “(i) DURATION OF PROVISIONAL APPROVAL; RE-
21 QUIREMENT TO BRING DRUG TO MARKET.—

22 “(1) DURATION; RENEWALS.—The period of
23 provisional approval for a drug approved under this
24 section is effective for a 2-year period. The sponsor
25 may request renewal for provisional approval status

1 for up to 3 subsequent 2-year periods by the Sec-
2 retary. Provisional approval status with respect to a
3 drug shall not exceed a total of 6 years from the ini-
4 tial date the sponsor was awarded provisional ap-
5 proval status.

6 “(2) **MARKETING REQUIREMENT.**—If any drug
7 that receives provisional approval status under this
8 section is not brought to market within 180 days of
9 the approval, such approval shall be rescinded.

10 “(j) **LIMITATION ON LIABILITY.**—With respect to any
11 claim under State law alleging that a drug sold or other-
12 wise made available pursuant to a grant of provisional ap-
13 proval under this section is unsafe or ineffective, no liabil-
14 ity in a cause of action shall lie against a sponsor or manu-
15 facturer, unless the relevant conduct constitutes reckless
16 or willful misconduct, gross negligence, or an intentional
17 tort under any applicable State law.

18 “(k) **APPLYING FOR FULL APPROVAL.**—

19 “(1) **IN GENERAL.**—Except as provided under
20 paragraph (2), the sponsor of a drug granted provi-
21 sional approval pursuant to this section may, at any
22 point, submit an application for full approval of such
23 drug under section 505 of this Act or section 351
24 of the Public Health Service Act, as applicable.

1 “(2) EFFECT OF RECESSION ON APPROVAL AND
2 AUTOMATIC APPROVAL.—

3 “(A) IN GENERAL.—The sponsor of a drug
4 granted provisional approval pursuant to this
5 section that has been rescinded under sub-
6 section (h)(3), may submit an application for
7 full approval of such drug under section 505 of
8 this Act or section 351 of the Public Health
9 Service Act at any time.

10 “(B) AUTOMATIC APPROVAL.—Such full
11 approval may be awarded at any time for any
12 drug granted provisional approval pursuant to
13 this section if the sponsor of the drug estab-
14 lishes a 15 percent improvement in an impor-
15 tant endpoint, including surrogate endpoints
16 not validated by the Food and Drug Adminis-
17 tration, compared to a standard drug.

18 “(3) REAL-TIME EPIDEMIC AND PANDEMIC VAC-
19 CINE APPROVAL.—

20 “(A) IN GENERAL.—In the case of a vac-
21 cine developed in response to an epidemic or
22 pandemic, including COVID–19, the Secretary
23 shall share data information regarding the ap-
24 proval of the vaccine with the Advisory Com-
25 mittee on Immunization Practices of the Cen-

1 ters for Disease Control and Prevention as the
2 review nears completion.

3 “(B) EVALUATION.—Any vaccine that has
4 been approved by the Secretary for an epidemic
5 or pandemic-related disease, including COVID–
6 19, shall be evaluated by the Advisory Com-
7 mittee on Immunization Practices of the Cen-
8 ters for Disease Control and Prevention not
9 later than 1 week after the date of submission
10 to the Advisory Committee by the Secretary of
11 the vaccine.

12 “(I) PATIENT ADVOCATE GENERAL.—Not later than
13 6 months after the date of enactment of the Promising
14 Pathway Act, the Secretary shall establish within the Of-
15 fice of the Commissioner, the position of Patient Advocate
16 General, who shall provide assistance to patients and their
17 families who use drugs under evaluation in this pathway
18 or drugs reviewed or approved under section 505 or sec-
19 tion 351 of the Public Health Service Act. Such assistance
20 shall include providing bi-informational communication
21 about maintaining patient health, delivery of proper in-
22 formed consent, participating in clinical investigations,
23 completing required documentation in order to participate
24 in the applicable programs, and providing other informa-
25 tion.”.

1 (b) CONFORMING AMENDMENT.—Section 505(a) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(a)) is amended by inserting “, or there is in effect
4 a provisional approval under section 524B with respect to
5 such drug” before the period.

6 (c) REIMBURSEMENT.—

7 (1) PRIVATE HEALTH INSURERS.—Section
8 2719A of the Public Health Service Act (42 U.S.C.
9 300gg–19a) is amended by adding at the end the
10 following:

11 “(e) TREATMENT OF CERTAIN DRUGS.—A group
12 health plan or health insurance issuer of group or indi-
13 vidual health insurance coverage shall not deny coverage
14 of any drug provisionally approved under section 524B of
15 the Federal Food, Drug, and Cosmetic Act on the basis
16 of such drug being experimental. In determining coverage
17 under the applicable plan or coverage, a group health plan
18 or health insurance issuer shall treat a drug provisionally
19 approved under such section in the same manner as such
20 plan or coverage would treat a drug approved under sec-
21 tion 505 of the Federal Food, Drug, and Cosmetic Act
22 or section 351 of this Act. Nothing in this subsection shall
23 be construed to require a group health plan or health in-
24 surance issuer to cover any specific drug provisionally ap-
25 proved under such section 524B.”.

1 (2) FEDERAL HEALTH CARE PROGRAMS.—The
2 requirement under subsection (e) of section 2719A
3 of the Public Health Service Act (as added by para-
4 graph (1)) shall apply with respect to coverage de-
5 terminations under a Federal health care program
6 (as defined in section 1128B(f) of the Social Secu-
7 rity Act (42 U.S.C. 1320a–7b(f))) in the same man-
8 ner such requirement applies under such subsection
9 (e).

10 (3) CONFORMING AMENDMENT.—Section
11 1927(k)(2)(A)(i) of the Social Security Act (42
12 U.S.C. 1396r–8(k)(2)(A)(i)) is amended—

13 (A) by striking “or which” and inserting “,
14 which”; and

15 (B) by inserting “, or which is provision-
16 ally approved under section 524B of such Act”
17 before the semicolon.

18 **SEC. 347. CONSOLIDATING EXCLUSIVITY PERIODS FOR**
19 **DRUGS TREATING RARE DISEASES AND CON-**
20 **DITIONS.**

21 (a) IN GENERAL.—Subsection (a) of section 527 of
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 360cc) is amended to read as follows:

24 “(a) EXCLUSIVITY.—

1 “(1) IN GENERAL.—Except as provided in sub-
2 section (b), if the Secretary approves an application
3 filed pursuant to section 505, or issues a license
4 under section 351 of the Public Health Service Act,
5 for a drug designated under section 526 for a rare
6 disease or condition, the Secretary may not approve
7 an application filed pursuant to section 505, or issue
8 a license under section 351 of the Public Health
9 Service Act, for the same drug for the same disease
10 or condition for a person who is not the holder of
11 such approved application or of such license until
12 the expiration of the exclusivity period described in
13 paragraph (2).

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

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

22 “(B) in the case of a drug that has pre-
23 viously received a period of exclusivity under
24 paragraph (1), a single 3-year period of exclu-
25 sivity with respect to any subsequent designa-

1 tion of such drug under such section for any
2 other rare disease or condition.

3 “(3) LIMITATION.—In the case of a drug that
4 has received two periods of exclusivity pursuant to
5 paragraph (1), no additional exclusivity period under
6 this section is available with respect to such drug,
7 regardless of whether such drug has been designated
8 under section 526 for a rare disease or condition
9 that is distinct from the rare disease or condition for
10 which such exclusivity periods were granted.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) Section 505(j)(5)(B)(iv)(II)(dd)(AA) of the
13 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 360cc) is amended by striking “7-year period” and
15 inserting “exclusivity period”.

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

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

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

5 (5) Section 527(b) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 360cc) is amended by
7 striking “the 7-year period” and inserting “any ex-
8 clusivity period”.

9 (6) Section 351(m)(2)(B) of the Public Health
10 Service Act (42 U.S.C. 262) is amended by striking
11 “rather than 7 years” and inserting “or 3 years and
12 6 months, rather than 7 years or 3 years, respec-
13 tively”.

14 (7) Section 351(m)(3)(B) of the Public Health
15 Service Act (42 U.S.C. 262) is amended by striking
16 “rather than 7 years” and inserting “or 3 years and
17 6 months, rather than 7 years or 3 years, respec-
18 tively”.

19 **SEC. 348. EXCLUSIVITY PERIOD FOR BRAND NAME BIO-**
20 **LOGICAL PRODUCTS.**

21 (a) **IN GENERAL.**—Section 351(k)(7)(A) of the Pub-
22 lic Health Service Act (42 U.S.C. 262(k)(7)(A)) is amend-
23 ed by striking “12 years” and inserting “5 years”.

24 (b) **CONFORMING CHANGES.**—Paragraphs (2)(A) and
25 (3)(A) of section 351(m) of the Public Health Service Act

1 (42 U.S.C. 262(m)) is amended by striking “12 years”
2 each place it appears and inserting “5 years”.

3 (c) APPLICABILITY.—This Act and the amendments
4 made by this Act apply only with respect to a biological
5 product for which the reference product (as such term is
6 used in section 351 of the Public Health Service Act (42
7 U.S.C. 262)) is licensed under subsection (a) of such sec-
8 tion on or after the date of enactment of this Act.

9 **SEC. 349. REGULATION OF MANUFACTURER-SPONSORED**
10 **COPAY CONTRIBUTIONS.**

11 Notwithstanding any other provision of law, the Sec-
12 retary of Health and Human Services may establish a
13 mechanism to regulate drug manufacturers’ financial con-
14 tributions to patient out-of-pocket costs, such as drug co-
15 pays.

16 **SEC. 350. ANTITRUST EXEMPTION FOR PRIVATE HEALTH**
17 **INSURER ISSUERS TO NEGOTIATE WHOLE-**
18 **SALE ACQUISITION PRICES OF PRESCRIP-**
19 **TION DRUGS PURCHASED FROM DRUG MANU-**
20 **FACTURERS.**

21 (a) EXEMPTION.—It shall not be a violation of the
22 antitrust laws for one or more private health insurer
23 issuers or their designated agents to jointly negotiate
24 wholesale acquisition prices of a prescription drug with a
25 manufacturer of a prescription drug with regards to the

1 reimbursement policies of the insurers of the manufactur-
2 er's drugs so long as no one single wholesale acquisition
3 price is jointly determined between the insurance issuers
4 or their designated agents.

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

6 (1) ANTITRUST LAWS.—The term “antitrust
7 laws” has the meaning given it in subsection (a) of
8 the 1st section of the Clayton Act (15 U.S.C. 12(a)),
9 except that such term includes section 5 of the Fed-
10 eral Trade Commission Act (15 U.S.C. 45) to the
11 extent such section 5 applies to unfair methods of
12 competition.

13 (2) HEALTH INSURANCE ISSUER.—The term
14 “health insurance issuer” means an insurance com-
15 pany, insurance service, or insurance organization
16 (including a health maintenance organization, as de-
17 fined in subparagraph (C)) which is licensed to en-
18 gage in the business of insurance in a State and
19 which is subject to State law which regulates insur-
20 ance (within the meaning of section 514(b)(2) of the
21 Employee Retirement Income Security Act of 1974
22 (29 U.S.C. 1144(b)(2))). Such term does not include
23 a group health plan.

1 (3) HEALTH MAINTENANCE ORGANIZATION.—

2 The term “health maintenance organization”
3 means—

4 (A) a Federally qualified health mainte-
5 nance organization (as defined in section
6 300e(a) of title 42 of the United States Code),

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

9 (C) a similar organization regulated under
10 State law for solvency in the same manner and
11 to the same extent as such a health mainte-
12 nance organization.

13 (4) MANUFACTURER.—The term “manufac-
14 turer” means anyone who is engaged in manufac-
15 turing, preparing, propagating, compounding, proc-
16 essing, packaging, repackaging, or labeling of a pre-
17 scription drug.

18 (5) PRESCRIPTION DRUG.—The term “prescrip-
19 tion drug” means any human drug required by Fed-
20 eral law or regulation to be dispensed only by a pre-
21 scription, including finished dosage forms and active
22 ingredients subject to section 503(b) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

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

4 **SEC. 351. BIOLOGICAL PRODUCT INNOVATION.**

5 Section 351(j) of the Public Health Service Act (42
6 U.S.C. 262(j)) is amended—

7 (1) by striking “except that a product” and in-
8 serting “except that—

9 “(1) a product”;

10 (2) by striking “Act.” and inserting “Act; and”;

11 and

12 (3) by adding at the end the following:

13 “(2) no requirement under such Act regarding
14 an official compendium (as defined in section 201(j)
15 of such Act), or other reference in such Act to an
16 official compendium (as so defined), shall apply with
17 respect to a biological product subject to regulation
18 under this section.”.

19 **SEC. 352. PROMPT APPROVAL OF DRUGS RELATED TO**
20 **SAFETY INFORMATION.**

21 Section 505 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 355) is amended by adding at the end the
23 following:

24 “(z) PROMPT APPROVAL OF DRUGS WHEN SAFETY
25 INFORMATION IS ADDED TO LABELING.—

1 “(1) GENERAL RULE.—A drug for which an ap-
2 plication has been submitted or approved under sub-
3 section (b)(2) or (j) shall not be considered ineligible
4 for approval under this section or misbranded under
5 section 502 on the basis that the labeling of the
6 drug omits safety information, including contra-
7 indications, warnings, precautions, dosing, adminis-
8 tration, or other information pertaining to safety,
9 when the omitted safety information is protected by
10 exclusivity under clause (iii) or (iv) of subsection
11 (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),
12 or section 527(a), or by an extension of such exclu-
13 sivity under section 505A or 505E.

14 “(2) LABELING.—Notwithstanding clauses (iii)
15 and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)
16 of subsection (c)(3)(E), or section 527, the Sec-
17 retary shall require that the labeling of a drug ap-
18 proved pursuant to an application submitted under
19 subsection (b)(2) or (j) that omits safety information
20 described in paragraph (1) include a statement of
21 any appropriate safety information that the Sec-
22 retary considers necessary to assure safe use.

23 “(3) AVAILABILITY AND SCOPE OF EXCLU-
24 SIVITY.—This subsection does not affect—

1 “(A) the availability or scope of exclusivity
2 or an extension of exclusivity described in sub-
3 paragraph (A) or (B) of section 505A(o)(3);

4 “(B) the question of the eligibility for ap-
5 proval under this section of any application de-
6 scribed in subsection (b)(2) or (j) that omits
7 any other aspect of labeling protected by exclu-
8 sivity under—

9 “(i) clause (iii) or (iv) of subsection
10 (j)(5)(F);

11 “(ii) clause (iii) or (iv) of subsection
12 (c)(3)(E); or

13 “(iii) section 527(a); or

14 “(C) except as expressly provided in para-
15 graphs (1) and (2), the operation of this section
16 or section 527.”.

17 **SEC. 353. CONGRESSIONAL REVIEW OF THE FOOD AND**
18 **DRUG ADMINISTRATION RULEMAKING.**

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

22 **“CHAPTER 10—CONGRESSIONAL REVIEW**
23 **OF FOOD AND DRUG ADMINISTRATION**
24 **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.

1 **“§ 920. Applicability**

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

4 **“§ 921. Congressional review**

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

14 “(i) a copy of the rule;

15 “(ii) a concise general statement relating to the
16 rule;

17 “(iii) a classification of the rule as a major or
18 nonmajor rule, including an explanation of the clas-
19 sification specifically addressing each criteria for a
20 major rule contained within sections 924(2)(A),
21 924(2)(B), and 924(2)(C);

1 “(iv) a list of any other related regulatory ac-
2 tions intended to implement the same statutory pro-
3 vision or regulatory objective as well as the indi-
4 vidual and aggregate economic effects of those ac-
5 tions; and

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

7 “(B) On the date of the submission of the report
8 under subparagraph (A), the Food and Drug Administra-
9 tion shall submit to the Comptroller General and make
10 available to each House of Congress—

11 “(i) a complete copy of the cost-benefit analysis
12 of the rule, if any, including an analysis of any jobs
13 added or lost, differentiating between public and pri-
14 vate sector jobs;

15 “(ii) the Food and Drug Administration’s ac-
16 tions pursuant to sections 603, 604, 605, 607, and
17 609 of this title;

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

21 “(iv) any other relevant information or require-
22 ments under any other Act and any relevant Execu-
23 tive orders.

24 “(C) Upon receipt of a report submitted under sub-
25 paragraph (A), each House shall provide copies of the re-

1 port to the chairman and ranking member of each stand-
2 ing committee with jurisdiction under the rules of the
3 House of Representatives or the Senate to report a bill
4 to amend the provision of law under which the rule is
5 issued.

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

15 “(B) The Food and Drug Administration shall co-
16 operate with the Comptroller General by providing infor-
17 mation relevant to the Comptroller General’s report under
18 subparagraph (A).

19 “(3) A major rule relating to a report submitted
20 under paragraph (1) shall take effect upon enactment of
21 a joint resolution of approval described in section 922 or
22 as provided for in the rule following enactment of a joint
23 resolution of approval described in section 922, whichever
24 is later.

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

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

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

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

22 “(c)(1) Notwithstanding any other provision of this
23 section (except subject to paragraph (3)), a major rule
24 may take effect for one 90-calendar-day period if the
25 President makes a determination under paragraph (2) and

1 submits written notice of such determination to the Con-
2 gress.

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

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

8 “(B) necessary for the enforcement of criminal
9 laws;

10 “(C) necessary for national security; or

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

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

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

21 “(A) in the case of the Senate, 60 session days;
22 or

23 “(B) in the case of the House of Representa-
24 tives, 60 legislative days,

1 before the date the Congress is scheduled to adjourn a
2 session of Congress through the date on which the same
3 or succeeding Congress first convenes its next session, sec-
4 tions 922 and 923 shall apply to such rule in the suc-
5 ceeding session of Congress.

6 “(2)(A) In applying sections 922 and 923 for pur-
7 poses of such additional review, a rule described under
8 paragraph (1) shall be treated as though—

9 “(i) such rule were published in the Federal
10 Register on—

11 “(I) in the case of the Senate, the 15th
12 session day; or

13 “(II) in the case of the House of Rep-
14 resentatives, the 15th legislative day,
15 after the succeeding session of Congress first con-
16 venes; and

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

19 “(B) Nothing in this paragraph shall be construed
20 to affect the requirement under subsection (a)(1) that a
21 report shall be submitted to Congress before a rule can
22 take effect.

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

1 **“§ 922. Congressional approval procedure for major**
2 **rules**

3 “(a)(1) For purposes of this section, the term ‘joint
4 resolution’ means only a joint resolution addressing a re-
5 port classifying a rule as major pursuant to section
6 921(a)(1)(A)(iii) that—

7 “(A) bears no preamble;

8 “(B) bears the following title (with blanks filled
9 as appropriate): ‘Approving the rule submitted by
10 _____ relating to _____.’;

11 “(C) includes after its resolving clause only the
12 following (with blanks filled as appropriate): ‘That
13 Congress approves the rule submitted by _____ re-
14 lating to _____.’; and

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

16 “(2) After a House of Congress receives a report
17 classifying a rule as major pursuant to section
18 921(a)(1)(A)(iii), the majority leader of that House (or
19 his or her respective designee) shall introduce (by request,
20 if appropriate) a joint resolution described in paragraph
21 (1)—

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

24 “(B) in the case of the Senate, within 3 session
25 days.

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

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

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

20 “(d)(1) In the Senate, when the committee or com-
21 mittees to which a joint resolution is referred have re-
22 ported, or when a committee or committees are discharged
23 (under subsection (c)) from further consideration of a
24 joint resolution described in subsection (a), it is at any
25 time thereafter in order (even though a previous motion

1 to the same effect has been disagreed to) for a motion
2 to proceed to the consideration of the joint resolution, and
3 all points of order against the joint resolution (and against
4 consideration of the joint resolution) are waived. The mo-
5 tion is not subject to amendment, or to a motion to post-
6 pone, or to a motion to proceed to the consideration of
7 other business. A motion to reconsider the vote by which
8 the motion is agreed to or disagreed to shall not be in
9 order. If a motion to proceed to the consideration of the
10 joint resolution is agreed to, the joint resolution shall re-
11 main the unfinished business of the Senate until disposed
12 of.

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

22 “(3) In the Senate, immediately following the conclu-
23 sion of the debate on a joint resolution described in sub-
24 section (a), and a single quorum call at the conclusion of
25 the debate if requested in accordance with the rules of the

1 Senate, the vote on final passage of the joint resolution
2 shall occur.

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

7 “(e) In the House of Representatives, if any com-
8 mittee to which a joint resolution described in subsection
9 (a) has been referred has not reported it to the House
10 at the end of 15 legislative days after its introduction,
11 such committee shall be discharged from further consider-
12 ation of the joint resolution, and it shall be placed on the
13 appropriate calendar. On the second and fourth Thursdays
14 of each month it shall be in order at any time for the
15 Speaker to recognize a Member who favors passage of a
16 joint resolution that has appeared on the calendar for at
17 least 5 legislative days to call up that joint resolution for
18 immediate consideration in the House without intervention
19 of any point of order. When so called up a joint resolution
20 shall be considered as read and shall be debatable for 1
21 hour equally divided and controlled by the proponent and
22 an opponent, and the previous question shall be considered
23 as ordered to its passage without intervening motion. It
24 shall not be in order to reconsider the vote on passage.
25 If a vote on final passage of the joint resolution has not

1 been taken by the third Thursday on which the Speaker
2 may recognize a Member under this subsection, such vote
3 shall be taken on that day.

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

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

9 “(B) the procedure in the receiving House shall
10 be the same as if no joint resolution had been re-
11 ceived from the other House until the vote on pas-
12 sage, when the joint resolution received from the
13 other House shall supplant the joint resolution of
14 the receiving House.

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

18 “(g) If either House has not taken a vote on final
19 passage of the joint resolution by the last day of the period
20 described in section 921(b)(2), then such vote shall be
21 taken on that day.

22 “(h) This section and section 923 are enacted by
23 Congress—

24 “(1) as an exercise of the rulemaking power of
25 the Senate and House of Representatives, respec-

1 tively, and as such is deemed to be part of the rules
2 of each House, respectively, but applicable only with
3 respect to the procedure to be followed in that
4 House in the case of a joint resolution described in
5 subsection (a) and superseding other rules only
6 where explicitly so; and

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

12 **“§ 923. Congressional disapproval procedure for**
13 **nonmajor rules**

14 “(a) For purposes of this section, the term ‘joint res-
15 olution’ means only a joint resolution introduced in the
16 period beginning on the date on which the report referred
17 to in section 921(a)(1)(A) is received by Congress and
18 ending 60 days thereafter (excluding days either House
19 of Congress is adjourned for more than 3 days during a
20 session of Congress), the matter after the resolving clause
21 of which is as follows: ‘That Congress disapproves the
22 nonmajor rule submitted by the _____ relating to
23 _____, and such rule shall have no force or effect.’ (The
24 blank spaces being appropriately filled in).

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

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

13 “(d)(1) In the Senate, when the committee to which
14 a joint resolution is referred has reported, or when a com-
15 mittee is discharged (under subsection (c)) from further
16 consideration of a joint resolution described in subsection
17 (a), it is at any time thereafter in order (even though a
18 previous motion to the same effect has been disagreed to)
19 for a motion to proceed to the consideration of the joint
20 resolution, and all points of order against the joint resolu-
21 tion (and against consideration of the joint resolution) are
22 waived. The motion is not subject to amendment, or to
23 a motion to postpone, or to a motion to proceed to the
24 consideration of other business. A motion to reconsider the
25 vote by which the motion is agreed to or disagreed to shall

1 not be in order. If a motion to proceed to the consideration
2 of the joint resolution is agreed to, the joint resolution
3 shall remain the unfinished business of the Senate until
4 disposed of.

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

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

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

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

4 “(1) after the expiration of the 60 session days
5 beginning with the applicable submission or publica-
6 tion date; or

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

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

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

19 “(2) With respect to a joint resolution described
20 in subsection (a) of the House receiving the joint
21 resolution—

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

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

3 **“§ 924. Definitions**

4 “For purposes of this chapter:

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

11 “(A) an annual cost on the economy of
12 \$100,000,000 or more, adjusted annually for
13 inflation;

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

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

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

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

4 “(A) any rule of particular applicability;

5 “(B) any rule relating to agency manage-
6 ment or personnel; or

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

11 “(4) The term ‘submission date or publication
12 date’, except as otherwise provided in this chapter,
13 means—

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

17 “(B) in the case of a nonmajor rule, the
18 later of—

19 “(i) the date on which the Congress
20 receives the report submitted under section
21 921(a)(1); and

22 “(ii) the date on which the nonmajor
23 rule is published in the Federal Register, if
24 so published.

1 **“§ 925. Judicial review**

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

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

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

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

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

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

23 “Notwithstanding section 921, any rule other than a
24 major rule which the Food and Drug Administration for
25 good cause finds (and incorporates the finding and a brief
26 statement of reasons therefore in the rule issued) that no-

1 tice and public procedure thereon are impracticable, un-
2 necessary, or contrary to the public interest, shall take ef-
3 fect at such time as the Food and Drug Administration
4 determines.

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

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

17 **“§ 929. Review of rules currently in effect**

18 “(a) ANNUAL REVIEW.—Beginning on the date that
19 is 6 months after the date of enactment of this section
20 and annually thereafter for the 9 years following, the Food
21 and Drug Administration shall designate not less than 10
22 percent of eligible rules made by the Food and Drug Ad-
23 ministration for review, and shall submit a report includ-
24 ing each such eligible rule in the same manner as a report
25 under section 921(a)(1). Section 921, section 922, and

1 section 923 shall apply to each such rule, subject to sub-
2 section (c) of this section. No eligible rule previously des-
3 ignated may be designated again.

4 “(b) SUNSET FOR ELIGIBLE RULES NOT EX-
5 TENDED.—Beginning after the date that is 10 years after
6 the date of enactment of this section, if Congress has not
7 enacted a joint resolution of approval for that eligible rule,
8 that eligible rule shall not continue in effect.

9 “(c) CONSOLIDATION; SEVERABILITY.—In applying
10 sections 921, 922, and 923 to eligible rules under this sec-
11 tion, the following shall apply:

12 “(1) The words ‘take effect’ shall be read as
13 ‘continue in effect’.

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

21 “(3) It shall be in order to consider any amend-
22 ment that provides for specific conditions on which
23 the approval of a particular eligible rule included in
24 the joint resolution is contingent.

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

4 “(d) DEFINITION.—In this section, the term ‘eligible
5 rule’ means a rule that is in effect as of the date of enact-
6 ment of this section.”.

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

12 “(E) BUDGETARY EFFECTS OF RULES
13 SUBJECT TO SECTION 922 OF TITLE 5, UNITED
14 STATES CODE.—Any rules subject to the con-
15 gressional approval procedure set forth in sec-
16 tion 922 of chapter 8 of title 5, United States
17 Code, affecting budget authority, outlays, or re-
18 ceipts shall be assumed to be effective unless it
19 is not approved in accordance with such sec-
20 tion.”.

21 (c) GOVERNMENT ACCOUNTABILITY OFFICE STUDY
22 OF RULES.—

23 (1) IN GENERAL.—The Comptroller General of
24 the United States shall conduct a study to deter-
25 mine, as of the date of the enactment of this Act—

1 (A) how many rules (as such term is de-
2 fined in section 924 of title 5, United States
3 Code) of the Food and Drug Administration
4 were in effect;

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

9 (C) the total estimated economic cost im-
10 posed by all such rules.

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

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

20 **SEC. 354. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**
21 **OF RULES.**

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

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

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

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

9 (b) REPORT.—Not later than 1 year after the date
10 of the enactment of this Act, the Comptroller General of
11 the United States shall submit a report to Congress that
12 contains the findings of the study conducted under sub-
13 section (a).

14 **Subtitle D—Prescription Drug and**
15 **Pharmacy Benefit Manager**
16 **Transparency**

17 **SEC. 361. PATENT DISCLOSURE REQUIREMENTS.**

18 (a) IN GENERAL.—Section 351 of the Public Health
19 Service Act (42 U.S.C. 262) is amended by adding at the
20 end the following:

21 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
22 TO PATENTS.—

23 “(1) APPROVED APPLICATION HOLDER LISTING
24 REQUIREMENTS.—

1 “(A) IN GENERAL.—Beginning on the date
2 of enactment of this subsection, within 30 days
3 of approval of an application under subsection
4 (a) or (k), the holder of such approved applica-
5 tion shall submit to the Secretary a list of each
6 patent required to be disclosed (as described in
7 paragraph (3)).

8 “(B) PREVIOUSLY APPROVED OR LI-
9 CENSED BIOLOGICAL PRODUCTS.—

10 “(i) PRODUCTS APPROVED UNDER
11 SECTION 351 OF THE PHSA.—Not later
12 than 30 days after the date of enactment
13 of the Fair Care Act of 2022, the holder
14 of a biological product license that was ap-
15 proved under subsection (a) or (k) before
16 the date of enactment of such Act shall
17 submit to the Secretary a list of each pat-
18 ent required to be disclosed (as described
19 in paragraph (3)).

20 “(ii) PRODUCTS APPROVED UNDER
21 SECTION 505 OF THE FFDCA.—Not later
22 than 30 days after March 23, 2021, the
23 holder of an approved application for a bio-
24 logical product under section 505 of the
25 Federal Food, Drug, and Cosmetic Act

1 that is deemed to be a license for the bio-
2 logical product under this section on
3 March 23, 2021, shall submit a list of each
4 patent required to be disclosed (as de-
5 scribed in paragraph (3)).

6 “(C) UPDATES.—The holder of a biological
7 product license approved under subsection (a)
8 or (k) shall submit to the Secretary a list that
9 includes—

10 “(i) any patent first required to be
11 disclosed (as described in paragraph (3))
12 after the submission under subparagraph
13 (A) or (B), as applicable, within 30 days of
14 the earlier of—

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

18 “(II) the date of approval of a
19 supplemental application for the bio-
20 logical product; and

21 “(ii) any patent, or any claim with re-
22 spect to a patent, included on the list pur-
23 suant to this paragraph with respect to the
24 biological product subsequently determined
25 to be invalid or unenforceable, within 30

1 days of a determination of patent inva-
2 lidity.

3 “(2) PUBLICATION OF INFORMATION.—

4 “(A) IN GENERAL.—Within 1 year of the
5 date of enactment of the Fair Care Act of
6 2022, the Secretary shall publish and make
7 available to the public a single, easily search-
8 able, list that includes—

9 “(i) the official and proprietary name
10 of each biological product licensed under
11 subsection (a) or (k), and of each biological
12 product application approved under section
13 505 of the Federal Food, Drug, and Cos-
14 metic Act and deemed to be a license for
15 the biological product under this section on
16 March 23, 2021;

17 “(ii) with respect to each biological
18 product described in clause (i), each patent
19 submitted in accordance with paragraph
20 (1);

21 “(iii) the date of licensure and appli-
22 cation number for each such biological
23 product;

24 “(iv) the marketing status, dosage
25 form, route of administration, strength,

1 and, if applicable, reference product, for
2 each such biological product;

3 “(v) the licensure status for each such
4 biological product, including whether the li-
5 cense at the time of listing is approved,
6 withdrawn, or revoked;

7 “(vi) any period of any exclusivity
8 under subsection (k)(7)(A) or subsection
9 (k)(7)(B) of this section or section 527 of
10 the Federal Food, Drug, and Cosmetic
11 Act, and any extension of such period in
12 accordance with subsection (m) of this sec-
13 tion with respect to each such biological
14 product, and the date on which such exclu-
15 sivity expires;

16 “(vii) information regarding any de-
17 termination related to biosimilarity or
18 interchangeability for each such biological
19 product; and

20 “(viii) information regarding approved
21 indications for each such biological prod-
22 uct, in such manner as the Secretary de-
23 termines appropriate.

24 “(B) UPDATES.—Eevery 30 days after the
25 publication of the first list under subparagraph

1 (A), the Secretary shall revise the list to in-
2 clude—

3 “(i)(I) each biological product licensed
4 under subsection (a) or (k) during the 30-
5 day period; and

6 “(II) with respect to each biological
7 product described in subclause (I), the in-
8 formation described in clauses (i) through
9 (viii) of subparagraph (A); and

10 “(ii) any updates to information pre-
11 viously published in accordance with sub-
12 paragraph (A).

13 “(3) PATENTS REQUIRED TO BE DISCLOSED.—

14 In this section, a ‘patent required to be disclosed’ is
15 any patent for which the holder of a biological prod-
16 uct license approved under subsection (a) or (k), or
17 a biological product application approved under sec-
18 tion 505 of the Federal Food, Drug, and Cosmetic
19 Act and deemed to be a license for a biological prod-
20 uct under this section on March 23, 2021, believes
21 a claim of patent infringement could reasonably be
22 asserted by the holder, or by a patent owner that
23 has granted an exclusive license to the holder with
24 respect to the biological product that is the subject
25 of such license, if a person not licensed by the holder

1 engaged in the making, using, offering to sell, sell-
2 ing, or importing into the United States of the bio-
3 logical product that is the subject of such license.”.

4 (b) DISCLOSURE OF PATENTS.—Section
5 351(l)(3)(A)(i) of the Public Health Service Act (42
6 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
7 in the list provided by the reference product sponsor under
8 subsection (o)(1)” after “a list of patents”.

9 (c) RESTRICTION ON CLAIMS OF PATENT INFRINGE-
10 MENT.—Section 271(e) of title 35, United States Code,
11 is amended by adding at the end the following:

12 “(7) The owner of a patent that should have
13 been included in the list described in section
14 351(o)(1) of the Public Health Service Act (42
15 U.S.C. 262(o)(1)), including any updates required
16 under subparagraph (C) of that section, but was not
17 timely included in such list, may not bring an action
18 under this section for infringement of the patent.”.

19 (d) REGULATIONS.—The Secretary of Health and
20 Human Services may promulgate regulations to carry out
21 subsection (o) of section 351 of the Public Health Service
22 Act (42 U.S.C. 262), as added by subsection (a).

23 (e) RULE OF CONSTRUCTION.—Nothing in this Act,
24 including an amendment made by this Act, shall be con-
25 strued to require or allow the Secretary of Health and

1 Human Services to delay the licensing of a biological prod-
2 uct under section 351 of the Public Health Service Act
3 (42 U.S.C. 262).

4 **SEC. 362. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
5 **TION DRUG BENEFITS.**

6 (a) IN GENERAL.—Subpart II of part A of title
7 XXVII of the Public Health Service Act (42 U.S.C.
8 300gg–11 et seq.) is amended by adding at the end the
9 following:

10 **“SEC. 2729A. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
11 **TION DRUG BENEFITS.**

12 “A group health plan or a health insurance issuer of-
13 fering group or individual health insurance coverage shall
14 not, and shall ensure that any entity that provides phar-
15 macy benefits management services under a contract with
16 any such health plan or health insurance coverage does
17 not, receive from a drug manufacturer a reduction in price
18 or other remuneration with respect to any prescription
19 drug received by an enrollee in the plan or coverage and
20 covered by the plan or coverage, unless—

21 “(1) any such reduction in price is reflected at
22 the point of sale to the enrollee; and

23 “(2) any such other remuneration is a flat fee-
24 based service fee that a manufacturer of prescription
25 drugs pays to a pharmacy benefit manager for serv-

1 by such sponsor shall provide that after
2 the date of receipt of a clean claim sub-
3 mitted by a pharmacy, the PDP sponsor
4 (or an agent of the PDP sponsor) may not
5 retroactively reduce payment on such claim
6 directly or indirectly through aggregated
7 effective rate or otherwise except in the
8 case such claim is found to not be a clean
9 claim (such as in the case of a claim lack-
10 ing required substantiating documentation)
11 during the course of a routine audit as
12 permitted pursuant to written agreement
13 between the PDP sponsor (or such an
14 agent) and such pharmacy. The previous
15 sentence shall not prohibit any retroactive
16 increase in payment to a pharmacy pursu-
17 ant to a written agreement between a PDP
18 sponsor (or an agent of such sponsor) and
19 such pharmacy.”.

20 (2) EFFECTIVE DATE.—The amendment made
21 by subsection (a) shall apply with respect to con-
22 tracts entered into on or after January 1, 2023.

23 (b) ELIMINATION OF DIR FEES.—

1 (1) PHARMACY BENEFITS MANAGER STAND-
2 ARDS UNDER THE MEDICARE PROGRAM FOR PRE-
3 SCRIPTION DRUG PLANS AND MA-PD PLANS.—

4 (A) IN GENERAL.—Section 1860D-12(b)
5 of the Social Security Act (42 U.S.C. 1395w-
6 112(b)) is amended by adding at the end the
7 following new paragraph:

8 “(7) PHARMACY BENEFITS MANAGER TRANS-
9 PARENCY REQUIREMENTS.—Each contract entered
10 into with a PDP sponsor under this part with re-
11 spect to a prescription drug plan offered by such
12 sponsor or with an MA organization offering an
13 MA-PD plan under part C shall provide that the
14 sponsor or organization, respectively, may not enter
15 into a contract with any pharmacy benefits manager
16 (referred to in this paragraph as a ‘PBM’) to man-
17 age the prescription drug coverage provided under
18 such plan, or to control the costs of the prescription
19 drug coverage under such plan, unless the PBM ad-
20 heres to the following criteria when handling person-
21 ally identifiable utilization and claims data or other
22 sensitive patient data:

23 “(A) The PBM may not transmit any per-
24 sonally identifiable utilization, protected health
25 information, or claims data, with respect to a

1 plan enrollee, to a pharmacy owned by a PBM
2 if the plan enrollee has not voluntarily elected
3 in writing or via secure electronic means to fill
4 that particular prescription at the PBM-owned
5 pharmacy.

6 “(B) The PBM may not require that a
7 plan enrollee use a retail pharmacy, mail order
8 pharmacy, specialty pharmacy, or other phar-
9 macy entity providing pharmacy services in
10 which the PBM has an ownership interest or
11 that has an ownership interest in the PBM, or
12 provide an incentive to a plan enrollee to en-
13 courage the enrollee to use a retail pharmacy,
14 mail order pharmacy, specialty pharmacy, or
15 other pharmacy entity providing pharmacy serv-
16 ices in which the PBM has an ownership inter-
17 est or that has an ownership interest in the
18 PBM, if the incentive is applicable only to such
19 pharmacies.”.

20 (B) REGULAR UPDATE OF PRESCRIPTION
21 DRUG PRICING STANDARD.—Paragraph (6) of
22 section 1860D–12(b) of the Social Security Act
23 (42 U.S.C. 1395w–112(b)) is amended to read
24 as follows:

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

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

12 “(i) update such standard not less fre-
13 quently than once every 7 days, beginning
14 with an initial update on January 1 of
15 each year, to accurately reflect the market
16 price of acquiring the drug;

17 “(ii) disclose to applicable pharmacies
18 and the contracting entities of such phar-
19 macies the sources used for making any
20 such update immediately without require-
21 ment of request;

22 “(iii) if the source for such a standard
23 for reimbursement is not publicly available,
24 disclose to the applicable pharmacies and
25 the respective contracting entities of such

1 pharmacies all individual drug prices to be
2 so updated in advance of the use of such
3 prices for the reimbursement of claims;

4 “(iv) establish a process to appeal, in-
5 vestigate, and resolve disputes regarding
6 individual drug prices that are less than
7 the pharmacy acquisition price for such
8 drug, which must be adjudicated within 7
9 days of the pharmacy filing its appeal; and

10 “(v) provide all such pricing data in
11 an .xml spreadsheet format or a com-
12 parable easily accessible and complete
13 spreadsheet format.

14 “(B) PRESCRIPTION DRUG PRICING
15 STANDARD DEFINED.—For purposes of sub-
16 paragraph (A), a standard for reimbursement
17 of a pharmacy is any methodology or formula
18 for varying the pricing of a drug or drugs dur-
19 ing the term of the pharmacy reimbursement
20 contract that is based on the cost of the drug
21 involved, including drug pricing references and
22 amounts that are based upon average wholesale
23 price, wholesale average cost, average manufac-
24 turer price, average sales price, maximum al-

1 lowable cost (MAC), or other costs, whether
2 publicly available or not.”.

3 (C) EFFECTIVE DATE.—The amendments
4 made by this section shall apply to plan years
5 beginning on or after January 1, 2023.

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

11 “(3) To the extent practicable, with respect to the
12 TRICARE retail pharmacy program described in sub-
13 section (a)(2)(E)(ii), the Secretary shall ensure that a con-
14 tract entered into with a TRICARE managed care support
15 contractor includes requirements described in section
16 1860D–12(b)(6) of the Social Security Act (42 U.S.C.
17 1395w–112(b)(6)) to ensure the provision of information
18 regarding the pricing standard for prescription drugs.”.

19 (3) PRESCRIPTION DRUG TRANSPARENCY IN
20 THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-
21 GRAM.—

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

1 “(p) A contract may not be made or a plan approved
2 under this chapter under which a carrier has an agree-
3 ment with a pharmacy benefits manager (in this sub-
4 section referred to as a ‘PBM’) to manage prescription
5 drug coverage or to control the costs of the prescription
6 drug coverage unless the carrier and PBM adhere to the
7 following criteria:

8 “(1) The PBM may not transmit any personally
9 identifiable utilization, protected health information,
10 or claims data with respect to an individual enrolled
11 under such contract or plan to a pharmacy owned by
12 the PBM if the individual has not voluntarily elected
13 in writing or via secure electronic means to fill that
14 particular prescription at such a pharmacy.

15 “(2) The PBM may not require that an indi-
16 vidual enrolled under such contract or plan use a re-
17 tail pharmacy, mail order pharmacy, specialty phar-
18 macy, or other pharmacy entity providing pharmacy
19 services in which the PBM has an ownership interest
20 or that has an ownership interest in the PBM or
21 provide an incentive to a plan enrollee to encourage
22 the enrollee to use a retail pharmacy, mail order
23 pharmacy, specialty pharmacy, or other pharmacy
24 entity providing pharmacy services in which the
25 PBM has an ownership interest or that has an own-

1 ership interest in the PBM, if the incentive is appli-
2 cable only to such pharmacies.

3 “(q)(1) If a contract made or plan approved under
4 this chapter provides for a standard for reimbursement
5 (as described in paragraph (2)) with respect to a prescrip-
6 tion drug plan, such contract or plan shall provide that
7 the applicable carrier—

8 “(A) update such standard not less frequently
9 than once every 7 days, beginning with an initial up-
10 date on January 1 of each year, to accurately reflect
11 the market price of acquiring the drug;

12 “(B) disclose to applicable pharmacies and the
13 contracting entities of such pharmacies the sources
14 used for making any such update immediately with-
15 out requirement of request;

16 “(C) if the source for such a standard for reim-
17 bursement is not publicly available, disclose to the
18 applicable pharmacies and contracting entities of
19 such pharmacies all individual drug prices to be so
20 updated in advance of the use of such prices for the
21 reimbursement of claims;

22 “(D) establish a process to appeal, investigate,
23 and resolve disputes regarding individual drug prices
24 that are less than the pharmacy acquisition price for

1 such drug, which must be adjudicated within 7 days
2 of the pharmacy filing its appeal; and

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

6 “(2) For purposes of paragraph (1), a standard for
7 reimbursement of a pharmacy is any methodology or for-
8 mula for varying the pricing of a drug or drugs during
9 the term of the pharmacy reimbursement contract that is
10 based on the cost of the drug involved, including drug pric-
11 ing references and amounts that are based upon average
12 wholesale price, wholesale average cost, average manufac-
13 turer price, average sales price, maximum allowable cost,
14 or other costs, whether publicly available or not.”.

15 (B) APPLICATION.—The amendment made
16 by subparagraph (A) shall apply to any contract
17 entered into under section 8902 of title 5,
18 United States Code, on or after the date of en-
19 actment of this section.

20 **SEC. 364. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
21 **EFIT MANAGER SERVICES.**

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

1 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**
2 **BENEFIT MANAGER SERVICES.**

3 “(a) IN GENERAL.—A group health plan or health
4 insurance issuer offering group health insurance coverage
5 or an entity or subsidiary providing pharmacy benefits
6 management services shall not enter into a contract with
7 a drug manufacturer, distributor, wholesaler, subcon-
8 tractor, rebate aggregator, or any associated third party
9 that limits the disclosure of information to plan sponsors
10 in such a manner that prevents the plan or coverage, or
11 an entity or subsidiary providing pharmacy benefits man-
12 agement services on behalf of a plan or coverage from
13 making the reports described in subsection (b).

14 “(b) REPORTS TO GROUP PLAN SPONSORS.—

15 “(1) IN GENERAL.—Beginning with the first
16 plan year that begins after the date of enactment of
17 the Fair Care Act of 2022, not less frequently than
18 once every 6 months, a health insurance issuer offer-
19 ing group health insurance coverage or an entity
20 providing pharmacy benefits management services
21 on behalf of a group health plan shall submit to the
22 plan sponsor (as defined in section 3(16)(B) of the
23 Employee Retirement Income Security Act of 1974)
24 of such group health plan or health insurance cov-
25 erage a report in accordance with this subsection
26 and make such report available to the plan sponsor

1 in a machine-readable format. Each such report
2 shall include, with respect to the applicable group
3 health plan or health insurance coverage—

4 “(A) information collected from drug man-
5 ufacturers by such issuer or entity on the total
6 amount of copayment assistance dollars paid, or
7 copayment cards applied, that were funded by
8 the drug manufacturer with respect to the en-
9 rollees in such plan or coverage;

10 “(B) a list of each covered drug dispensed
11 during the reporting period, including, with re-
12 spect to each such drug during the reporting
13 period—

14 “(i) the brand name, chemical entity,
15 and National Drug Code;

16 “(ii) the number of enrollees for
17 whom the drug was filled during the plan
18 year, the total number of prescription fills
19 for the drug (including original prescrip-
20 tions and refills), and the total number of
21 dosage units of the drug dispensed across
22 the plan year, including whether the dis-
23 pensing channel was by retail, mail order,
24 or specialty pharmacy;

1 “(iii) the wholesale acquisition cost,
2 listed as cost per days supply and cost per
3 pill, or in the case of a drug in another
4 form, per dose;

5 “(iv) the total out-of-pocket spending
6 by enrollees on such drug, including en-
7 rollee spending through copayments, coin-
8 surance, and deductibles; and

9 “(v) for any drug for which gross
10 spending of the group health plan or
11 health insurance coverage exceeded
12 \$10,000 during the reporting period—

13 “(I) a list of all other available
14 drugs in the same therapeutic cat-
15 egory or class, including brand name
16 drugs and biological products and ge-
17 neric drugs or biosimilar biological
18 products that are in the same thera-
19 peutic category or class; and

20 “(II) the rationale for preferred
21 formulary placement of a particular
22 drug or drugs in that therapeutic cat-
23 egory or class;

24 “(C) a list of each therapeutic category or
25 class of drugs that were dispensed under the

1 health plan or health insurance coverage during
2 the reporting period, and, with respect to each
3 such therapeutic category or class of drugs,
4 during the reporting period—

5 “(i) total gross spending by the plan,
6 before manufacturer rebates, fees, or other
7 manufacturer remuneration;

8 “(ii) the number of enrollees who
9 filled a prescription for a drug in that cat-
10 egory or class;

11 “(iii) if applicable to that category or
12 class, a description of the formulary tiers
13 and utilization mechanisms (such as prior
14 authorization or step therapy) employed
15 for drugs in that category or class;

16 “(iv) the total out-of-pocket spending
17 by enrollees, including enrollee spending
18 through copayments, coinsurance, and
19 deductibles; and

20 “(v) for each therapeutic category or
21 class under which 3 or more drugs are in-
22 cluded on the formulary of such plan or
23 coverage—

24 “(I) the amount received, or ex-
25 pected to be received, from drug man-

1 manufacturers in rebates, fees, alternative
2 discounts, or other remuneration—

3 “(aa) to be paid by drug
4 manufacturers for claims in-
5 curred during the reporting pe-
6 riod; or

7 “(bb) that is related to utili-
8 zation of drugs, in such thera-
9 peutic category or class;

10 “(II) the total net spending, after
11 deducting rebates, price concessions,
12 alternative discounts or other remu-
13 nation from drug manufacturers, by
14 the health plan or health insurance
15 coverage on that category or class of
16 drugs; and

17 “(III) the net price per course of
18 treatment or 30-day supply incurred
19 by the health plan or health insurance
20 coverage and its enrollees, after man-
21 ufacturer rebates, fees, and other re-
22 munerations for drugs dispensed within
23 such therapeutic category or class
24 during the reporting period;

1 “(D) total gross spending on prescription
2 drugs by the plan or coverage during the re-
3 porting period, before rebates and other manu-
4 facturer fees or remuneration;

5 “(E) total amount received, or expected to
6 be received, by the health plan or health insur-
7 ance coverage in drug manufacturer rebates,
8 fees, alternative discounts, and all other remu-
9 neration received from the manufacturer or any
10 third party, other than the plan sponsor, re-
11 lated to utilization of drug or drug spending
12 under that health plan or health insurance cov-
13 erage during the reporting period;

14 “(F) the total net spending on prescription
15 drugs by the health plan or health insurance
16 coverage during the reporting period; and

17 “(G) amounts paid directly or indirectly in
18 rebates, fees, or any other type of remuneration
19 to brokers, consultants, advisors, or any other
20 individual or firm who referred the group health
21 plan’s or health insurance issuer’s business to
22 the pharmacy benefit manager.

23 “(2) PRIVACY REQUIREMENTS.—Health insur-
24 ance issuers offering group health insurance cov-
25 erage and entities providing pharmacy benefits man-

1 agement services on behalf of a group health plan
2 shall provide information under paragraph (1) in a
3 manner consistent with the privacy, security, and
4 breach notification regulations promulgated under
5 section 264(c) of the Health Insurance Portability
6 and Accountability Act of 1996 (or successor regula-
7 tions), and shall restrict the use and disclosure of
8 such information according to such privacy regula-
9 tions.

10 “(3) DISCLOSURE AND REDISCLOSURE.—

11 “(A) LIMITATION TO BUSINESS ASSOCI-
12 ATES.—A group health plan receiving a report
13 under paragraph (1) may disclose such informa-
14 tion only to business associates of such plan as
15 defined in section 160.103 of title 45, Code of
16 Federal Regulations (or successor regulations).

17 “(B) CLARIFICATION REGARDING PUBLIC
18 DISCLOSURE OF INFORMATION.—Nothing in
19 this section prevents a health insurance issuer
20 offering group health insurance coverage or an
21 entity providing pharmacy benefits management
22 services on behalf of a group health plan from
23 placing reasonable restrictions on the public dis-
24 closure of the information contained in a report
25 described in paragraph (1), except that such

1 issuer or entity may not restrict disclosure of
2 such report to governmental agencies pursuant
3 to an investigation or enforcement action.

4 “(C) LIMITED FORM OF REPORT.—The
5 Secretary shall define through rulemaking a
6 limited form of the report under paragraph (1)
7 required of plan sponsors who are drug manu-
8 facturers, drug wholesalers, or other direct par-
9 ticipants in the drug supply chain, in order to
10 prevent anti-competitive behavior.

11 “(c) LIMITATIONS ON SPREAD PRICING.—

12 “(1) PRESCRIPTION DRUG TRANSACTIONS WITH
13 PHARMACIES INDEPENDENT OF THE ISSUER OR
14 PHARMACY BENEFITS MANAGER.—If the pharmacy
15 that dispenses a prescription drug to an enrollee in
16 a group health plan or group or individual health in-
17 surance coverage is not wholly or partially owned by
18 such plan, such issuer, or an entity providing phar-
19 macy benefit management services under such plan
20 or coverage, such plan, issuer, or entity shall not
21 charge the plan, issuer, or enrollee a price for such
22 prescription drug that exceeds the price paid to the
23 pharmacy.

24 “(2) INTRA-COMPANY PRESCRIPTION DRUG
25 TRANSACTIONS.—If the mail order, specialty, or re-

1 tail pharmacy that dispenses a prescription drug to
2 an enrollee in a group health plan or health insur-
3 ance coverage is wholly or partially owned by, and
4 submits claims to, such health insurance issuer or
5 an entity providing pharmacy benefit management
6 services under a group health plan or group or indi-
7 vidual health insurance coverage, the price charged
8 for such drug by such pharmacy to such group
9 health plan or health insurance issuer offering group
10 or individual health insurance coverage may not ex-
11 ceed the lesser of—

12 “(A) the amount paid to the pharmacy for
13 acquisition of the drug; or

14 “(B) the median price charged to the
15 group health plan or health insurance issuer
16 when the same drug is dispensed to enrollees in
17 the plan or coverage by other similarly situated
18 pharmacies not wholly or partially owned by the
19 health insurance issuer or entity providing
20 pharmacy benefits management services, as de-
21 scribed in paragraph (1).

22 “(3) SUPPLEMENTARY REPORTING FOR INTRA-
23 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A
24 health insurance issuer of group health insurance
25 coverage or an entity providing pharmacy benefits

1 management services under a group health plan or
2 group health insurance coverage that conducts
3 transactions with a wholly or partially owned phar-
4 macy, as described in paragraph (2), shall submit,
5 together with the report under subsection (b), a sup-
6 plementary report every 6 months to the plan spon-
7 sor that includes—

8 “(A) an explanation of any benefit design
9 parameters that encourage enrollees in the plan
10 or coverage to fill prescriptions at mail order,
11 specialty, or retail pharmacies that are wholly
12 or partially owned by that issuer or entity;

13 “(B) the percentage of total prescriptions
14 charged to the plan, coverage, or enrollees in
15 the plan or coverage, that were dispensed by
16 mail order, specialty, or retail pharmacies that
17 are wholly or partially owned by the issuer or
18 entity providing pharmacy benefits management
19 services; and

20 “(C) a list of all drugs dispensed by such
21 wholly or partially owned pharmacy and
22 charged to the plan or coverage, or enrollees of
23 the plan or coverage, during the applicable
24 quarter, and, with respect to each drug—

1 “(i) the amount charged per course of
2 treatment or 30-day supply with respect to
3 enrollees in the plan or coverage, including
4 amounts charged to the plan or coverage
5 and amounts charged to the enrollee;

6 “(ii) the median amount charged to
7 the plan or coverage, per course of treat-
8 ment or 30-day supply, including amounts
9 paid by the enrollee, when the same drug
10 is dispensed by other pharmacies that are
11 not wholly or partially owned by the issuer
12 or entity and that are included in the
13 pharmacy network of that plan or cov-
14 erage;

15 “(iii) the interquartile range of the
16 costs, per course of treatment or 30-day
17 supply, including amounts paid by the en-
18 rollee, when the same drug is dispensed by
19 other pharmacies that are not wholly or
20 partially owned by the issuer or entity and
21 that are included in the pharmacy network
22 of that plan or coverage; and

23 “(iv) the lowest cost per course of
24 treatment or 30-day supply, for such drug,
25 including amounts charged to the plan or

1 issuer and enrollee, that is available from
2 any pharmacy included in the network of
3 the plan or coverage.

4 “(d) FULL REBATE PASS-THROUGH TO PLAN.—

5 “(1) IN GENERAL.—A pharmacy benefits man-
6 ager, a third-party administrator of a group health
7 plan, a health insurance issuer offering group health
8 insurance coverage, or an entity providing pharmacy
9 benefits management services under such health
10 plan or health insurance coverage shall remit 100
11 percent of rebates, fees, alternative discounts, and
12 all other remuneration received from a pharma-
13 ceutical manufacturer, distributor or any other third
14 party, that are related to utilization of drugs under
15 such health plan or health insurance coverage, to the
16 group health plan.

17 “(2) FORM AND MANNER OF REMITTANCE.—

18 Such rebates, fees, alternative discounts, and other
19 remuneration shall be—

20 “(A) remitted to the group health plan in
21 a timely fashion after the period for which such
22 rebates, fees, or other remuneration is cal-
23 culated, and in no case later than 90 days after
24 the end of such period;

1 “(B) fully disclosed and enumerated to the
2 group health plan sponsor, as described in
3 (b)(1);

4 “(C) available for audit by the plan spon-
5 sor, or a third party designated by a plan spon-
6 sor no less than once per plan year; and

7 “(D) returned to the issuer or entity pro-
8 viding pharmaceutical benefit management
9 services by the group health plan if audits by
10 such issuer or entity indicate that the amounts
11 received are incorrect after such amounts have
12 been paid to the group health plan.

13 “(3) AUDIT OF REBATE CONTRACTS.—A phar-
14 macy benefits manager, a third-party administrator
15 of a group health plan, a health insurance issuer of-
16 fering group health insurance coverage, or an entity
17 providing pharmacy benefits management services
18 under such health plan or health insurance coverage
19 shall make rebate contracts with drug manufactur-
20 ers available for audit by such plan sponsor or des-
21 ignated third party, subject to confidentiality agree-
22 ments to prevent re-disclosure of such contracts.

23 “(e) ENFORCEMENT.—

1 “(1) IN GENERAL.—The Secretary, in consulta-
2 tion with the Secretary of Labor and the Secretary
3 of the Treasury, shall enforce this section.

4 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
5 TION.—A health insurance issuer or an entity pro-
6 viding pharmacy benefit management services that
7 violates subsection (a), fails to provide information
8 required under subsection (b), engages in spread
9 pricing as defined in subsection (c), or fails to com-
10 ply with the requirements of subsection (d), or a
11 drug manufacturer that fails to provide information
12 under subsection (b)(1)(A), in a timely manner shall
13 be subject to a civil monetary penalty in the amount
14 of \$10,000 for each day during which such violation
15 continues or such information is not disclosed or re-
16 ported.

17 “(3) FALSE INFORMATION.—A health insurance
18 issuer, entity providing pharmacy benefit manage-
19 ment services, or drug manufacturer that knowingly
20 provides false information under this section shall be
21 subject to a civil money penalty in an amount not
22 to exceed \$100,000 for each item of false informa-
23 tion. Such civil money penalty shall be in addition to
24 other penalties as may be prescribed by law.

1 “(4) PROCEDURE.—The provisions of section
2 1128A of the Social Security Act, other than sub-
3 section (a) and (b) and the first sentence of sub-
4 section (c)(1) of such section shall apply to civil
5 monetary penalties under this subsection in the
6 same manner as such provisions apply to a penalty
7 or proceeding under section 1128A of the Social Se-
8 curity Act.

9 “(5) SAFE HARBOR.—The Secretary may waive
10 penalties under paragraph (2), or extend the period
11 of time for compliance with a requirement of this
12 section, for an entity in violation of this section that
13 has made a good-faith effort to comply with this sec-
14 tion.

15 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
16 tion shall be construed to prohibit payments to entities
17 offering pharmacy benefits management services for bona
18 fide services using a fee structure not contemplated by this
19 section, provided that such fees are transparent to group
20 health plans and health insurance issuers.

21 “(g) DEFINITIONS.—In this section—

22 “(1) the term ‘similarly situated pharmacy’
23 means, with respect to a particular pharmacy, an-
24 other pharmacy that is approximately the same size
25 (as measured by the number of prescription drugs

1 dispensed), and that serves patients in the same geo-
2 graphical area, whether through physical locations or
3 mail order; and

4 “(2) the term ‘wholesale acquisition cost’ has
5 the meaning given such term in section
6 1847A(c)(6)(B) of the Social Security Act.”.

7 **SEC. 365. STUDY BY COMPTROLLER GENERAL OF UNITED**
8 **STATES.**

9 (a) **IN GENERAL.**—The Comptroller General of the
10 United States (referred to in this section as the “Comp-
11 troller General”) shall, in consultation with appropriate
12 stakeholders, conduct a study on the role of pharmacy
13 benefit managers.

14 (b) **PERMISSIBLE EXAMINATION.**—In conducting the
15 study required under subsection (a), the Comptroller Gen-
16 eral may examine various qualitative and quantitative as-
17 pects of the role of pharmacy benefit managers, such as
18 the following:

19 (1) The role that pharmacy benefit managers
20 play in the pharmaceutical supply chain.

21 (2) The state of competition among pharmacy
22 benefit managers, including the market share for the
23 Nation’s largest pharmacy benefit managers.

24 (3) The use of rebates and fees by pharmacy
25 benefit managers, including—

1 (A) the extent to which rebates are passed
2 on to health plans and whether such rebates are
3 passed on to individuals enrolled in such plans;

4 (B) the extent to which rebates are kept by
5 such pharmacy benefit managers; and

6 (C) the role of any fees charged by such
7 pharmacy benefit managers.

8 (4) Whether pharmacy benefit managers struc-
9 ture their formularies in favor of high-rebate pre-
10 scription drugs over lower-cost, lower-rebate alter-
11 natives.

12 (5) The average prior authorization approval
13 time for pharmacy benefit managers.

14 (6) Factors affecting the use of step therapy by
15 pharmacy benefit managers.

16 (c) REPORT.—Not later than 3 years after the date
17 of enactment of this Act, the Comptroller General shall
18 submit to the Secretary of Health and Human Services,
19 the Committee on Health, Education, Labor, and Pen-
20 sions of the Senate, and the Committee on Energy and
21 Commerce of the House of Representatives a report con-
22 taining the results of the study conducted under sub-
23 section (a), including policy recommendations.

1 **Subtitle E—Medicare and Medicaid**
2 **Prescription Drug Reforms**

3 **SEC. 371. MEDICARE PART D MODERNIZATION REDESIGN.**

4 (a) BENEFIT STRUCTURE REDESIGN.—Section
5 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
6 102(b)) is amended—

7 (1) in paragraph (2)—

8 (A) in subparagraph (A), in the matter
9 preceding clause (i), by inserting “for a year
10 preceding 2023 and for costs above the annual
11 deductible specified in paragraph (1) and up to
12 the annual out-of-pocket threshold specified in
13 paragraph (4)(B) for 2023 and each subsequent
14 year” after “paragraph (3)”;

15 (B) in subparagraph (C)—

16 (i) in clause (i), in the matter pre-
17 ceding subclause (I), by inserting “for a
18 year preceding 2023,” after “paragraph
19 (4),”; and

20 (ii) in clause (ii)(III), by striking
21 “and each subsequent year” and inserting
22 “, 2021, and 2022”; and

23 (C) in subparagraph (D)—

24 (i) in clause (i)—

1 (I) in the matter preceding sub-
2 clause (I), by inserting “for a year
3 preceding 2023,” after “paragraph
4 (4),”; and

5 (II) in subclause (I)(bb), by
6 striking “a year after 2018” and in-
7 serting “each of years 2018 through
8 2022”; and

9 (ii) in clause (ii)(V), by striking
10 “2019 and each subsequent year” and in-
11 serting “each of years 2019 through
12 2022”;

13 (2) in paragraph (3)(A)—

14 (A) in the matter preceding clause (i), by
15 inserting “for a year preceding 2023,” after
16 “and (4),”; and

17 (B) in clause (ii), by striking “for a subse-
18 quent year” and inserting “for each of years
19 2007 through 2022”;

20 (3) in paragraph (4)—

21 (A) in subparagraph (A)—

22 (i) in clause (i)—

23 (I) by redesignating subclauses
24 (I) and (II) as items (aa) and (bb),

1 respectively, and indenting appro-
2 priately;

3 (II) in the matter preceding item
4 (aa), as redesignated by subclause (I),
5 by striking “is equal to the greater
6 of—” and inserting “is equal to—

7 “(I) for a year preceding 2023,
8 the greater of—”;

9 (III) by striking the period at the
10 end of item (bb), as redesignated by
11 subclause (I), and inserting “; and”;
12 and

13 (IV) by adding at the end the fol-
14 lowing:

15 “(II) for 2023 and each suc-
16 ceeding year, \$0.”; and

17 (ii) in clause (ii)—

18 (I) by striking “clause (i)(I)” and
19 inserting “clause (i)(I)(aa)”; and

20 (II) by adding at the end the fol-
21 lowing new sentence: “The Secretary
22 shall continue to calculate the dollar
23 amounts specified in clause (i)(I)(aa),
24 including with the adjustment under

1 this clause, after 2022 for purposes of
2 section 1860D–14(a)(1)(D)(iii).”;

3 (B) in subparagraph (B)—

4 (i) in clause (i)—

5 (I) in subclause (V), by striking
6 “or” at the end;

7 (II) in subclause (VI)—

8 (aa) by striking “for a sub-
9 sequent year” and inserting “for
10 2021 and 2022”; and

11 (bb) by striking the period
12 at the end and inserting a semi-
13 colon; and

14 (III) by adding at the end the
15 following new subclauses:

16 “(VII) for 2023, is equal to
17 \$3,100; or

18 “(VIII) for a subsequent year, is
19 equal to the amount specified in this
20 subparagraph for the previous year,
21 increased by the annual percentage in-
22 crease described in paragraph (6) for
23 the year involved.”; and

24 (ii) in clause (ii), by striking “clause
25 (i)(II)” and inserting “clause (i)”;

1 (C) in subparagraph (C)(i), by striking
2 “and for amounts” and inserting “and for a
3 year preceding 2023 for amounts”; and

4 (D) in subparagraph (E), by striking “In
5 applying” and inserting “For each of 2011
6 through 2022, in applying”.

7 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

8 (1) IN GENERAL.—Section 1860D–2(b)(2)(A)
9 of the Social Security Act (42 U.S.C. 1395w–
10 102(b)(2)(A)), as amended by subsection (a), is
11 amended—

12 (A) by redesignating clauses (i) and (ii) as
13 subclauses (I) and (II) and moving such sub-
14 clauses 2 ems to the right;

15 (B) by striking “25 PERCENT COINSUR-
16 ANCE.—Subject to” and inserting “COINSUR-
17 ANCE.—

18 “(i) IN GENERAL.—Subject to”;

19 (C) in each of subclauses (I) and (II), as
20 redesignated by subparagraph (A), by striking
21 “25 percent” and inserting “the applicable per-
22 centage (as defined in clause (ii))”; and

23 (D) by adding at the end the following new
24 clause:

1 “(ii) APPLICABLE PERCENTAGE DE-
2 FINED.—For purposes of clause (i), the
3 term ‘applicable percentage’ means—

4 “(I) for a year preceding 2023,
5 25 percent; and

6 “(II) for 2023 and each subse-
7 quent year, 20 percent.”.

8 (2) CONFORMING AMENDMENT.—Section
9 1860D–14(a)(2)(D) of the Social Security Act (42
10 U.S.C. 1395w–114(a)(2)(D)) is amended by striking
11 “25 percent” and inserting “the applicable percent-
12 age”.

13 (c) DECREASING REINSURANCE PAYMENT
14 AMOUNT.—Section 1860D–15(b) of the Social Security
15 Act (42 U.S.C. 1395w–115(b)) is amended—

16 (1) in paragraph (1)—

17 (A) by striking “equal to 80 percent” and
18 inserting “equal to—

19 “(A) for a year preceding 2023, 80 per-
20 cent”;

21 (B) in subparagraph (A), as added by
22 paragraph (1), by striking the period at the end
23 and inserting “; and”; and

24 (C) by adding at the end the following new
25 subparagraph:

1 “(B) for 2023 and each subsequent year,
2 the sum of—

3 “(i) an amount equal to the applicable
4 percentage specified in paragraph (5)(A) of
5 such allowable reinsurance costs attrib-
6 utable to that portion of gross prescription
7 drug costs as specified in paragraph (3) in-
8 curred in the coverage year after such indi-
9 vidual has incurred costs that exceed the
10 annual out-of-pocket threshold specified in
11 section 1860D–2(b)(4)(B) with respect to
12 applicable drugs (as defined in section
13 1860D–14B(g)(2)); and

14 “(ii) an amount equal to the applica-
15 ble percentage specified in paragraph
16 (5)(B) of allowable reinsurance costs at-
17 tributable to that portion of gross prescrip-
18 tion drug costs as specified in paragraph
19 (3) incurred in the coverage year after
20 such individual has incurred costs that ex-
21 ceed the annual out-of-pocket threshold
22 specified in section 1860D–2(b)(4)(B) with
23 respect to covered part D drugs that are
24 not applicable drugs (as so defined).”;

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

3 “(5) APPLICABLE PERCENTAGE SPECIFIED.—
4 For purposes of paragraph (1)(B), the applicable
5 percentage specified in this paragraph is—

6 “(A) with respect to applicable drugs (as
7 defined in section 1860D–14B(g)(2))—

8 “(i) for 2023, 60 percent;

9 “(ii) for 2024, 40 percent; and

10 “(iii) for 2025 and each subsequent
11 year, 20 percent; and

12 “(B) with respect to covered part D drugs
13 that are not applicable drugs (as so defined)—

14 “(i) for 2023, 80 percent;

15 “(ii) for 2024, 60 percent; and

16 “(iii) for 2025 and each subsequent
17 year, 40 percent.”.

18 (d) MANUFACTURER DISCOUNT PROGRAM DURING
19 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

20 (1) IN GENERAL.—Part D of title XVIII of the
21 Social Security Act is amended by inserting after
22 section 1860D–14A (42 U.S.C. 1495w–114) the fol-
23 lowing new section:

1 **“SEC. 1860D-14B. MANUFACTURER DISCOUNT PROGRAM.**

2 “(a) ESTABLISHMENT.—The Secretary shall estab-
3 lish a manufacturer discount program (in this section re-
4 ferred to as the ‘program’). Under the program, the Sec-
5 retary shall enter into agreements described in subsection
6 (b) with manufacturers and provide for the performance
7 of the duties described in subsection (c). The Secretary
8 shall establish a model agreement for use under the pro-
9 gram by not later than January 1, 2022, in consultation
10 with manufacturers, and allow for comment on such model
11 agreement.

12 “(b) TERMS OF AGREEMENT.—

13 “(1) IN GENERAL.—

14 “(A) AGREEMENT.—An agreement under
15 this section shall require the manufacturer to
16 provide applicable beneficiaries access to dis-
17 counted prices for applicable drugs of the man-
18 ufacturer that are dispensed on or after Janu-
19 ary 1, 2023.

20 “(B) PROVISION OF DISCOUNTED PRICES
21 AT THE POINT-OF-SALE.—The discounted prices
22 described in subparagraph (A) shall be provided
23 to the applicable beneficiary at the pharmacy or
24 by the mail order service at the point-of-sale of
25 an applicable drug.

1 “(2) PROVISION OF APPROPRIATE DATA.—Each
2 manufacturer with an agreement in effect under this
3 section shall collect and have available appropriate
4 data, as determined by the Secretary, to ensure that
5 it can demonstrate to the Secretary compliance with
6 the requirements under the program.

7 “(3) COMPLIANCE WITH REQUIREMENTS FOR
8 ADMINISTRATION OF PROGRAM.—Each manufac-
9 turer with an agreement in effect under this section
10 shall comply with requirements imposed by the Sec-
11 retary or a third party with a contract under sub-
12 section (d)(3), as applicable, for purposes of admin-
13 istering the program, including any determination
14 under subparagraph (A) of subsection (c)(1) or pro-
15 cedures established under such subsection (c)(1).

16 “(4) LENGTH OF AGREEMENT.—

17 “(A) IN GENERAL.—An agreement under
18 this section shall be effective for an initial pe-
19 riod of not less than 12 months and shall be
20 automatically renewed for a period of not less
21 than 1 year unless terminated under subpara-
22 graph (B).

23 “(B) TERMINATION.—

24 “(i) BY THE SECRETARY.—The Sec-
25 retary may provide for termination of an

1 agreement under this section for a knowing
2 and willful violation of the requirements of
3 the agreement or other good cause shown.
4 Such termination shall not be effective ear-
5 lier than 30 days after the date of notice
6 to the manufacturer of such termination.
7 The Secretary shall provide, upon request,
8 a manufacturer with a hearing concerning
9 such a termination, and such hearing shall
10 take place prior to the effective date of the
11 termination with sufficient time for such
12 effective date to be repealed if the Sec-
13 retary determines appropriate.

14 “(ii) BY A MANUFACTURER.—A man-
15 ufacturer may terminate an agreement
16 under this section for any reason. Any
17 such termination shall be effective, with re-
18 spect to a plan year—

19 “(I) if the termination occurs be-
20 fore January 30 of a plan year, as of
21 the day after the end of the plan year;
22 and

23 “(II) if the termination occurs on
24 or after January 30 of a plan year, as

1 of the day after the end of the suc-
2 ceeding plan year.

3 “(iii) EFFECTIVENESS OF TERMI-
4 NATION.—Any termination under this sub-
5 paragraph shall not affect discounts for
6 applicable drugs of the manufacturer that
7 are due under the agreement before the ef-
8 fective date of its termination.

9 “(iv) NOTICE TO THIRD PARTY.—The
10 Secretary shall provide notice of such ter-
11 mination to a third party with a contract
12 under subsection (d)(3) within not less
13 than 30 days before the effective date of
14 such termination.

15 “(5) EFFECTIVE DATE OF AGREEMENT.—An
16 agreement under this section shall take effect on a
17 date determined appropriate by the Secretary, which
18 may be at the start of a calendar quarter.

19 “(c) DUTIES DESCRIBED.—The duties described in
20 this subsection are the following:

21 “(1) ADMINISTRATION OF PROGRAM.—Admin-
22 istering the program, including—

23 “(A) the determination of the amount of
24 the discounted price of an applicable drug of a
25 manufacturer;

1 “(B) the establishment of procedures
2 under which discounted prices are provided to
3 applicable beneficiaries at pharmacies or by
4 mail order service at the point-of-sale of an ap-
5 plicable drug;

6 “(C) the establishment of procedures to
7 ensure that, not later than the applicable num-
8 ber of calendar days after the dispensing of an
9 applicable drug by a pharmacy or mail order
10 service, the pharmacy or mail order service is
11 reimbursed for an amount equal to the dif-
12 ference between—

13 “(i) the negotiated price of the appli-
14 cable drug; and

15 “(ii) the discounted price of the appli-
16 cable drug;

17 “(D) the establishment of procedures to
18 ensure that the discounted price for an applica-
19 ble drug under this section is applied before any
20 coverage or financial assistance under other
21 health benefit plans or programs that provide
22 coverage or financial assistance for the pur-
23 chase or provision of prescription drug coverage
24 on behalf of applicable beneficiaries as the Sec-
25 retary may specify; and

1 “(E) providing a reasonable dispute resolu-
2 tion mechanism to resolve disagreements be-
3 tween manufacturers, applicable beneficiaries,
4 and the third party with a contract under sub-
5 section (d)(3).

6 “(2) MONITORING COMPLIANCE.—

7 “(A) IN GENERAL.—The Secretary shall
8 monitor compliance by a manufacturer with the
9 terms of an agreement under this section.

10 “(B) NOTIFICATION.—If a third party
11 with a contract under subsection (d)(3) deter-
12 mines that the manufacturer is not in compli-
13 ance with such agreement, the third party shall
14 notify the Secretary of such noncompliance for
15 appropriate enforcement under subsection (e).

16 “(3) COLLECTION OF DATA FROM PRESCRIP-
17 TION DRUG PLANS AND MA-PD PLANS.—The Sec-
18 retary may collect appropriate data from prescrip-
19 tion drug plans and MA-PD plans in a timeframe
20 that allows for discounted prices to be provided for
21 applicable drugs under this section.

22 “(d) ADMINISTRATION.—

23 “(1) IN GENERAL.—Subject to paragraph (2),
24 the Secretary shall provide for the implementation of

1 this section, including the performance of the duties
2 described in subsection (c).

3 “(2) LIMITATION.—In providing for the imple-
4 mentation of this section, the Secretary shall not re-
5 ceive or distribute any funds of a manufacturer
6 under the program.

7 “(3) CONTRACT WITH THIRD PARTIES.—The
8 Secretary shall enter into a contract with 1 or more
9 third parties to administer the requirements estab-
10 lished by the Secretary in order to carry out this
11 section. At a minimum, the contract with a third
12 party under the preceding sentence shall require
13 that the third party—

14 “(A) receive and transmit information be-
15 tween the Secretary, manufacturers, and other
16 individuals or entities the Secretary determines
17 appropriate;

18 “(B) receive, distribute, or facilitate the
19 distribution of funds of manufacturers to ap-
20 propriate individuals or entities in order to
21 meet the obligations of manufacturers under
22 agreements under this section;

23 “(C) provide adequate and timely informa-
24 tion to manufacturers, consistent with the
25 agreement with the manufacturer under this

1 section, as necessary for the manufacturer to
2 fulfill its obligations under this section; and

3 “(D) permit manufacturers to conduct
4 periodic audits, directly or through contracts, of
5 the data and information used by the third
6 party to determine discounts for applicable
7 drugs of the manufacturer under the program.

8 “(4) PERFORMANCE REQUIREMENTS.—The
9 Secretary shall establish performance requirements
10 for a third party with a contract under paragraph
11 (3) and safeguards to protect the independence and
12 integrity of the activities carried out by the third
13 party under the program under this section.

14 “(5) ADMINISTRATION.—Chapter 35 of title 44,
15 United States Code, shall not apply to the program
16 under this section.

17 “(6) FUNDING.—For purposes of carrying out
18 this section, the Secretary shall provide for the
19 transfer, from the Federal Supplementary Medical
20 Insurance Trust Fund under section 1841 to the
21 Centers for Medicare & Medicaid Services Program
22 Management Account, of \$4,000,000 for each of fis-
23 cal years 2020 through 2023, to remain available
24 until expended.”.

25 “(e) ENFORCEMENT.—

1 “(1) AUDITS.—Each manufacturer with an
2 agreement in effect under this section shall be sub-
3 ject to periodic audit by the Secretary.

4 “(2) CIVIL MONEY PENALTY.—

5 “(A) IN GENERAL.—The Secretary shall
6 impose a civil money penalty on a manufacturer
7 that fails to provide applicable beneficiaries dis-
8 counts for applicable drugs of the manufacturer
9 in accordance with such agreement for each
10 such failure in an amount the Secretary deter-
11 mines is commensurate with the sum of—

12 “(i) the amount that the manufac-
13 turer would have paid with respect to such
14 discounts under the agreement, which will
15 then be used to pay the discounts which
16 the manufacturer had failed to provide;
17 and

18 “(ii) 25 percent of such amount.

19 “(B) APPLICATION.—The provisions of
20 section 1128A (other than subsections (a) and
21 (b)) shall apply to a civil money penalty under
22 this paragraph in the same manner as such
23 provisions apply to a penalty or proceeding
24 under section 1128A(a).

1 “(f) CLARIFICATION REGARDING AVAILABILITY OF
2 OTHER COVERED PART D DRUGS.—Nothing in this sec-
3 tion shall prevent an applicable beneficiary from pur-
4 chasing a covered part D drug that is not an applicable
5 drug (including a generic drug or a drug that is not on
6 the formulary of the prescription drug plan or MA–PD
7 plan that the applicable beneficiary is enrolled in).

8 “(g) DEFINITIONS.—In this section:

9 “(1) APPLICABLE BENEFICIARY.—The term
10 ‘applicable beneficiary’ means an individual who, on
11 the date of dispensing a covered part D drug—

12 “(A) is enrolled in a prescription drug plan
13 or an MA–PD plan;

14 “(B) is not enrolled in a qualified retiree
15 prescription drug plan; and

16 “(C) has incurred costs for covered part D
17 drugs in the year that are above the annual de-
18 ductible specified in section 1860D–2(b)(1) for
19 such year.

20 “(2) APPLICABLE DRUG.—The term ‘applicable
21 drug’ means, with respect to an applicable bene-
22 ficiary, a covered part D drug—

23 “(A) approved under a new drug applica-
24 tion under section 505(e) of the Federal Food,
25 Drug, and Cosmetic Act or, in the case of a bio-

1 logic product, licensed under section 351 of the
2 Public Health Service Act (including a product
3 licensed under subsection (k) of such section
4 351); and

5 “(B)(i) if the PDP sponsor of the prescrip-
6 tion drug plan or the MA organization offering
7 the MA–PD plan uses a formulary, which is on
8 the formulary of the prescription drug plan or
9 MA–PD plan that the applicable beneficiary is
10 enrolled in;

11 “(ii) if the PDP sponsor of the prescrip-
12 tion drug plan or the MA organization offering
13 the MA–PD plan does not use a formulary, for
14 which benefits are available under the prescrip-
15 tion drug plan or MA–PD plan that the appli-
16 cable beneficiary is enrolled in; or

17 “(iii) is provided through an exception or
18 appeal.

19 “(3) APPLICABLE NUMBER OF CALENDAR
20 DAYS.—The term ‘applicable number of calendar
21 days’ means—

22 “(A) with respect to claims for reimburse-
23 ment submitted electronically, 14 days; and

24 “(B) with respect to claims for reimburse-
25 ment submitted otherwise, 30 days.

1 “(4) DISCOUNTED PRICE.—

2 “(A) IN GENERAL.—The term ‘discounted
3 price’ means—

4 “(i) with respect to an applicable drug
5 dispensed for an applicable beneficiary who
6 has incurred costs that are below the an-
7 nual out-of-pocket threshold specified in
8 section 1860D–2(b)(4)(B) for the year, 93
9 percent of the negotiated price of the ap-
10 plicable drug of a manufacturer; and

11 “(ii) with respect to an applicable
12 drug dispensed for an applicable bene-
13 ficiary who has incurred costs for covered
14 part D drugs in the year that are equal to
15 or exceed the annual out-of-pocket thresh-
16 old specified in section 1860D–2(b)(4)(B)
17 for the year, 86 percent of the negotiated
18 price of the applicable drug of a manufac-
19 turer.

20 “(B) CLARIFICATION.—Nothing in this
21 section shall be construed as affecting the re-
22 sponsibility of an applicable beneficiary for pay-
23 ment of a dispensing fee for an applicable drug.

24 “(C) CLARIFICATION FOR CERTAIN
25 CLAIMS.—With respect to the amount of the ne-

1 negotiated price of an individual claim for an ap-
2 plicable drug with respect to an applicable bene-
3 ficiary, the manufacturer of the applicable drug
4 shall provide—

5 “(i) the discounted price under clause
6 (i) of subparagraph (A) only on the portion
7 of the negotiated price of the applicable
8 drug that falls above the deductible speci-
9 fied in section 1860D–2(b)(1) for the year
10 and below the annual out-of-pocket thresh-
11 old specified in section 1860D–2(b)(4)(B)
12 for the year; and

13 “(ii) the discounted price under clause
14 (ii) of subparagraph (A) only on the por-
15 tion of the negotiated price of the applica-
16 ble drug that falls at or above such annual
17 out-of-pocket threshold.

18 “(5) MANUFACTURER.—The term ‘manufac-
19 turer’ means any entity which is engaged in the pro-
20 duction, preparation, propagation, compounding,
21 conversion, or processing of prescription drug prod-
22 ucts, either directly or indirectly by extraction from
23 substances of natural origin, or independently by
24 means of chemical synthesis, or by a combination of
25 extraction and chemical synthesis. Such term does

1 not include a wholesale distributor of drugs or a re-
2 tail pharmacy licensed under State law.

3 “(6) NEGOTIATED PRICE.—The term ‘nego-
4 tiated price’ has the meaning given such term in sec-
5 tion 1860D–2(d)(1)(B), except that such negotiated
6 price shall not include any dispensing fee for the ap-
7 plicable drug.

8 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
9 PLAN.—The term ‘qualified retiree prescription drug
10 plan’ has the meaning given such term in section
11 1860D–22(a)(2).”.

12 (2) SUNSET OF MEDICARE COVERAGE GAP DIS-
13 COUNT PROGRAM.—Section 1860D–14A of the So-
14 cial Security Act (42 U.S.C. 1395–114a) is amend-
15 ed—

16 (A) in subsection (a), in the first sentence,
17 by striking “The Secretary” and inserting
18 “Subject to subsection (h), the Secretary”; and

19 (B) by adding at the end the following new
20 subsection:

21 “(h) SUNSET OF PROGRAM.—

22 “(1) IN GENERAL.—The program shall not
23 apply to applicable drugs dispensed on or after Jan-
24 uary 1, 2023, and, subject to paragraph (2), agree-

1 ments under this section shall be terminated as of
2 such date.

3 “(2) CONTINUED APPLICATION FOR APPLICA-
4 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
5 provisions of this section (including all responsibil-
6 ities and duties) shall continue to apply after Janu-
7 ary 1, 2023, with respect to applicable drugs dis-
8 pensed prior to such date.”.

9 (3) INCLUSION OF ACTUARIAL VALUE OF MANU-
10 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11
11 of the Social Security Act (42 U.S.C. 1395w–111)
12 is amended—

13 (A) in subsection (b)(2)(C)(iii)—

14 (i) by striking “assumptions regarding
15 the reinsurance” and inserting “assump-
16 tions regarding—

17 “(I) the reinsurance”; and

18 (ii) by adding at the end the fol-
19 lowing:

20 “(II) for 2023 and each subse-
21 quent year, the manufacturer dis-
22 counts provided under section 1860D–
23 14B subtracted from the actuarial
24 value to produce such bid; and”; and

25 (B) in subsection (c)(1)(C)—

1 (i) by striking “an actuarial valuation
2 of the reinsurance” and inserting “an ac-
3 tuarial valuation of—

4 “(i) the reinsurance”;

5 (ii) in clause (i), as added by clause
6 (i) of this subparagraph, by adding “and”
7 at the end; and

8 (iii) by adding at the end the fol-
9 lowing:

10 “(ii) for 2023 and each subsequent
11 year, the manufacturer discounts provided
12 under section 1860D–14B;”.

13 (4) CLARIFICATION REGARDING EXCLUSION OF
14 MANUFACTURER DISCOUNTS FROM TROOP.—Section
15 1860D–2(b)(4) of the Social Security Act (42
16 U.S.C. 1395w–102(b)(4)) is amended—

17 (A) in subparagraph (C), by inserting “and
18 subject to subparagraph (F)” after “subpara-
19 graph (E)”; and

20 (B) by adding at the end the following new
21 subparagraph:

22 “(F) CLARIFICATION REGARDING EXCLU-
23 SION OF MANUFACTURER DISCOUNTS.—In ap-
24 plying subparagraph (A), incurred costs shall

1 not include any manufacturer discounts pro-
2 vided under section 1860D–14B.”.

3 (e) DETERMINATION OF ALLOWABLE REINSURANCE
4 COSTS.—Section 1860D–15(b) of the Social Security Act
5 (42 U.S.C. 1395w–115(b)) is amended—

6 (1) in paragraph (2)—

7 (A) by striking “COSTS.—For purposes”
8 and inserting “COSTS.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), for purposes”; and

11 (B) by adding at the end the following new
12 subparagraph:

13 “(B) INCLUSION OF MANUFACTURER DIS-
14 COUNTS ON APPLICABLE DRUGS.—For purposes
15 of applying subparagraph (A), the term ‘allow-
16 able reinsurance costs’ shall include the portion
17 of the negotiated price (as defined in section
18 1860D–14B(g)(6)) of an applicable drug (as
19 defined in section 1860D–14B(g)(2)) that was
20 paid by a manufacturer under the manufacturer
21 discount program under section 1860D–14B.”;
22 and

23 (2) in paragraph (3)—

1 (A) in the first sentence, by striking “For
2 purposes” and inserting “Subject to paragraph
3 (2)(B), for purposes”; and

4 (B) in the second sentence, by inserting
5 “or, in the case of an applicable drug, by a
6 manufacturer” after “by the individual or
7 under the plan”.

8 (f) UPDATING RISK ADJUSTMENT METHODOLOGIES
9 TO ACCOUNT FOR PART D MODERNIZATION REDE-
10 SIGN.—Section 1860D–15(c) of the Social Security Act
11 (42 U.S.C. 1395w–115(c)) is amended by adding at the
12 end the following new paragraph:

13 “(3) UPDATING RISK ADJUSTMENT METH-
14 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
15 TION REDESIGN.—The Secretary shall update the
16 risk adjustment methodologies used to adjust bid
17 amounts pursuant to this subsection as appropriate
18 to take into account changes in benefits under this
19 part pursuant to the amendments made by section
20 371 of the Fair Care Act of 2022.”.

21 (g) CONDITIONS FOR COVERAGE OF DRUGS UNDER
22 THIS PART.—Section 1860D–43 of the Social Security
23 Act (42 U.S.C. 1395w–153) is amended—

24 (1) in subsection (a)—

1 (A) in paragraph (2), by striking “and” at
2 the end;

3 (B) in paragraph (3), by striking the pe-
4 riod at the end and inserting a semicolon; and

5 (C) by adding at the end the following new
6 paragraphs:

7 “(4) participate in the manufacturer discount
8 program under section 1860D–14B;

9 “(5) have entered into and have in effect an
10 agreement described in subsection (b) of such sec-
11 tion 1860D–14B with the Secretary; and

12 “(6) have entered into and have in effect, under
13 terms and conditions specified by the Secretary, a
14 contract with a third party that the Secretary has
15 entered into a contract with under subsection (d)(3)
16 of such section 1860D–14B.”;

17 (2) by striking subsection (b) and inserting the
18 following:

19 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
20 of subsection (a) shall apply to covered part D drugs dis-
21 pensed under this part on or after January 1, 2011, and
22 before January 1, 2023, and paragraphs (4) through (6)
23 of such subsection shall apply to covered part D drugs
24 dispensed on or after January 1, 2023.”; and

1 (3) in subsection (c), by striking paragraph (2)
2 and inserting the following:

3 “(2) the Secretary determines that in the period
4 beginning on January 1, 2011, and ending on De-
5 cember 31, 2011 (with respect to paragraphs (1)
6 through (3) of subsection (a)), or the period begin-
7 ning on January 1, 2023, and ending December 31,
8 2023 (with respect to paragraphs (4) through (6) of
9 such subsection), there were extenuating cir-
10 cumstances.”.

11 (h) CONFORMING AMENDMENTS.—

12 (1) Section 1860D–2 of the Social Security Act
13 (42 U.S.C. 1395w–102) is amended—

14 (A) in subsection (a)(2)(A)(i)(I), by strik-
15 ing “, or an increase in the initial” and insert-
16 ing “or for a year preceding 2023 an increase
17 in the initial”;

18 (B) in subsection (c)(1)(C)—

19 (i) in the subparagraph heading, by
20 striking “AT INITIAL COVERAGE LIMIT”;
21 and

22 (ii) by inserting “for a year preceding
23 2023 or the annual out-of-pocket threshold
24 specified in subsection (b)(4)(B) for the
25 year for 2023 and each subsequent year”

1 after “subsection (b)(3) for the year” each
2 place it appears; and

3 (C) in subsection (d)(1)(A), by striking “or
4 an initial” and inserting “or for a year pre-
5 ceding 2023 an initial”.

6 (2) Section 1860D–4(a)(4)(B)(i) of the Social
7 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
8 amended by striking “the initial” and inserting “for
9 a year preceding 2023, the initial”.

10 (3) Section 1860D–14(a) of the Social Security
11 Act (42 U.S.C. 1395w–114(a)) is amended—

12 (A) in paragraph (1)—

13 (i) in subparagraph (C), by striking
14 “The continuation” and inserting “For a
15 year preceding 2023, the continuation”;

16 (ii) in subparagraph (D)(iii), by strik-
17 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
18 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

19 (iii) in subparagraph (E), by striking
20 “The elimination” and inserting “For a
21 year preceding 2023, the elimination”; and

22 (B) in paragraph (2)—

23 (i) in subparagraph (C), by striking
24 “The continuation” and inserting “For a

1 year preceding 2023, the continuation”;

2 and

3 (ii) in subparagraph (E)—

4 (I) by inserting “for a year pre-
5 ceding 2023,” after “subsection (e)”;

6 and

7 (II) by striking “1860D-
8 2(b)(4)(A)(i)(I)” and inserting
9 “1860D-2(b)(4)(A)(i)(I)(aa)”.

10 (4) Section 1860D-21(d)(7) of the Social Secu-
11 rity Act (42 U.S.C. 1395w-131(d)(7)) is amended
12 by striking “section 1860D-2(b)(B)(4)(B)(i)” and
13 inserting “section 1860D-2(b)(B)(4)(C)(i)”.

14 (5) Section 1860D-22(a)(2)(A) of the Social
15 Security Act (42 U.S.C. 1395w-132(a)(2)(A)) is
16 amended—

17 (A) by striking “the value of any discount”
18 and inserting the following: “the value of—

19 “(i) for years prior to 2023, any dis-
20 count”;

21 (B) in clause (i), as inserted by subpara-
22 graph (A) of this paragraph, by striking the pe-
23 riod at the end and inserting “; and”; and

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

1 “(ii) for 2023 and each subsequent
2 year, any discount provided pursuant to
3 section 1860D–14B.”.

4 (6) Section 1860D–41(a)(6) of the Social Secu-
5 rity Act (42 U.S.C. 1395w–151(a)(6)) is amended—

6 (A) by inserting “for a year before 2023”
7 after “1860D–2(b)(3)”; and

8 (B) by inserting “for such year” before the
9 period.

10 (i) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to plan year 2023 and subsequent
12 plan years.

13 **SEC. 372. MAXIMUM MONTHLY CAP ON COST-SHARING PAY-**
14 **MENTS UNDER PRESCRIPTION DRUG PLANS**
15 **AND MA-PD PLANS.**

16 (a) IN GENERAL.—Section 1860D–2(b) of the Social
17 Security Act (42 U.S.C. 1395w–102(b)), as amended by
18 section 121, is amended—

19 (1) in paragraph (2)—

20 (A) in subparagraph (A), by striking “and
21 (D)” and inserting “, (D), and (E)”; and

22 (B) by adding at the end the following new
23 subparagraph:

24 “(E) MAXIMUM MONTHLY CAP ON COST-
25 SHARING PAYMENTS.—

1 “(i) IN GENERAL.—For plan years be-
2 ginning on or after January 1, 2023, the
3 Secretary shall, through notice and com-
4 ment rulemaking, establish a process under
5 which each PDP sponsor offering a pre-
6 scription drug plan and each MA organiza-
7 tion offering an MA–PD plan shall provide
8 to any enrollee, including an enrollee who
9 is a subsidy eligible individual (as defined
10 in paragraph (3) of section 1860D–14(a)),
11 the option to elect with respect to a plan
12 year to have their monthly cost-sharing
13 payments under the plan capped in accord-
14 ance with this subparagraph.

15 “(ii) DETERMINATION OF MAXIMUM
16 MONTHLY CAP.—For each month in the
17 plan year after an enrollee in a prescrip-
18 tion drug plan or an MA–PD plan has
19 made an election pursuant to clause (i),
20 the PDP sponsor or MA organization shall
21 determine a maximum monthly cap (as de-
22 fined in clause (iv)) for such enrollee.

23 “(iii) BENEFICIARY MONTHLY PAY-
24 MENTS.—With respect to an enrollee who
25 has made an election pursuant to clause

1 (i), for each month described in clause (ii),
2 the PDP sponsor or MA organization shall
3 bill such enrollee an amount (not to exceed
4 the maximum monthly cap) for the out-of-
5 pocket costs of such enrollee in such
6 month.

7 “(iv) MAXIMUM MONTHLY CAP DE-
8 FINED.—In this subparagraph, the term
9 ‘maximum monthly cap’ means, with re-
10 spect to an enrollee—

11 “(I) for the first month in which
12 this subparagraph applies, an amount
13 determined by calculating—

14 “(aa) the annual out-of-
15 pocket threshold specified in
16 paragraph (4)(B) minus the in-
17 curred costs of the enrollee as de-
18 scribed in paragraph (4)(C); di-
19 vided by

20 “(bb) the number of months
21 remaining in the plan year; and

22 “(II) for a subsequent month, an
23 amount determined by calculating—

24 “(aa) the sum of any re-
25 maining out-of-pocket costs owed

1 by the enrollee from a previous
2 month that have not yet been
3 billed to the enrollee and any ad-
4 ditional costs incurred by the en-
5 rollee; divided by

6 “(bb) the number of months
7 remaining in the plan year.

8 “(v) ADDITIONAL REQUIREMENTS.—
9 The following requirements shall apply
10 with respect to the option to make an elec-
11 tion pursuant to clause (i) under this sub-
12 paragraph:

13 “(I) SECRETARIAL RESPONSIBIL-
14 ITIES.—The Secretary shall provide
15 information to part D eligible individ-
16 uals on the option to make such elec-
17 tion through educational materials, in-
18 cluding through the notices provided
19 under section 1804(a).

20 “(II) TIMING OF ELECTION.—An
21 enrollee in a prescription drug plan or
22 an MA–PD plan may make such an
23 election—

24 “(aa) prior to the beginning
25 of the plan year; or

1 “(bb) in any month during
2 the plan year.

3 “(III) PDP SPONSOR AND MA
4 ORGANIZATION RESPONSIBILITIES.—
5 Each PDP sponsor offering a pre-
6 scription drug plan or MA organiza-
7 tion offering an MA–PD plan—

8 “(aa) may not limit the op-
9 tion for an enrollee to make such
10 an election to certain covered
11 part D drugs;

12 “(bb) shall, prior to the plan
13 year, notify prospective enrollees
14 of the option to make such an
15 election in promotional materials;

16 “(cc) shall include informa-
17 tion on such option in enrollee
18 educational materials;

19 “(dd) shall have in place a
20 mechanism to notify a pharmacy
21 during the plan year when an en-
22 rollee incurs out-of-pocket costs
23 with respect to covered part D
24 drugs that make it likely the en-

1 enrollee may benefit from making
2 such an election;

3 “(ee) shall provide that a
4 pharmacy, after receiving a noti-
5 fication described in item (dd)
6 with respect to an enrollee, in-
7 forms the enrollee of such notifi-
8 cation;

9 “(ff) shall ensure that such
10 an election by an enrollee has no
11 effect on the amount paid to
12 pharmacies (or the timing of
13 such payments) with respect to
14 covered part D drugs dispensed
15 to the enrollee; and

16 “(gg) shall have in place a
17 financial reconciliation process to
18 correct inaccuracies in payments
19 made by an enrollee under this
20 subparagraph with respect to
21 covered part D drugs during the
22 plan year.

23 “(IV) FAILURE TO PAY AMOUNT
24 BILLED.—If an enrollee fails to pay
25 the amount billed for a month as re-

1 quired under this subparagraph, the
2 election of the enrollee pursuant to
3 clause (i) shall be terminated and en-
4 rollee shall pay the cost-sharing other-
5 wise applicable for any covered part D
6 drugs subsequently dispensed to the
7 enrollee up to the annual out-of-pock-
8 et threshold specified in paragraph
9 (4)(B).

10 “(V) CLARIFICATION REGARDING
11 PAST DUE AMOUNTS.—Nothing in this
12 subparagraph shall be construed as
13 prohibiting a PDP sponsor or an MA
14 organization from billing an enrollee
15 for an amount owed under this sub-
16 paragraph.

17 “(VI) TREATMENT OF UNSET-
18 TLED BALANCES.—Any unsettled bal-
19 ances with respect to amounts owed
20 under this subparagraph shall be
21 treated as plan losses and the Sec-
22 retary shall not be liable for any such
23 balances outside of those assumed as
24 losses estimated in plan bids.”; and

25 (2) in paragraph (4)—

1 (A) in subparagraph (C), by striking “and
2 subject to subparagraph (F)” and inserting
3 “and subject to subparagraphs (F) and (G)”;
4 and

5 (B) by adding at the end the following new
6 subparagraph:

7 “(G) INCLUSION OF COSTS PAID UNDER
8 MAXIMUM MONTHLY CAP OPTION.—In applying
9 subparagraph (A), with respect to an enrollee
10 who has made an election pursuant to clause (i)
11 of paragraph (2)(E), costs shall be treated as
12 incurred if such costs are paid by a PDP spon-
13 sor or an MA organization under the process
14 provided under such paragraph.”.

15 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
16 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
17 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
18 ing at the end the following new paragraph:

19 “(4) SAME MAXIMUM MONTHLY CAP ON COST-
20 SHARING.—For plan years beginning on or after
21 January 1, 2023, the maximum monthly cap on
22 cost-sharing payments under the process provided
23 under subsection (b)(2)(E) shall apply to such cov-
24 erage.”.

1 **SEC. 373. MEDICARE PART B REBATE BY MANUFACTURERS**
2 **FOR DRUGS OR BIOLOGICALS WITH PRICES**
3 **INCREASING FASTER THAN INFLATION.**

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

7 “(h) REBATE BY MANUFACTURERS FOR DRUGS OR
8 BIOLOGICALS WITH PRICES INCREASING FASTER THAN
9 INFLATION.—

10 “(1) REQUIREMENTS.—

11 “(A) SECRETARIAL PROVISION OF INFOR-
12 MATION.—Not later than 6 months after the
13 end of each rebate period (as defined in para-
14 graph (2)(A)) beginning on or after January 1,
15 2023, the Secretary shall, for each rebatable
16 drug (as defined in paragraph (2)(B)), report
17 to each manufacturer of such rebatable drug
18 the following for such rebate period:

19 “(i) Information on the total number
20 of units of the billing and payment code
21 described in subparagraph (A)(i) of para-
22 graph (3) with respect to such rebatable
23 drug and rebate period.

24 “(ii) Information on the amount (if
25 any) of the excess average sales price in-
26 crease described in subparagraph (A)(ii) of

1 such paragraph for such rebatable drug
2 and rebate period.

3 “(iii) The rebate amount specified
4 under such paragraph for such rebatable
5 drug and rebate period.

6 “(B) MANUFACTURER REBATE.—

7 “(i) IN GENERAL.—Subject to clause
8 (ii), for each rebate period beginning on or
9 after January 1, 2023, the manufacturer
10 of a rebatable drug shall, for such drug,
11 not later than 30 days after the date of re-
12 ceipt from the Secretary of the information
13 and rebate amount pursuant to subpara-
14 graph (A) for such rebate period, provide
15 to the Secretary a rebate that is equal to
16 the amount specified in paragraph (3) for
17 such drug for such rebate period.

18 “(ii) EXEMPTION FOR SHORTAGES.—
19 The Secretary may reduce or waive the re-
20 bate under this subparagraph with respect
21 to a rebatable drug that is listed on the
22 drug shortage list maintained by the Food
23 and Drug Administration pursuant to sec-
24 tion 506E of the Federal Food, Drug, and
25 Cosmetic Act.

1 “(C) REQUEST FOR RECONSIDERATION.—
2 The Secretary shall establish procedures under
3 which a manufacturer of a rebatable drug may
4 request a reconsideration by the Secretary of
5 the rebate amount specified under paragraph
6 (3) for such rebatable drug and rebate period,
7 as reported to the manufacturer pursuant to
8 subparagraph (A)(iii).

9 “(2) REBATE PERIOD AND REBATABLE DRUG
10 DEFINED.—In this subsection:

11 “(A) REBATE PERIOD.—The term ‘rebate
12 period’ means a calendar quarter beginning on
13 or after January 1, 2023.

14 “(B) REBATABLE DRUG.—The term
15 ‘rebatable drug’ means a single source drug or
16 biological (other than a biosimilar biological
17 product)—

18 “(i) described in section
19 1842(o)(1)(C) for which the payment
20 amount is provided under this section; or

21 “(ii) for which payment is made sepa-
22 rately under section 1833(i) or section
23 1833(t) and for which the payment
24 amount is calculated based on the payment
25 amount under this section.

1 “(3) REBATE AMOUNT.—

2 “(A) IN GENERAL.—For purposes of para-
3 graph (1)(B), the amount specified in this para-
4 graph for a rebatable drug assigned to a billing
5 and payment code for a rebate period is, subject
6 to paragraph (4), the amount equal to the prod-
7 uct of—

8 “(i) subject to subparagraph (B), the
9 total number of units of the billing and
10 payment code for such rebatable drug fur-
11 nished during the rebate period; and

12 “(ii) the amount (if any) by which—

13 “(I) the amount determined
14 under subsection (b)(4) for such
15 rebatable drug during the rebate pe-
16 riod; exceeds

17 “(II) the inflation-adjusted base
18 payment amount determined under
19 subparagraph (C) of this paragraph
20 for such rebatable drug during the re-
21 bate period.

22 “(B) EXCLUDED UNITS.—For purposes of
23 subparagraph (A)(i), the total number of units
24 of the billing and payment code for rebatable
25 drugs furnished during a rebate period shall not

1 include units with respect to which the manu-
2 facturer provides a discount under the program
3 under section 340B of the Public Health Serv-
4 ice Act or a rebate under section 1927.

5 “(C) DETERMINATION OF INFLATION-AD-
6 JUSTED PAYMENT AMOUNT.—The inflation-ad-
7 justed payment amount determined under this
8 subparagraph for a rebatable drug for a rebate
9 period is—

10 “(i) the amount determined under
11 subsection (b)(4) for such rebatable drug
12 in the payment amount benchmark quarter
13 (as defined in subparagraph (D)); in-
14 creased by

15 “(ii) the percentage by which the re-
16 bate period CPI-U (as defined in subpara-
17 graph (F)) for the rebate period exceeds
18 the benchmark period CPI-U (as defined
19 in subparagraph (E)).

20 “(D) PAYMENT AMOUNT BENCHMARK
21 QUARTER.—The term ‘payment amount bench-
22 mark quarter’ means the calendar quarter be-
23 ginning July 1, 2019.

24 “(E) BENCHMARK PERIOD CPI-U.—The
25 term ‘benchmark period CPI-U’ means the con-

1 sumer price index for all urban consumers
2 (United States city average) for July 2019.

3 “(F) REBATE PERIOD CPI–U.—The term
4 ‘rebate period CPI–U’ means, with respect to a
5 rebate period, the consumer price index for all
6 urban consumers (United States city average)
7 for the last month of the calendar quarter that
8 is two calendar quarters prior to the rebate pe-
9 riod.

10 “(4) APPLICATION TO NEW DRUGS.—In the
11 case of a rebatable drug first approved or licensed
12 by the Food and Drug Administration after July 1,
13 2021, the following shall apply:

14 “(A) DURING INITIAL PERIOD.—For quar-
15 ters during the initial period in which the pay-
16 ment amount for such drug is determined using
17 the methodology described in subsection
18 (c)(4)—

19 “(i) clause (ii)(I) of paragraph (3)(A)
20 shall be applied as if the reference to ‘the
21 amount determined under subsection
22 (b)(4),’ were a reference to ‘the wholesale
23 acquisition cost applicable under subsection
24 (c)(4)’;

1 “(ii) clause (i) of paragraph (3)(C)
2 shall be applied—

3 “(I) as if the reference to ‘the
4 amount determined under subsection
5 (b)(4),’ were a reference to ‘the whole-
6 sale acquisition cost applicable under
7 subsection (c)(4)’; and

8 “(II) as if the term ‘payment
9 amount benchmark quarter’ were de-
10 fined under paragraph (3)(D) as the
11 first full calendar quarter after the
12 day on which the drug was first mar-
13 keted; and

14 “(iii) clause (ii) of paragraph (3)(C)
15 shall be applied as if the term ‘benchmark
16 period CPI-U’ were defined under para-
17 graph (4)(E) as if the reference to ‘July
18 2019’ under such paragraph were a ref-
19 erence to ‘the first month of the first full
20 calendar quarter after the day on which
21 the drug was first marketed’.

22 “(B) AFTER INITIAL PERIOD.—For quar-
23 ters beginning after such initial period—

24 “(i) clause (i) of paragraph (3)(C)
25 shall be applied as if the term ‘payment

1 amount benchmark quarter’ were defined
2 under paragraph (3)(D) as the first full
3 calendar quarter for which the Secretary is
4 able to compute an average sales price for
5 the rebatable drug; and

6 “(ii) clause (ii) of paragraph (3)(C)
7 shall be applied as if the term ‘benchmark
8 period CPI–U’ were defined under para-
9 graph (4)(E) as if the reference to ‘July
10 2019’ under such paragraph were a ref-
11 erence to ‘the first month of the first full
12 calendar quarter for which the Secretary is
13 able to compute an average sales price for
14 the rebatable drug’.

15 “(5) REBATE DEPOSITS.—Amounts paid as re-
16 bates under paragraph (1)(B) shall be deposited into
17 the Federal Supplementary Medical Insurance Trust
18 Fund established under section 1841.

19 “(6) ENFORCEMENT.—

20 “(A) CIVIL MONEY PENALTY.—

21 “(i) IN GENERAL.—The Secretary
22 shall impose a civil money penalty on a
23 manufacturer that fails to comply with the
24 requirements under paragraph (1)(B) with
25 respect to providing a rebate for a

1 rebatable drug for a rebate period for each
2 such failure in an amount equal to the sum
3 of—

4 “(I) the rebate amount specified
5 pursuant to paragraph (3) for such
6 drug for such rebate period; and

7 “(II) 25 percent of such amount.

8 “(ii) APPLICATION.—The provisions
9 of section 1128A (other than subsections
10 (a) (with respect to amounts of penalties
11 or additional assessments) and (b)) shall
12 apply to a civil money penalty under this
13 subparagraph in the same manner as such
14 provisions apply to a penalty or proceeding
15 under section 1128A(a).

16 “(B) NO PAYMENT FOR MANUFACTURERS
17 WHO FAIL TO PAY PENALTY.—If the manufac-
18 turer of a rebatable drug fails to pay a civil
19 money penalty under subparagraph (A) with re-
20 spect to the failure to provide a rebate for a
21 rebatable drug for a rebate period by a date
22 specified by the Secretary after the imposition
23 of such penalty, no payment shall be available
24 under this part for such rebatable drug for cal-
25 endar quarters beginning on or after such date

1 until the Secretary determines the manufac-
2 turer has paid the penalty due under such sub-
3 paragraph.”.

4 (b) IMPLEMENTATION.—Section 1847A(g) of the So-
5 cial Security Act (42 U.S.C. 1395w–3(g)) is amended—

6 (1) in paragraph (4), by striking “and” at the
7 end;

8 (2) in paragraph (5), by striking the period at
9 the end and inserting “; and”; and

10 (3) by adding at the end the following new
11 paragraph:

12 “(6) determination of the rebate amount for a
13 rebatable drug under paragraph (3) of subsection
14 (h), including with respect to a new drug pursuant
15 to paragraph (4) of such subsection, including—

16 “(A) a decision by the Secretary with re-
17 spect to a request for reconsideration under
18 paragraph (1)(C); and

19 “(B) the determination of—

20 “(i) the total number of units of the
21 billing and payment code under paragraph
22 (3)(A)(i); and

23 “(ii) the inflation-adjusted payment
24 amount under paragraph (3)(C).”.

1 (c) CONFORMING AMENDMENT TO PART B ASP CAL-
2 CULATION.—Section 1847A(c)(3) of the Social Security
3 Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting
4 “or subsection (h)” after “section 1927”.

5 **SEC. 374. MARKET BASED PART B PRICING INDEX.**

6 Notwithstanding any provision of part B of title
7 XVIII of the Social Security Act, the Secretary of Health
8 and Human Services may make payments for drugs pay-
9 able under such part based on an international pricing
10 index. In using such an index, the Secretary shall take
11 into account whether the market of each country included
12 in such index is a price-controlled or free market and give
13 more weight under such index to countries with market-
14 based drug policies.

15 **SEC. 375. INNOVATION MODEL TESTING OF MEDICARE**
16 **DRUG PAYMENTS.**

17 Notwithstanding any provision of section 1115A, the
18 Secretary of Health and Human Services may, under such
19 section, test a model to integrate benefits provided for
20 drugs under parts A, B, and D of title XVIII of the Social
21 Security Act.

1 **SEC. 376. MODIFICATION OF MAXIMUM REBATE AMOUNT**
2 **UNDER MEDICAID DRUG REBATE PROGRAM.**

3 (a) IN GENERAL.—Subparagraph (D) of section
4 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–
5 8(c)(2)) is amended to read as follows:

6 “(D) MAXIMUM REBATE AMOUNT.—

7 “(i) IN GENERAL.—Except as pro-
8 vided in clause (ii), in no case shall the
9 sum of the amounts applied under para-
10 graph (1)(A)(ii) and this paragraph with
11 respect to each dosage form and strength
12 of a single source drug or an innovator
13 multiple source drug for a rebate period
14 exceed—

15 “(I) for rebate periods beginning
16 after December 31, 2009, and before
17 September 30, 2023, 100 percent of
18 the average manufacturer price of the
19 drug; and

20 “(II) for rebate periods beginning
21 on or after October 1, 2023, 125 per-
22 cent of the average manufacturer
23 price of the drug.

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

1 “(I) IN GENERAL.—If the aver-
2 age manufacturer price with respect
3 to each dosage form and strength of
4 a single source drug or an innovator
5 multiple source drug increases on or
6 after October 1, 2022, and such in-
7 creased average manufacturer price
8 exceeds the inflation-adjusted average
9 manufacturer price determined with
10 respect to such drug under subclause
11 (II) for the rebate period, clause (i)
12 shall not apply and there shall be no
13 limitation on the sum of the amounts
14 applied under paragraph (1)(A)(ii)
15 and this paragraph for the rebate pe-
16 riod with respect to each dosage form
17 and strength of the single source drug
18 or innovator multiple source drug.

19 “(II) INFLATION-ADJUSTED AV-
20 ERAGE MANUFACTURER PRICE DE-
21 FINED.—In this clause, the term ‘in-
22 flation-adjusted average manufacturer
23 price’ means, with respect to a single
24 source drug or an innovator multiple
25 source drug and a rebate period, the

1 average manufacturer price for each
2 dosage form and strength of the drug
3 for the calendar quarter beginning
4 July 1, 1990 (without regard to
5 whether or not the drug has been sold
6 or transferred to an entity, including
7 a division or subsidiary of the manu-
8 facturer, after the 1st day of such
9 quarter), increased by the percentage
10 by which the consumer price index for
11 all urban consumers (United States
12 city average) for the month before the
13 month in which the rebate period be-
14 gins exceeds such index for September
15 1990.”.

16 (b) TREATMENT OF SUBSEQUENTLY APPROVED
17 DRUGS.—Section 1927(c)(2)(B) of the Social Security Act
18 (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting
19 “and clause (ii)(II) of subparagraph (D)” after “clause
20 (ii)(II) of subparagraph (A)”.

21 (c) TECHNICAL AMENDMENTS.—Section
22 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42
23 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

24 (1) by striking “subparagraph (A)” and insert-
25 ing “paragraph (3)(A)”; and

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

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

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

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

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

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

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

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

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

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

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

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

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

1 is based, or the number of plaintiffs, defendants, or
2 other parties, or the number of causes of action.

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

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

23 (12) MEDICAL PRODUCT.—The term “medical
24 product” means a drug, device, or biological product
25 intended for humans, and the terms “drug”, “de-

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

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

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

1 overhead costs or charges for legal services are not
2 deductible disbursements or costs for such purpose.

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

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

15 **SEC. 382. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

16 (a) STATUTE OF LIMITATIONS.—

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

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

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

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

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

11 (A) upon proof of fraud;

12 (B) intentional concealment; or

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

16 (3) ACTIONS BY A MINOR.—Actions by a minor
17 shall be commenced within 3 years after the date of
18 the occurrence of the breach or tort or 3 years after
19 the date of the medical or health care treatment that
20 is the subject of the claim is completed (whichever
21 occurs first) except that actions by a minor under
22 the full age of 6 years shall be commenced within 3
23 years after the date of the occurrence of the breach
24 or tort, 3 years after the date of the medical or
25 health care treatment that is the subject of the claim

1 is completed, or 1 year after the injury is discovered,
2 or through the use of reasonable diligence should
3 have been discovered, or prior to the minor's 8th
4 birthday, whichever provides a longer period. Such
5 time limitation shall be tolled for minors for any pe-
6 riod during which a parent or guardian and a health
7 care provider have committed fraud or collusion in
8 the failure to bring an action on behalf of the in-
9 jured minor.

10 (b) STATE FLEXIBILITY.—No provision of subsection
11 (a) shall be construed to preempt any State law (whether
12 effective before, on, or after the date of the enactment of
13 this Act) that—

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

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

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

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

1 **SEC. 383. COMPENSATING PATIENT INJURY.**

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

7 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
8 health care lawsuit, the amount of noneconomic damages,
9 if available, shall not exceed \$250,000, regardless of the
10 number of parties against whom the action is brought or
11 the number of separate claims or actions brought with re-
12 spect to the same injury.

13 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
14 DAMAGES.—For purposes of applying the limitation in
15 subsection (b), future noneconomic damages shall not be
16 discounted to present value. The jury shall not be in-
17 formed about the maximum award for noneconomic dam-
18 ages. An award for noneconomic damages in excess of
19 \$250,000 shall be reduced either before the entry of judg-
20 ment, or by amendment of the judgment after entry of
21 judgment, and such reduction shall be made before ac-
22 counting for any other reduction in damages required by
23 law. If separate awards are rendered for past and future
24 noneconomic damages and the combined awards exceed
25 \$250,000, the future noneconomic damages shall be re-
26 duced first.

1 (d) FAIR SHARE RULE.—In any health care lawsuit,
2 each party shall be liable for that party's several share
3 of any damages only and not for the share of any other
4 person. Each party shall be liable only for the amount of
5 damages allocated to such party in direct proportion to
6 such party's percentage of responsibility. Whenever a
7 judgment of liability is rendered as to any party, a sepa-
8 rate judgment shall be rendered against each such party
9 for the amount allocated to such party. For purposes of
10 this section, the trier of fact shall determine the propor-
11 tion of responsibility of each party for the claimant's
12 harm.

13 (e) STATE FLEXIBILITY.—No provision of this sec-
14 tion shall be construed to preempt any State law (whether
15 effective before, on, or after the date of the enactment of
16 this Act) that specifies a particular monetary amount of
17 economic or noneconomic damages (or the total amount
18 of damages) that may be awarded in a health care lawsuit,
19 regardless of whether such monetary amount is greater
20 or lesser than is provided for under this section.

21 **SEC. 384. MAXIMIZING PATIENT RECOVERY.**

22 (a) COURT SUPERVISION OF SHARE OF DAMAGES
23 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
24 suit, the court shall supervise the arrangements for pay-
25 ment of damages to protect against conflicts of interest

1 that may have the effect of reducing the amount of dam-
2 ages awarded that are actually paid to claimants. In par-
3 ticular, in any health care lawsuit in which the attorney
4 for a party claims a financial stake in the outcome by vir-
5 tue of a contingent fee, the court shall have the power
6 to restrict the payment of a claimant's damage recovery
7 to such attorney, and to redirect such damages to the
8 claimant based upon the interests of justice and principles
9 of equity. In no event shall the total of all contingent fees
10 for representing all claimants in a health care lawsuit ex-
11 ceed the following limits:

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

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

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

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

20 (b) APPLICABILITY.—The limitations in this section
21 shall apply whether the recovery is by judgment, settle-
22 ment, mediation, arbitration, or any other form of alter-
23 native dispute resolution. In a health care lawsuit involv-
24 ing a minor or incompetent person, a court retains the
25 authority to authorize or approve a fee that is less than

1 the maximum permitted under this section. The require-
2 ment for court supervision in the first two sentences of
3 subsection (a) applies only in civil actions.

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

10 **SEC. 385. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
11 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
12 **SUITS.**

13 (a) IN GENERAL.—In any health care lawsuit, if an
14 award of future damages, without reduction to present
15 value, equaling or exceeding \$50,000 is made against a
16 party with sufficient insurance or other assets to fund a
17 periodic payment of such a judgment, the court shall, at
18 the request of any party, enter a judgment ordering that
19 the future damages be paid by periodic payments, in ac-
20 cordance with the Uniform Periodic Payment of Judg-
21 ments Act promulgated by the National Conference of
22 Commissioners on Uniform State Laws.

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

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

7 **SEC. 386. PRODUCT LIABILITY FOR HEALTH CARE PRO-**
8 **VIDERS.**

9 A health care provider who prescribes, or who dis-
10 penses pursuant to a prescription, a medical product ap-
11 proved, licensed, or cleared by the Food and Drug Admin-
12 istration shall not be named as a party to a product liabil-
13 ity lawsuit involving such product and shall not be liable
14 to a claimant in a class action lawsuit against the manu-
15 facturer, distributor, or seller of such product.

16 **SEC. 387. EFFECT ON OTHER LAWS.**

17 (a) VACCINE INJURY.—

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

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

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

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

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

15 **SEC. 388. LIMITATION ON EXPERT WITNESS TESTIMONY.**

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

20 (1) the recognized standard of acceptable pro-
21 fessional practice and the specialty thereof, if any,
22 that the defendant practices, which shall be the type
23 of acceptable professional practice recognized in the
24 defendant's community or in a community similar to

1 the defendant's community that was in place at the
2 time the alleged injury or wrongful action occurred;

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

6 (3) that as a proximate result of the defend-
7 ant's negligent act or omission, the claimant suf-
8 fered injuries which would not otherwise have oc-
9 curred,

10 unless the person was licensed to practice, in the State
11 or a contiguous bordering State, a profession or specialty
12 which would make the person's expert testimony relevant
13 to the issues in the case and had practiced this profession
14 or specialty in one of these States during the year pre-
15 ceding the date that the alleged injury or wrongful act
16 occurred.

17 (b) APPLICABILITY.—The requirements set forth in
18 subsection (a) shall also apply to expert witnesses testi-
19 fying for the defendant as rebuttal witnesses.

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

23 **SEC. 389. EXPERT WITNESS QUALIFICATIONS.**

24 (a) IN GENERAL.—In any health care lawsuit, an in-
25 dividual shall not give expert testimony on the appropriate

1 standard of practice or care involved unless the individual
2 is licensed as a health professional in one or more States
3 and the individual meets the following criteria:

4 (1) If the party against whom or on whose be-
5 half the testimony is to be offered is or claims to be
6 a specialist, the expert witness shall specialize at the
7 time of the occurrence that is the basis for the law-
8 suit in the same specialty or claimed specialty as the
9 party against whom or on whose behalf the testi-
10 mony is to be offered. If the party against whom or
11 on whose behalf the testimony is to be offered is or
12 claims to be a specialist who is board certified, the
13 expert witness shall be a specialist who is board cer-
14 tified in that specialty or claimed specialty.

15 (2) During the 1-year period immediately pre-
16 ceding the occurrence of the action that gave rise to
17 the lawsuit, the expert witness shall have devoted a
18 majority of the individual's professional time to one
19 or more of the following:

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

24 (B) The instruction of students in an ac-
25 credited health professional school or accredited

1 residency or clinical research program in the
2 same health profession as the defendant and, if
3 the defendant is or claims to be a specialist, in
4 an accredited health professional school or ac-
5 credited residency or clinical research program
6 in the same specialty or claimed specialty.

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

12 (A) Active clinical practice as a general
13 practitioner.

14 (B) Instruction of students in an accred-
15 ited health professional school or accredited
16 residency or clinical research program in the
17 same health profession as the defendant.

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

24 (c) POWER OF COURT.—Nothing in this section shall
25 limit the power of the trial court in a health care lawsuit

1 to disqualify an expert witness on grounds other than the
2 qualifications set forth under this subsection.

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

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

12 **SEC. 390. COMMUNICATIONS FOLLOWING UNANTICIPATED**
13 **OUTCOME.**

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

1 (b) STATE FLEXIBILITY.—No provision of this sec-
2 tion shall be construed to preempt any State law (whether
3 effective before, on, or after the date of the enactment of
4 this Act) that makes additional communications inadmis-
5 sible as evidence of an admission of liability or as evidence
6 of an admission against interest.

7 **SEC. 391. AFFIDAVIT OF MERIT.**

8 (a) REQUIRED FILING.—Subject to subsection (b),
9 the plaintiff in a health care lawsuit alleging negligence
10 or, if the plaintiff is represented by an attorney, the plain-
11 tiff's attorney shall file simultaneously with the health
12 care lawsuit an affidavit of merit signed by a health pro-
13 fessional who meets the requirements for an expert wit-
14 ness under section 242 of this Act. The affidavit of merit
15 shall certify that the health professional has reviewed the
16 notice and all medical records supplied to him or her by
17 the plaintiff's attorney concerning the allegations con-
18 tained in the notice and shall contain a statement of each
19 of the following:

- 20 (1) The applicable standard of practice or care.
21 (2) The health professional's opinion that the
22 applicable standard of practice or care was breached
23 by the health professional or health facility receiving
24 the notice.

1 (3) The actions that should have been taken or
2 omitted by the health professional or health facility
3 in order to have complied with the applicable stand-
4 ard of practice or care.

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

8 (5) A listing of the medical records reviewed.

9 (b) FILING EXTENSION.—Upon motion of a party for
10 good cause shown, the court in which the complaint is filed
11 may grant the plaintiff or, if the plaintiff is represented
12 by an attorney, the plaintiff’s attorney an additional 28
13 days in which to file the affidavit required under sub-
14 section (a).

15 (c) STATE FLEXIBILITY.—No provision of this sec-
16 tion shall be construed to preempt any State law (whether
17 effective before, on, or after the date of the enactment of
18 this Act) that establishes additional requirements for the
19 filing of an affidavit of merit or similar pre-litigation docu-
20 mentation.

21 **SEC. 392. NOTICE OF INTENT TO COMMENCE LAWSUIT.**

22 (a) ADVANCE NOTICE.—A person shall not com-
23 mence a health care lawsuit against a health care provider
24 unless the person has given the health care provider 90
25 days written notice before the action is commenced.

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

6 (c) 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 establishes a different time period for the
10 filing of written notice.

11 **SEC. 393. LIMITATION ON LIABILITY FOR VOLUNTEER**
12 **HEALTH CARE PROFESSIONALS.**

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

16 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**
17 **HEALTH CARE PROFESSIONALS.**

18 “(a) LIMITATION ON LIABILITY.—A physician shall
19 not be liable under Federal or State law in any civil action
20 for any harm caused by an act or omission of such physi-
21 cian, or attending medical personnel supporting such phy-
22 sician, if such act or omission—

23 “(1) occurs in the course of furnishing qualified
24 charity care (as such term is defined in section
25 199B of the Internal Revenue Code of 1986); and

1 “(2) was not grossly negligent.

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

7 “(c) DEFINITIONS.—In this section:

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

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

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

19 **SEC. 394. RULES OF CONSTRUCTION.**

20 (a) HEALTH CARE LAWSUITS.—Unless otherwise
21 specified in this subtitle, the provisions governing health
22 care lawsuits set forth in this subtitle preempt, subject to
23 subsections (b) and (c), State law to the extent that State
24 law prevents the application of any provisions of law estab-
25 lished by or under this subtitle. The provisions governing

1 health care lawsuits set forth in this subtitle supersede
2 chapter 171 of title 28, United States Code, to the extent
3 that such chapter—

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

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

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

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

22 **SEC. 395. EFFECTIVE DATE.**

23 This subtitle shall apply to any health care lawsuit
24 brought in a Federal or State court, or subject to an alter-
25 native dispute resolution system, that is initiated on or

1 after the date of the enactment of this subtitle, except that
2 any health care lawsuit arising from an injury occurring
3 prior to the date of the enactment of this subtitle shall
4 be governed by the applicable statute of limitations provi-
5 sions in effect at the time the cause of action accrued.

6 **TITLE IV—MEDICARE AND** 7 **MEDICAID REFORMS**

8 **Subtitle A—Medicaid Reforms**

9 **SEC. 401. MEDICAID PAYMENT REFORM.**

10 (a) IN GENERAL.—Title XIX of the Social Security
11 Act (42 U.S.C. 1396 et seq.) is amended by inserting after
12 section 1903 the following section:

13 **“SEC. 1903A. REFORMED PAYMENT TO STATES.**

14 “(a) REFORMED PAYMENT SYSTEM.—

15 “(1) IN GENERAL.—For quarters beginning on
16 or after the implementation date (as defined in sub-
17 section (k)(1)), in the case of a State that elects (in
18 a time and manner specified by the Secretary) to
19 apply this section, in lieu of amounts otherwise pay-
20 able to such State under this title (including any
21 payments attributable to section 1923), except as
22 otherwise provided in this section, the amount pay-
23 able to such State shall be equal to the sum of the
24 following:

1 “(A) ADJUSTED AGGREGATE BENE-
2 FICIARY-BASED AMOUNT.—The aggregate bene-
3 ficiary-based amount specified in subsection (b)
4 for the quarter and the State, adjusted under
5 subsection (e).

6 “(B) CHRONIC CARE QUALITY BONUS.—
7 The amount (if any) of the chronic care quality
8 bonus payment specified in subsection (f) for
9 the quarter for the State.

10 “(2) REQUIREMENT OF STATE SHARE.—

11 “(A) IN GENERAL.—A State shall make,
12 from non-Federal funds, expenditures in an
13 amount equal to its State share (as determined
14 under subparagraph (B)) for a quarter for
15 items, services, and other costs for which, but
16 for paragraph (1), Federal funds would have
17 been payable under this title.

18 “(B) STATE SHARE.—The State share for
19 a State for a quarter in a fiscal year is equal
20 to the product of—

21 “(i) the aggregate beneficiary-based
22 amount specified in subsection (b) for the
23 quarter and the State; and

24 “(ii) the ratio of—

1 “(I) the State percentage de-
2 scribed in subparagraph (D)(ii) for
3 such State and fiscal year; to

4 “(II) the Federal percentage de-
5 scribed in subparagraph (D)(i) for
6 such State and fiscal year.

7 “(C) NONPAYMENT FOR FAILURE TO PAY
8 STATE SHARE.—

9 “(i) IN GENERAL.—If a State fails to
10 expend the amount required under sub-
11 paragraph (A) for a quarter in a fiscal
12 year, the amount payable to the State
13 under paragraph (1) shall be reduced by
14 the product of the amount by which the
15 State payment is less than the State share
16 and the ratio of—

17 “(I) the Federal percentage de-
18 scribed in subparagraph (D)(i) for
19 such State and fiscal year; to

20 “(II) the State percentage de-
21 scribed in subparagraph (D)(ii) for
22 such State and fiscal year.

23 “(ii) GRACE PERIOD.—A State shall
24 not be considered to have failed to provide
25 payment of its required State share for a

1 quarter under subparagraph (A) if the ag-
2 gregate State payment towards the State's
3 required State share for the 4-quarter pe-
4 riod beginning with such quarter exceeds
5 the required State share amount for such
6 4-quarter period.

7 “(D) FEDERAL AND STATE PERCENT-
8 AGES.—In this paragraph, with respect to a
9 State and a fiscal year:

10 “(i) FEDERAL PERCENTAGE.—The
11 Federal percentage described in this clause
12 is 75 percent or, if higher, the Federal
13 medical assistance percentage for such
14 State for such fiscal year.

15 “(ii) STATE PERCENTAGE.—The State
16 percentage described in this clause is 100
17 percent minus the Federal percentage de-
18 scribed in clause (i).

19 “(E) RULES FOR CREDITING TOWARD
20 STATE SHARE.—

21 “(i) GENERAL LIMITATION TO MATCH-
22 ABLE EXPENDITURES.—A payment for ex-
23 penditures shall not be counted toward the
24 State share under subparagraph (A) unless
25 Federal payments may be used for such

1 expenditures consistent with paragraph
2 (3)(B).

3 “(ii) FURTHER LIMITATIONS ON AL-
4 LOWABLE EXPENDITURES.—A payment for
5 expenditures shall not be counted towards
6 the State share under subparagraph (A) if
7 the expenditure is for any of the following:

8 “(I) ABORTION.—Expenditures
9 for an abortion.

10 “(II) INTERGOVERNMENTAL
11 TRANSFERS.—An expenditure that is
12 attributable to an intergovernmental
13 transfer.

14 “(III) CERTIFIED PUBLIC EX-
15 PENDITURES.—An expenditure that is
16 attributable to certified public expend-
17 itures.

18 “(iii) CREDITING FRAUD AND ABUSE
19 RECOVERIES.—Amounts recovered by a
20 State through the operation of its Medicaid
21 fraud and abuse control unit described in
22 section 1903(q) shall be fully counted to-
23 ward the State share under subparagraph
24 (A).

1 “(F) CONSTRUCTION.—Nothing in the
2 paragraph shall be construed as preventing a
3 State from expending, from non-Federal funds,
4 an amount under this title in excess of the
5 amount of the State share.

6 “(G) DETERMINATION BASED UPON SUB-
7 MITTED CLAIMS.—In applying this paragraph
8 with respect to expenditures of a State for a
9 quarter, the determination of the expenditures
10 for such State for such quarter shall be made
11 after the end of the period (which, as of the
12 date of the enactment of this section, is 2
13 years) for which the Secretary accepts claims
14 for payment under this title with respect to
15 such quarter.

16 “(3) USE OF FEDERAL PAYMENTS.—

17 “(A) APPLICATION OF MEDICAID LIMITA-
18 TIONS.—A State may only use Federal pay-
19 ments received under subsection (a) for expend-
20 itures for which Federal funds would have been
21 payable under this title but for this section.

22 “(B) LIMITATION FOR CERTAIN ELIGI-
23 BLES.—

24 “(i) APPLICATION OF 100 PERCENT
25 FEDERAL POVERTY LINE LIMIT ON ELIGI-

1 BILITY.—Subject to clause (iii), a State
2 may not use such Federal payments to
3 provide medical assistance for an indi-
4 vidual who has an income (as determined
5 under clause (ii)) that exceeds 100 percent
6 of the poverty line (as defined in section
7 2110(c)(5)) applicable to a family of the
8 size involved.

9 “(ii) DETERMINATION OF INCOME
10 USING MODIFIED ADJUSTED GROSS IN-
11 COME WITHOUT ANY 5 PERCENT IN-
12 CREASE.—In determining income for pur-
13 poses of clause (i) under section
14 1902(e)(14) (relating to modified adjusted
15 gross income), the following rules shall
16 apply:

17 “(I) APPLICATION OF SPEND
18 DOWN.—The State shall take into ac-
19 count the costs incurred for medical
20 care or for any other type of remedial
21 care recognized under State law in the
22 same manner and to the same extent
23 that such State takes such costs into
24 account for purposes of section
25 1902(a)(17).

1 “(II) DISREGARD OF 5 PERCENT
2 INCREASE.—Subparagraph (I) of sec-
3 tion 1902(e)(14) (relating to a 5 per-
4 cent reduction) shall not apply.

5 “(iii) EXCEPTION.—Clause (i) shall
6 not apply to an individual who is—

7 “(I) a woman described in clause
8 (i) of section 1903(v)(4)(A);

9 “(II) a child who is an individual
10 described in clause (i) of section
11 1905(a);

12 “(III) enrolled in a State plan
13 under this title as of the date of the
14 enactment of this section for the pe-
15 riod of continuous enrollment; or

16 “(IV) described in section
17 1902(e)(14)(D) (relating to modified
18 adjusted gross income).

19 “(iv) CLARIFICATION RELATED TO
20 COMMUNITY SPOUSE.—Nothing in this
21 subparagraph shall supersede the applica-
22 tion of section 1924 (related to community
23 spouse income and assets).

24 “(4) EXCEPTIONS FOR PASS-THROUGH PAY-
25 MENTS.—

1 “(A) IN GENERAL.—Paragraph (1) shall
2 not apply, and amounts shall continue to be
3 payable under this title (and not under sub-
4 section (a)), in the case of the following pay-
5 ments (and related administrative costs and ex-
6 penditures):

7 “(i) PAYMENTS TO TERRITORIES.—
8 Payments to a State other than the 50
9 States and the District of Columbia.

10 “(ii) MEDICARE COST-SHARING.—
11 Payments attributable to Medicare cost-
12 sharing under section 1905(p).

13 “(iii) PEDIATRIC VACCINES.—Pay-
14 ments attributable to section 1928.

15 “(iv) EMERGENCY SERVICES FOR CER-
16 TAIN INDIVIDUALS.—Payments for treat-
17 ment of emergency medical conditions at-
18 tributable to the application of section
19 1903(v)(2).

20 “(v) INDIAN HEALTH CARE FACILI-
21 TIES.—Payments for medical assistance
22 described in the third sentence of section
23 1905(b).

24 “(vi) EMPLOYER-SPONSORED INSUR-
25 ANCE (ESI).—Payments for medical assist-

1 ance attributable to payments to employers
2 for employer-sponsored health benefits cov-
3 erage.

4 “(vii) OTHER POPULATIONS WITH
5 LIMITED BENEFIT COVERAGE.—Other pay-
6 ments that are determined by the Sec-
7 retary to be related to a specified popu-
8 lation for which the medical assistance
9 under this title is limited and does not in-
10 clude any inpatient, nursing facility, or
11 long-term care services.

12 “(B) CERTAIN EXPENSES.—Paragraph (1)
13 shall not apply, and amounts shall continue to
14 be payable under this title (and not under sub-
15 section (a)), in the case of the following:

16 “(i) ADMINISTRATION OF MEDICARE
17 PRESCRIPTION DRUG BENEFIT.—Expendi-
18 tures described in section 1935(b) (relating
19 to administration of the Medicare prescrip-
20 tion drug benefit).

21 “(ii) PAYMENTS FOR HIT BONUSES.—
22 Payments under section 1903(a)(3)(F) (re-
23 lating to payments to encourage the adop-
24 tion and use of certified EHR technology).

1 “(iii) PAYMENTS FOR DESIGN, DEVEL-
2 OPMENT, AND INSTALLATION OF MMIS AND
3 ELIGIBILITY SYSTEMS.—Payments under
4 subparagraphs (A)(i) and (H)(i) of section
5 1903(a)(3) for expenditures for design, de-
6 velopment, and installation of the Medicaid
7 management information systems and
8 mechanized verification and information
9 retrieval systems (related to eligibility).

10 “(5) PAYMENT OF AMOUNTS.—

11 “(A) IN GENERAL.—Except as the Sec-
12 retary may otherwise provide, amounts shall be
13 payable to a State under subsection (a) in the
14 same manner as amounts are payable under
15 subsection (d) of section 1903 to a State under
16 subsection (a) of such section.

17 “(B) INFORMATION AND FORMS.—

18 “(i) SUBMISSION.—As a condition of
19 receiving payment under subsection (a), a
20 State shall submit such information, in
21 such form, and manner, as the Secretary
22 shall specify, including information nec-
23 essary to make the computations under
24 subsections (c)(2)(C) and (e).

1 “(ii) UNIFORM REPORTING.—The
2 Secretary shall develop such forms as may
3 be needed to assure a system of uniform
4 reporting of such information across
5 States.

6 “(C) REQUIRED REPORTING OF INFORMA-
7 TION ON MEDICAL LOSS RATIOS FOR MANAGED
8 CARE.—The information required to be reported
9 under subparagraph (B)(i) shall include infor-
10 mation on the medical loss ratio with respect to
11 coverage provided under each Medicaid man-
12 aged care plan with a contract with the State
13 under section 1903(m) or 1932.

14 “(b) AGGREGATE BENEFICIARY-BASED AMOUNT.—

15 “(1) IN GENERAL.—The aggregate beneficiary-
16 based amount specified in this subsection for a State
17 for a quarter is equal to the sum of the products,
18 for each of the categories of Medicaid beneficiaries
19 specified in paragraph (2), of the following:

20 “(A) BENEFICIARY-BASED QUARTERLY
21 AMOUNT.—The beneficiary-based quarterly
22 amount for such category computed under sub-
23 section (c) for such State for such quarter.

24 “(B) NUMBER OF INDIVIDUALS IN CAT-
25 EGORY.—Subject to subsection (d), the average

1 number of Medicaid beneficiaries enrolled in
2 such category in the State in such quarter.

3 “(2) CATEGORIES.—The categories specified in
4 this paragraph are the following:

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

7 “(B) BLIND OR DISABLED.—A category of
8 Medicaid beneficiaries not described in subpara-
9 graph (A) who are described in section
10 1937(a)(2)(B)(ii).

11 “(C) CHILDREN.—A category of Medicaid
12 beneficiaries not described in subparagraph (B)
13 who are under 21 years of age.

14 “(D) OTHER ADULTS.—A category of any
15 Medicaid beneficiaries who are not described in
16 a previous subparagraph of this paragraph.

17 “(c) COMPUTATION OF PER BENEFICIARY, PER CAT-
18 EGORY QUARTERLY AMOUNT.—

19 “(1) IN GENERAL.—For a State, for each cat-
20 egory of beneficiary for a quarter—

21 “(A) FIRST REFORM YEAR.—For quarters
22 in the first reform year (as defined in sub-
23 section (k)(2)), the beneficiary-based quarterly
24 amount is equal to $\frac{1}{4}$ of the base average per
25 beneficiary Federal payments for such State for

1 such category determined under paragraph (2),
2 increased by a factor that reflects the sum of
3 the following:

4 “(i) HISTORICAL MEDICAL CARE COM-
5 PONENT OF CPI THROUGH PREVIOUS RE-
6 FORM YEAR.—The percentage increase in
7 the historical medical care component of
8 the Consumer Price Index for all urban
9 consumers (U.S. city average) from the
10 midpoint of the base fiscal year (as defined
11 in paragraph (6)) to the midpoint of the
12 fiscal year preceding the first reform year.

13 “(ii) PROJECTED MEDICAL CARE COM-
14 PONENT OF CPI FOR THE FIRST REFORM
15 YEAR.—The percentage increase in the
16 projected medical care component of the
17 Consumer Price Index for all urban con-
18 sumers (U.S. city average) from the mid-
19 point of the previous fiscal year referred to
20 in clause (i) to the midpoint of the first re-
21 form year.

22 “(B) SECOND AND THIRD REFORM
23 YEARS.—The beneficiary-based quarterly
24 amount for a State for a category for quarters
25 in the second reform year or the third reform

1 year is equal to the beneficiary-based quarterly
2 amount under this paragraph for such State
3 and category for the previous reform year in-
4 creased by the per beneficiary percentage in-
5 crease (as defined in subparagraph (E)) for
6 such category and reform year.

7 “(C) FOURTH THROUGH TENTH REFORM
8 YEARS.—The beneficiary-based quarterly
9 amount for a State for a category for quarters
10 in a reform year beginning with the fourth re-
11 form year and ending with the tenth reform
12 year is—

13 “(i) in the case of a State that is a
14 high per beneficiary State or a low per
15 beneficiary State (as defined in paragraph
16 (4)(B)(iii)) for the category, the amount
17 determined under clause (i) or (ii) of para-
18 graph (4)(B) for such State, category, and
19 reform year; or

20 “(ii) in the case of any other State,
21 the beneficiary-based quarterly amount
22 under this paragraph for such State and
23 category for the previous reform year in-
24 creased by the per beneficiary percentage

1 increase for such category and reform
2 year.

3 “(D) ELEVENTH REFORM YEAR AND SUB-
4 SEQUENT REFORM YEARS.—The beneficiary-
5 based quarterly amount for a State for a cat-
6 egory for quarters in a reform year beginning
7 with the eleventh reform year is equal to the
8 beneficiary-based quarterly amount under this
9 paragraph for such State and category for the
10 previous reform year increased by the per bene-
11 ficiary percentage increase for such category
12 and reform year.

13 “(E) ANNUAL PERCENTAGE INCREASE BE-
14 GINNING WITH SECOND REFORM YEAR.—For
15 purposes of this subsection, the term ‘per bene-
16 ficiary percentage increase’ means, for a reform
17 year, the sum of—

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

24 “(ii) one percentage point.

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

3 “(A) AVERAGE PER CATEGORY.—

4 “(i) IN GENERAL.—The Secretary
5 shall determine, consistent with this para-
6 graph and paragraph (3), a base per bene-
7 ficiary, per category amount for each of
8 the 50 States and the District of Columbia
9 equal to the average amount, per Medicaid
10 beneficiary, of Federal payments under
11 this title, including payments attributable
12 to disproportionate share hospital pay-
13 ments under section 1923, for each of the
14 categories of beneficiaries under subsection
15 (b)(2) for the base fiscal year for each of
16 the 50 States and the District of Colum-
17 bia.

18 “(ii) BEST AVAILABLE DATA.—The
19 determination under clause (i) shall ini-
20 tially be estimated by the Secretary, based
21 upon the best available data at the time
22 the determination is made.

23 “(iii) UPDATES.—The determination
24 under clause (i) shall be updated by the
25 Secretary on an annual basis based upon

1 improved data. The Secretary shall adjust
2 the amounts under subsection (a)(1)(A) to
3 reflect changes in the amounts so deter-
4 mined based on such updates.

5 “(B) EXCLUSION OF PASS-THROUGH PAY-
6 MENTS.—In computing base per beneficiary,
7 per category amounts under subparagraph
8 (A)(i) the Secretary shall exclude payments de-
9 scribed in subsection (a)(4).

10 “(C) STANDARDIZATION.—

11 “(i) IN GENERAL.—In computing each
12 such amount, the Secretary shall stand-
13 ardize the amount in order to remove the
14 variation attributable to the following:

15 “(I) RISK FACTORS.—Such risk
16 factors as age, health and disability
17 status (including high cost medical
18 conditions), gender, institutional sta-
19 tus, and such other factors as the
20 Secretary determines to be appro-
21 priate, so as to ensure actuarial
22 equivalence.

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

1 “(ii) METHOD OF STANDARDIZA-
2 TION.—

3 “(I) CONSULTATION IN DEVEL-
4 OPMENT OF RISK STANDARDIZA-
5 TION.—In developing the methodology
6 for risk standardization for purposes
7 of clause (i)(I), the Secretary shall
8 consult with the Medicaid and CHIP
9 Payment and Access Commission, the
10 Medicare Payment Advisory Commis-
11 sion, and the National Association of
12 Medicaid Directors.

13 “(II) METHOD FOR RISK STAND-
14 ARDIZATION.—In carrying out clause
15 (i)(I), the Secretary may apply the
16 hierarchal condition category method-
17 ology under section 1853(a)(1)(C). If
18 the Secretary uses such methodology,
19 the Secretary shall adjust the applica-
20 tion of such methodology to take into
21 account the differences in services
22 provided under this title compared to
23 title XVIII, such as the coverage of
24 long term care, pregnancy, and pedi-
25 atric services.

1 “(III) METHOD FOR GEOGRAPHIC
2 STANDARDIZATION.—The Secretary
3 shall apply the standardization under
4 clause (i)(II) in a manner similar to
5 that applied under section
6 1853(c)(4)(A)(iii).

7 “(iii) APPLICATION ON A NATIONAL,
8 BUDGET NEUTRAL BASIS.—The standard-
9 ization under clause (i) shall be designed
10 and implemented on a uniform national
11 basis and shall be budget neutral so as to
12 not result in any aggregate change in pay-
13 ments under subsection (a).

14 “(iv) RESPONSE TO NEW RISK.—Sub-
15 ject to clause (iii), the Secretary may ad-
16 just the standardization under clause (i) to
17 respond promptly to new instances of com-
18 municable diseases and other public health
19 hazards.

20 “(v) REFERENCE TO APPLICATION OF
21 RISK ADJUSTMENT.—For rules related to
22 the application of risk adjustment to
23 amounts under subsection (a)(1)(A), see
24 subsection (e).

1 “(D) ADJUSTMENT FOR TEMPORARY FMAP
2 INCREASES.—In computing each base per bene-
3 ficiary, per category amounts under subpara-
4 graph (A)(i) the Secretary shall disregard por-
5 tions of payments that are attributable to a
6 temporary increase in the Federal matching
7 rates, including those attributable to the fol-
8 lowing:

9 “(i) PPACA DISASTER FMAP.—Sec-
10 tion 1905(aa).

11 “(ii) ARRA.—Section 5001 of the
12 American Recovery and Reinvestment Act
13 of 2009 (42 U.S.C. 1396d note).

14 “(iii) EXTRAORDINARY EMPLOYER
15 PENSION CONTRIBUTION.—Section 614 of
16 the Children’s Health Insurance Program
17 Reauthorization Act of 2009 (42 U.S.C.
18 1396d note).

19 “(3) ALLOCATION OF NONMEDICAL ASSISTANCE
20 PAYMENTS.—The Secretary shall establish rules for
21 the allocation of payments under this title (other
22 than those payments described in paragraph (1) or
23 (5) of section 1903(a) and including such payments
24 attributable to section 1923)—

1 “(A) among different categories of bene-
2 ficiaries; and

3 “(B) between payments included under
4 subsection (a)(1) and payments described in
5 subsection (a)(4).

6 “(4) TRANSITION TO A CORRIDOR AROUND THE
7 NATIONAL AVERAGE.—

8 “(A) DETERMINATION OF NATIONAL AVER-
9 AGE BASE PER BENEFICIARY, PER CATEGORY
10 AMOUNT.—Subject to subparagraph (C), the
11 Secretary shall determine a national average
12 base per beneficiary, per category amount equal
13 to the average of the base per beneficiary, per
14 category amounts for each of the 50 States and
15 the District of Columbia determined under
16 paragraph (2), weighted by the average number
17 of beneficiaries in each such category and State
18 as determined by the Secretary consistent with
19 subsection (d) for the base fiscal year.

20 “(B) TRANSITION ADJUSTMENT.—

21 “(i) HIGH PER BENEFICIARY
22 STATES.—In the case of a high per bene-
23 ficiary State (as defined in clause (iii)(I))
24 for a category, the beneficiary-based quar-
25 terly amount for such State and category

1 for a quarter in a reform year (beginning
2 with the fourth reform year and ending
3 with the tenth reform year) is equal to the
4 sum of—

5 “(I) the product of the State-spe-
6 cific factor for such reform year (as
7 defined in clause (iv)) and the bene-
8 ficiary-based quarterly amount that
9 would otherwise be determined under
10 paragraph (1) for such State and cat-
11 egory if the State were a State de-
12 scribed in clause (ii) of paragraph
13 (1)(C), instead of a State described in
14 clause (i) of such paragraph; and

15 “(II) the product of 1 minus the
16 State-specific factor for such reform
17 year and the beneficiary-based quar-
18 terly amount that would otherwise be
19 determined under paragraph (1) for a
20 State and category if the base per
21 beneficiary, per category amount de-
22 termined under paragraph (2) for the
23 State and category were equal to 110
24 percent of the national average base
25 per beneficiary, per category amount

1 determined under subparagraph (A)
2 for such category.

3 “(ii) LOW PER BENEFICIARY
4 STATES.—In the case of a low per bene-
5 ficiary State (as defined in clause (iii)(II))
6 for a category, the beneficiary-based quar-
7 terly amount for such State and category
8 for a quarter in a reform year (beginning
9 with the fourth reform year and ending
10 with the tenth reform year) is equal to the
11 sum of—

12 “(I) the product of the State-spe-
13 cific factor for such reform year and
14 the beneficiary-based quarterly
15 amount that would otherwise be deter-
16 mined under paragraph (1) for such
17 State and category if the State were
18 a State described in clause (ii) of
19 paragraph (1)(C), instead of a State
20 described in clause (i) of such para-
21 graph; and

22 “(II) the product of 1 minus the
23 State-specific factor for such reform
24 year and the beneficiary-based quar-
25 terly amount that would otherwise be

1 determined under paragraph (1) for a
2 State and category if the base per
3 beneficiary, per category amount de-
4 termined under paragraph (2) for the
5 State and category were equal to 90
6 percent of the national average base
7 per beneficiary, per category amount
8 determined under subparagraph (A)
9 for such category.

10 “(iii) HIGH AND LOW PER BENE-
11 FICIARY STATES DEFINED.—In this sub-
12 paragraph:

13 “(I) HIGH PER BENEFICIARY
14 STATE.—The term ‘high per bene-
15 ficiary State’ means, with respect to a
16 category, a State for which the base
17 per beneficiary, per category amount
18 determined under paragraph (2) for
19 such category is greater than 110 per-
20 cent of the national average base per
21 beneficiary, per category amount de-
22 termined under subparagraph (A) for
23 such category.

24 “(II) LOW PER BENEFICIARY
25 STATE.—The term ‘low per bene-

1 beneficiary State’ means, with respect to a
2 category, a State for which the base
3 per beneficiary, per category amount
4 determined under paragraph (2) for
5 such category is less than 90 percent
6 of the national average base per bene-
7 ficiary, per category amount deter-
8 mined under subparagraph (A) for
9 such category.

10 “(iv) STATE-SPECIFIC FACTOR.—In
11 this subparagraph, the term ‘State-specific
12 factor’ means—

13 “(I) for the fourth reform year,

14 $\frac{7}{8}$; and

15 “(II) for a subsequent reform
16 year, the State-specific factor under
17 this clause for the previous reform
18 year minus $\frac{1}{8}$.

19 “(C) NO ADDITIONAL EXPENDITURES.—

20 “(i) DETERMINATION OF INCREASE IN
21 FEDERAL EXPENDITURES.—For each cat-
22 egory for each reform year (beginning with
23 the fourth reform year and ending with the
24 tenth reform year), the Secretary shall de-

1 termine whether the application of this
2 paragraph—

3 “(I) to the category for the re-
4 form year will result in an aggregate
5 increase in the aggregate Federal ex-
6 penditures under subsection (a); and

7 “(II) to all the categories for the
8 reform year will result in a net aggre-
9 gate increase in the aggregate Federal
10 expenditures under subsection (a).

11 “(ii) ADJUSTMENT.—If the Secretary
12 determines under clause (i)(II) that the
13 application of this paragraph to all the cat-
14 egories for a reform year will result in a
15 net aggregate increase in the aggregate
16 Federal expenditures under subsection (a),
17 the Secretary shall reduce the national av-
18 erage base per beneficiary, per category
19 amount computed under subparagraph (A)
20 for each of the categories determined
21 under clause (i)(I) for which there will be
22 an aggregate increase in the aggregate
23 Federal expenditures under subsection (a)
24 by such uniform percentage as will ensure
25 that there is no net aggregate Federal ex-

1 penditure increase described in clause
2 (i)(II) for the reform year.

3 “(5) REPORTS ON PER BENEFICIARY RATES;
4 APPEALS.—

5 “(A) REPORT TO STATES.—Not later than
6 8 months after the date of the enactment of
7 this section, the Secretary shall submit to each
8 State the Secretary’s initial determination of—

9 “(i) the base per beneficiary, per cat-
10 egory amounts under paragraph (2) for
11 such State; and

12 “(ii) the national average base per
13 beneficiary, per category amounts under
14 paragraph (4)(A).

15 “(B) OPPORTUNITY TO APPEAL.—Not
16 later than 3 months after the date a State re-
17 ceives notice of the Secretary’s initial deter-
18 mination of such base per beneficiary, per cat-
19 egory amounts for such State under subpara-
20 graph (A)(i), the State may file with the Sec-
21 retary, in a form and manner specified by the
22 Secretary, an appeal of such determination.

23 “(C) DETERMINATION ON APPEAL.—Not
24 later than 3 months after receiving such an ap-
25 peal, the Secretary shall make a final deter-

1 mination on such amounts for such State. If no
2 such appeal is received for a State, the Sec-
3 retary’s initial determination under subpara-
4 graph (A)(i) shall become final.

5 “(6) BASE FISCAL YEAR DEFINED.—In this
6 section, the term ‘base fiscal year’ means the latest
7 fiscal year, ending before the date of the enactment
8 of this section, for which the Secretary determines
9 that adequate data are available to make the com-
10 putations required under this subsection.

11 “(d) NOT COUNTING INDIVIDUALS TO ACCOUNT FOR
12 EXCLUDED PAYMENTS.—Under rules specified by the
13 Secretary, individuals shall not be counted as Medicaid
14 beneficiaries for purposes of subsection (b)(1)(B) and sub-
15 section (c)(2)(A) to the extent that such individuals—

16 “(1) are receiving medical assistance for which
17 payments described under subsection (a)(4)(A) are
18 made; or

19 “(2) would not have been eligible to enroll
20 under the State plan (or waiver of such plan) in the
21 State in which such individual is so enrolled if the
22 rules for eligibility for enrollment under such plan
23 (or waiver) were the same as such rules for eligi-
24 bility in effect as of January 1, 2009.

25 “(e) RISK ADJUSTMENT.—

1 “(1) IN GENERAL.—The amount under sub-
2 section (a)(1)(A) shall be adjusted under this sub-
3 section in an appropriate manner, specified by the
4 Secretary and consistent with paragraph (2), to take
5 into account—

6 “(A) the factors described in subsection
7 (c)(2)(C)(i)(I) within a category of bene-
8 ficiaries; and

9 “(B) variations in costs on a county-by-
10 county basis for medical assistance and admin-
11 istrative expenses.

12 “(2) METHOD OF ADJUSTMENT.—

13 “(A) IN GENERAL.—The adjustments
14 under paragraph (1) shall be made in a manner
15 similar to the manner in which similar adjust-
16 ments are made under subsection (c)(2)(C) and
17 consistent with the requirements of clause (iii)
18 of such subsection and subparagraph (B).

19 “(B) BIENNIAL UPDATE OF RISK ADJUST-
20 MENT METHODOLOGY.—In applying clause
21 (i)(I) of subsection (c)(2)(C) for purposes of
22 subparagraph (A), the Secretary shall, in con-
23 sultation with the entities described in clause
24 (ii)(I) of such subsection, update the risk ad-

1 justment methodology applied as appropriate
2 not less often than every 2 years.

3 “(f) CHRONIC CARE QUALITY BONUS PAYMENTS.—

4 “(1) DETERMINATION OF BONUS PAYMENTS.—

5 If the Secretary determines that, based on the re-
6 ports under paragraph (5), with respect to cat-
7 egories of chronic disease for which chronic care per-
8 formance targets had been established under para-
9 graph (3) for each category of Medicaid beneficiaries
10 specified under subsection (b)(2) such targets have
11 been met by a State for a reform year, the Secretary
12 shall make an additional payment to such State in
13 the amount specified in paragraph (6) for each quar-
14 ter in the succeeding reform year. Such payments
15 shall be made in a manner specified by the Secretary
16 and may only be used consistent with subsection
17 (a)(3).

18 “(2) IDENTIFICATION OF CATEGORIES OF
19 CHRONIC DISEASE.—The Secretary shall determine
20 the categories of chronic disease for which bonus
21 payments may be available under this subsection for
22 each category of Medicaid beneficiaries.

23 “(3) ADOPTION OF QUALITY MEASUREMENT
24 SYSTEM AND IDENTIFICATION OF PERFORMANCE
25 TARGETS.—

1 “(A) SYSTEM AND DATA.—With respect to
2 the categories of chronic disease under para-
3 graph (2), the Secretary shall adopt a quality
4 measurement system that uses data described
5 in paragraph (4) and is similar to the Five-Star
6 Quality Rating System used to indicate the per-
7 formance of Medicare Advantage plans under
8 part C of title XVIII.

9 “(B) TARGETS.—Using such system and
10 data, the Secretary shall establish for each re-
11 form year the chronic care performance targets
12 for purposes of the payments under paragraph
13 (1). Such performance targets shall be estab-
14 lished in consultation with States, associations
15 representing individuals with chronic illnesses,
16 entities providing treatment to such individuals
17 for such chronic illnesses, and other stake-
18 holders, including the National Association of
19 Medicaid Directors and the National Governors
20 Association.

21 “(4) DATA TO BE USED.—The data to be used
22 under paragraph (3) shall include—

23 “(A) data collected through methods such
24 as—

1 “(i) the ‘Healthcare Effectiveness
2 Data and Information Set’ (also known as
3 ‘HEDIS’) (or an appropriate successor
4 performance measurement tool);

5 “(ii) the ‘Consumer Assessment of
6 Healthcare Providers and Systems’ (also
7 known as ‘CAHPS’) (or an appropriate
8 successor performance measurement tool);
9 and

10 “(iii) the ‘Health Outcomes Survey’
11 (also known as ‘HOS’) (or an appropriate
12 successor performance measurement tool);
13 and

14 “(B) other data collected by the State.

15 “(5) REPORTS.—

16 “(A) IN GENERAL.—Each State shall col-
17 lect, analyze, and report to the Secretary, at a
18 frequency and in a manner to be established by
19 the Secretary, data described in paragraph (4)
20 that permit the Secretary to monitor the State’s
21 performance relative to the chronic care per-
22 formance targets established under paragraph
23 (3).

24 “(B) REVIEW AND VERIFICATION.—The
25 Secretary may review the data collected by the

1 State under subparagraph (A) to verify the
2 State’s analysis of such data with respect to the
3 performance targets under paragraph (3).

4 “(6) AMOUNT OF BONUS PAYMENTS.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graphs (B) and (C), with respect to each cat-
7 egory of Medicaid beneficiaries, in the case of
8 a State that the Secretary determines, based on
9 the chronic care performance targets set under
10 paragraph (3) for a reform year for such cat-
11 egory, performs—

12 “(i) in the top five States in such cat-
13 egory, subject to subparagraph (C)(ii), the
14 amount of the bonus for each quarter in
15 the succeeding reform year shall be 10 per-
16 cent of the payment amount otherwise paid
17 to the State under subsection (a) for indi-
18 viduals enrolled under the plan within such
19 category;

20 “(ii) in the next five States in such
21 category, subject to subparagraph (C)(ii),
22 the amount of the bonus for each such
23 quarter shall be 5 percent of the payment
24 amount otherwise paid to the State under

1 subsection (a) for individuals enrolled
2 under the plan within such category;

3 “(iii) in the next five States in such
4 category, subject to clauses (i) and (iii) of
5 subparagraph (C), the amount of the
6 bonus for each such quarter shall be 3 per-
7 cent of the payment amount otherwise paid
8 to the State under subsection (a) for indi-
9 viduals enrolled under the plan within such
10 category;

11 “(iv) in the next five States in such
12 category, subject to clauses (i) and (iii) of
13 subparagraph (C), the amount of the
14 bonus for each such quarter shall be 2 per-
15 cent of the payment amount otherwise paid
16 to the State under subsection (a) for indi-
17 viduals enrolled under the plan within such
18 category; and

19 “(v) in the next five States in such
20 category, subject to clauses (i) and (iii) of
21 subparagraph (C), the amount of the
22 bonus for each such quarter shall be 1 per-
23 cent of the payment amount otherwise paid
24 to the State under subsection (a) for indi-

1 viduals enrolled under the plan within such
2 category.

3 “(B) AGGREGATE ANNUAL LIMIT FOR
4 EACH CATEGORY OF MEDICAID BENE-
5 FICIARIES.—

6 “(i) IN GENERAL.—In no case may
7 the aggregate amount of bonuses under
8 this subsection for quarters in a reform
9 year for a category of Medicaid bene-
10 ficiaries exceed the limit specified in clause
11 (ii) for the reform year.

12 “(ii) LIMIT.—The limit specified in
13 this clause—

14 “(I) for the second reform year is
15 equal to \$250,000,000; or

16 “(II) for a subsequent reform
17 year is equal to the limit specified in
18 this clause for the previous reform
19 year increased by the per beneficiary
20 percentage increase determined under
21 paragraph (1)(E) of subsection (c).

22 “(C) LIMITATION AND PRORATION OF BO-
23 NUSES BASED ON APPLICATION OF AGGREGATE
24 LIMIT.—

1 “(i) NO BONUS FOR THIRD OR SUBSE-
2 QUENT TIERS UNLESS AGGREGATE LIMIT
3 NOT REACHED ON FIRST TWO TIERS.—No
4 bonus shall be payable under clause (iii),
5 (iv), or (v) of subparagraph (A) for a cat-
6 egory of Medicaid beneficiaries for a quar-
7 ter in a reform year unless the aggregate
8 amount of bonuses under clauses (i) and
9 (ii) of such subparagraph for such category
10 and reform year is less than the limit spec-
11 ified in subparagraph (B)(ii) for the re-
12 form year.

13 “(ii) PRORATION FOR FIRST TWO
14 TIERS.—If the aggregate amount of bo-
15 nuses under clauses (i) and (ii) of subpara-
16 graph (A) for a category of Medicaid bene-
17 ficiaries for quarters in a reform year ex-
18 ceeds the limit specified in subparagraph
19 (B)(ii) for the reform year, the amount of
20 each such bonus shall be prorated in a
21 manner so the aggregate amount of such
22 bonuses is equal to such limit.

23 “(iii) PRORATION FOR NEXT THREE
24 TIERS.—If the aggregate amount of bo-
25 nuses under clauses (i) and (ii) of subpara-

1 graph (A) for a category of Medicaid bene-
2 ficiaries for quarters in a reform year is
3 less than the limit specified in subpara-
4 graph (B)(ii) for the reform year, but the
5 aggregate amount of bonuses under clauses
6 (i) through (v) of subparagraph (A) for the
7 category and such quarters in the reform
8 year exceeds the limit specified in subpara-
9 graph (B)(ii) for the reform year, the
10 amount of each bonus in clauses (iii), (iv),
11 and (v) of subparagraph (A) shall be pro-
12 rated in a manner so the aggregate
13 amount of all the bonuses under subpara-
14 graph (A) is equal to such limit.

15 “(g) STATE OPTION FOR RECEIVING MEDICARE PAY-
16 MENTS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVID-
17 UALS.—

18 “(1) IN GENERAL.—Under this subsection a
19 State may elect for quarters beginning on or after
20 the implementation date in a reform year to receive
21 payment from the Secretary under paragraph (3).
22 As a condition of receiving such payment, the State
23 shall agree to provide to full-benefit dual eligible in-
24 dividuals eligible for medical assistance under the
25 State plan—

1 “(A) the medical assistance to which such
2 eligible individuals would otherwise be entitled
3 under this title; and

4 “(B) any items and services which such eli-
5 gible individuals would otherwise receive under
6 title XVIII.

7 “(2) PROVIDER PAYMENT REQUIREMENT.—

8 “(A) IN GENERAL.—A State electing the
9 option under this subsection shall provide pay-
10 ment to health care providers for the items and
11 services described under paragraph (1)(B) at a
12 rate that is not less than the rate at which pay-
13 ments would be made to such providers for such
14 items and services under title XVIII.

15 “(B) FLEXIBILITY IN PAYMENT METH-
16 ODS.—Nothing in subparagraph (A) shall be
17 construed as preventing a State from using al-
18 ternative payment methodologies (such as bun-
19 dled payments or the use of accountable care
20 organizations (as such term is used in section
21 1899)) for purposes of making payments to
22 health care providers for items and services pro-
23 vided to dual eligible individuals in the State
24 under the option under this subsection.

1 “(3) PAYMENTS TO STATES IN LIEU OF MEDI-
2 CARE PAYMENTS.—With respect to a full-benefit
3 dual eligible individual, in the case of a State that
4 elects the option under paragraph (1) for quarters in
5 a reform year—

6 “(A) the Secretary shall not make any pay-
7 ment under title XVIII for items and services
8 furnished to such individual for such quarters;
9 and

10 “(B) the Secretary shall pay to the State,
11 in addition to the amounts paid to such State
12 under subsection (a), the amount that the Sec-
13 retary would, but for this subsection, otherwise
14 pay under title XVIII for items and services
15 furnished to such an individual in such State
16 for such quarters.

17 “(4) FULL-BENEFIT DUAL ELIGIBLE INDI-
18 VIDUAL DEFINED.—In this subsection, the term
19 ‘full-benefit dual eligible individual’ means an indi-
20 vidual who meets the requirements of section
21 1935(c)(6)(A)(ii).

22 “(h) AUDITS.—The Secretary shall conduct such au-
23 dits on the number and classification of Medicaid bene-
24 ficiaries under such subsections and expenditures under

1 this section as may be necessary to ensure appropriate
2 payments under this section.

3 “(i) TREATMENT OF WAIVERS.—

4 “(1) NO IMPACT ON CURRENT WAIVERS.—In
5 the case of a waiver of requirements of this title pur-
6 suant to section 1115 or other law that is in effect
7 as of the date of the enactment of this section, noth-
8 ing in this section shall be construed to affect such
9 waiver for the period of the waiver as approved as
10 of such date.

11 “(2) APPLICATION OF BUDGET NEUTRALITY TO
12 SUBSEQUENT WAIVERS AND RENEWALS TAKING SEC-
13 TION INTO ACCOUNT.—In the case of a waiver of re-
14 quirements of this title pursuant to section 1115 or
15 other law that is approved or renewed after the date
16 of the enactment of this section, to the extent that
17 such approval or renewal is conditioned upon a dem-
18 onstration of budget neutrality, budget neutrality
19 shall be determined taking into account the applica-
20 tion of this section.

21 “(j) REPORT TO CONGRESS.—Not later than Janu-
22 ary 1 of the second reform year, the Secretary shall submit
23 to Congress a report on the implementation of this section.

24 “(k) DEFINITIONS.—In this section:

1 “(1) IMPLEMENTATION DATE.—The term ‘im-
2 plementation date’ means—

3 “(A) July 1, 2023, if this section is en-
4 acted on or before July 1, 2022; or

5 “(B) July 1, 2024, if this section is en-
6 acted after July 1, 2022.

7 “(2) REFORM YEARS.—

8 “(A) The term ‘reform year’ means a fiscal
9 year beginning with the first reform year.

10 “(B) The term ‘first reform year’ means
11 the fiscal year in which the implementation date
12 occurs.

13 “(C) The terms ‘second’, ‘third’, and suc-
14 cessive similar terms mean, with respect to a
15 reform year, the second, third, or successive re-
16 form year, respectively, succeeding the first re-
17 form year.”.

18 (b) CONFORMING AMENDMENTS.—

19 (1) CONTINUED APPLICATION OF CLAWBACK
20 PROVISIONS.—

21 (A) CONTINUED APPLICATION.—Sub-
22 sections (a) and (c)(1)(C) of section 1935 of
23 such Act (42 U.S.C. 1396u–5) are each amend-
24 ed by inserting “or 1903A(a)” after “1903(a)”.

1 (B) TECHNICAL AMENDMENT.—Section
2 1935(d)(1) of the Social Security Act (42
3 U.S.C. 1396u–5(d)(1)) is amended by inserting
4 “except as provided in section 1903A(g)” after
5 “any other provision of this title”.

6 (2) PAYMENT RULES UNDER SECTION 1903.—

7 (A) Section 1903(a) of the Social Security
8 Act (42 U.S.C. 1396b(a)) is amended, in the
9 matter before paragraph (1), by inserting “and
10 section 1903A” after “except as otherwise pro-
11 vided in this section”.

12 (B) Section 1903(d) of such Act (42
13 U.S.C. 1396b(d)) is amended—

14 (i) in paragraph (1), by inserting
15 “and under section 1903A” after “sub-
16 sections (a) and (b)”;

17 (ii) in paragraph (2)—

18 (I) in subparagraph (A), by in-
19 serting “or section 1903A” after “was
20 made under this section”; and

21 (II) in subparagraph (B), by in-
22 serting “or section 1903A” after
23 “under subsection (a)”;

24 (iii) in paragraph (4)—

1 (I) by striking “under this sub-
2 section” and inserting “, with respect
3 to this section or section 1903A,
4 under this subsection”; and

5 (II) by striking “under this sec-
6 tion” and inserting “under the respec-
7 tive section”; and

8 (iv) in paragraph (5), by inserting “or
9 section 1903A” after “overpayment under
10 this section”.

11 (3) CONFORMING WAIVER AUTHORITY.—Section
12 1115(a)(2)(A) of the Social Security Act (42 U.S.C.
13 1315(a)(2)(A)) is amended by striking “or 1903”
14 and inserting “1903, or 1903A”.

15 (4) REPORT ON ADDITIONAL CONFORMING
16 AMENDMENTS NEEDED.—Not later than 6 months
17 after the date of the enactment of this Act, the Sec-
18 retary of Health and Human Services shall submit
19 to Congress a report that includes a description of
20 any additional technical and conforming amend-
21 ments to law that are required to properly carry out
22 this Act.

1 **SEC. 402. INCOME LIMITATIONS FOR REFUNDABLE CRED-**
2 **ITS FOR COVERAGE UNDER A QUALIFIED**
3 **HEALTH PLAN.**

4 (a) IN GENERAL.—Subparagraphs (A) and (B) of
5 section 36B(c)(1) of the Internal Revenue Code of 1986
6 are amended by inserting after “100 percent” each place
7 such term appears the following: “(or, in the case of a
8 taxpayer enrolled through an Exchange utilized by such
9 State that makes the election described in section 1903A
10 of the Social Security Act, the percentage established by
11 such State under part A of title IV of such Act for pur-
12 poses of eligibility under title XIX of such Act as of Janu-
13 ary 1, 2009)”.

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

17 **SEC. 403. MEDICAID ELIGIBILITY DETERMINATIONS.**

18 (a) STATE FLEXIBILITY TO USE CONTRACTORS TO
19 MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF
20 STATE.—Section 1902(a)(5) of the Social Security Act
21 (42 U.S.C. 1396a(a)(5)) is amended by inserting before
22 the semicolon at the end the following: “, but such deter-
23 minations of eligibility may be made, at the option of a
24 State, under a contract with another State or local agency
25 or a contractor so long as the contract does not provide
26 incentives for the agency or contractor to delay eligibility

1 determinations or to deny eligibility for individuals other-
2 wise eligible for medical assistance”.

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

7 “(L) FREQUENCY OF ELIGIBILITY REDE-
8 TERMINATIONS.—Beginning on October 1,
9 2022, and notwithstanding subparagraph (H),
10 in the case of an individual whose eligibility for
11 medical assistance under the State plan under
12 this title (or a waiver of such plan) is deter-
13 mined based on the application of modified ad-
14 justed gross income under subparagraph (A)
15 and who is so eligible on the basis of clause
16 (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection
17 (a)(10)(A), at the option of the State, the State
18 plan may provide that the individual’s eligibility
19 shall be redetermined every 6 months (or such
20 shorter number of months as the State may
21 elect).”.

1 **SEC. 404. LOWERING SAFE HARBOR THRESHOLD WITH RE-**
2 **SPECT TO STATE TAXES ON HEALTH CARE**
3 **PROVIDERS.**

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

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

8 “(I) beginning”; and

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

11 “(II) beginning on or after January 1,
12 2021, and before January 1, 2030, ‘4 percent’
13 shall be substituted for ‘6 percent’ each place it
14 appears;

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

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

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

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

4 **SEC. 405. PROVIDING FOR STATE APPROVAL AND IMPLE-**
5 **MENTATION OF SPECIFIED WAIVERS UNDER**
6 **THE MEDICAID PROGRAM.**

7 Section 1115 of the Social Security Act (42 U.S.C.
8 1315) is amended—

9 (1) in subsection (d)—

10 (A) in paragraph (1), by striking “An ap-
11 plication” and inserting “Subject to paragraph
12 (4), an application”; and

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

15 “(4)(A) An experimental, pilot, or demonstra-
16 tion project undertaken under subsection (a) may be
17 approved or renewed by a State if such project is de-
18 scribed in subparagraph (B).

19 “(B) An experimental, pilot, or demonstration
20 project is described in this subparagraph if such
21 project provides for a waiver of requirements with
22 respect to a State plan (or a waiver of such plan)
23 under title XIX such that—

1 “(i) individuals enrolled under such plan
2 (or such waiver) may elect to participate in
3 such project with respect to a year; and

4 “(ii) such individuals who elect to so par-
5 ticipate are furnished with primary care serv-
6 ices (as described in section 223(c)(1)(D)(ii)(I)
7 of the Internal Revenue Code of 1986) through
8 a direct primary care service arrangement (as
9 defined in such section).

10 “(C) For purposes of a State’s approval or re-
11 newal of an experimental, pilot, or demonstration
12 project under subparagraph (A), each reference to
13 ‘the Secretary’ in subsection (a) shall be deemed to
14 be a reference to ‘the State.’”; and

15 (2) in subsection (e), by inserting “(other than
16 such a project that is described in paragraph
17 (4)(B))” before the period at the end.

18 **SEC. 406. DEDUCTION FOR QUALIFIED CHARITY CARE.**

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

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

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

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

3 “(A) the fee (as published on a publicly
4 available website of such physician) for physi-
5 cians’ services that are qualified charity care
6 furnished by such taxpayer during such year,
7 and

8 “(B) for each visit by a patient to such
9 physician during which qualified charity care is
10 furnished, half of so much of the lowest sub-
11 scription fee of such physician that is attrib-
12 utable to a month, and

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

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

17 “(1) UNREIMBURSED MEDICARE-BASED
18 VALUE.—The term ‘unreimbursed Medicare-based
19 value’ means, with respect to physicians’ services,
20 the amount payable for such services under the phy-
21 sician fee schedule established under section 1848 of
22 the Social Security Act.

23 “(2) QUALIFIED CHARITY CARE.—The term
24 ‘qualified charity care’ means physicians’ services
25 that are furnished—

1 “(A) without expectation of reimburse-
2 ment, and

3 “(B) to an individual enrolled—

4 “(i) under a State plan under title
5 XIX of the Social Security Act (or a waiv-
6 er of such plan), or

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

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

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

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

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

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

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

“Sec. 199B. Qualified charity care.”.

5 **Subtitle B—Medicare Reforms**

6 **SEC. 411. OFF-CAMPUS PROVIDER-BASED DEPARTMENT** 7 **MEDICARE SITE NEUTRAL PAYMENT.**

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

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

13 “(1) IN GENERAL.—With respect to items and
 14 services furnished in an off-campus provider-based
 15 department, payment under this section for such
 16 items and services shall be the amount determined
 17 under the fee schedule under section 1848 for such
 18 items and services furnished if furnished in a physi-
 19 cian office setting.

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

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall apply with respect to items and serv-
3 ices furnished on or after January 1, 2023.

4 **SEC. 412. ELIMINATING FEHBP ELIGIBILITY FOR ANNU-**
5 **ITANTS.**

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

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

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

22 **SEC. 413. ELIMINATION OF MEDICARE ELIGIBILITY FOR**
23 **CERTAIN INDIVIDUALS.**

24 (a) ENROLLMENT PROHIBITION.—

1 (1) PART B.—Section 1836 of the Social Secu-
2 rity Act (42 U.S.C. 1395o) is amended by striking
3 the period at the end and inserting “, except that an
4 individual who attains age 65 on or after January
5 1, 2032, and is an individual who, upon attaining
6 such age, has earned \$10,000,000 or more in life-
7 time wages, shall not be eligible to so enroll.”.

8 (2) PART D.—Section 1860D–1(a)(3)(A) of
9 such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amend-
10 ed by striking the period at the end and inserting
11 “, excluding an individual who, upon attaining age
12 65, has earned \$10,000,000 or more in lifetime
13 wages.”.

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

17 “(aa) ADDITIONAL LIMITATION ON NEWLY ELIGI-
18 BLE BENEFICIARIES.—

19 “(1) IN GENERAL.—Notwithstanding any other
20 provision of this section, on or after January 1,
21 2032, a medicare supplemental policy may not be
22 sold or issued to a targeted newly eligible Medicare
23 beneficiary.

24 “(2) TARGETED NEWLY ELIGIBLE MEDICARE
25 BENEFICIARY.—For purposes of this subsection, the

1 term ‘targeted newly eligible Medicare beneficiary’
2 means an individual who, upon attaining the age of
3 65, has earned \$10,000,000 or more in lifetime
4 wages.’’.

5 **SEC. 414. MEDICARE PART D TAX DEDUCTION.**

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

12 (b) EFFECTIVE DATE.—The amendment made by
13 this section shall apply to taxable years beginning after
14 December 31, 2022.

15 **SEC. 415. REPEAL OF NET INVESTMENT INCOME TAX.**

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

18 (b) EFFECTIVE DATE.—The amendment made by
19 this section shall apply to taxable years beginning after
20 December 31, 2022.

21 **SEC. 416. MEDICARE COVERAGE OF BAD DEBT.**

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

24 (1) in subparagraph (T)—

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

3 (B) in clause (v)—

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

6 (ii) by striking “or a subsequent fiscal
7 year” and inserting “through 2023”; and

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

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

12 “(vi) for cost reporting periods beginning dur-
13 ing fiscal year 2023 or a subsequent fiscal year, by
14 the percent applicable for cost reporting periods be-
15 ginning during the previous fiscal year, increased
16 (through fiscal year 2026) by 10 percentage
17 points.”;

18 (2) in subparagraph (V)—

19 (A) in clause (i)—

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

22 (ii) in subclause (IV)—

23 (I) by striking “during fiscal
24 year” and inserting “during fiscal
25 years 2017 through 2023”; and

1 (II) by striking the period at the
2 end and inserting “; and”; and

3 (iii) by adding at the end the fol-
4 lowing new subclause:

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

11 (B) in clause (ii)—

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

14 (ii) in subclause (IV)—

15 (I) by striking “a subsequent fis-
16 cal year” and inserting “fiscal years
17 2015 through 2021”;

18 (II) by striking the period at the
19 end and inserting “; and”; and

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

22 “(V) for cost reporting periods beginning
23 during fiscal year 2021 or a subsequent fiscal
24 year, shall be reduced by the percent applicable
25 for cost reporting periods beginning during the

1 previous fiscal year, increased (through fiscal
2 year 2024) by 10 percentage points.”; and

3 (3) in subparagraph (W)(i)—

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

6 (B) in subclause (III)—

7 (i) by striking “during a subsequent
8 fiscal year” and inserting “during fiscal
9 years 2015 through 2021”; and

10 (ii) by striking the period at the end
11 and inserting “; and”; and

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

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

20 **Subtitle C—Medicare Choice and** 21 **Competition**

22 **SEC. 421. COMPETITIVE BIDDING AND PREMIUMS UNDER** 23 **UNIFIED MEDICARE.**

24 (a) IN GENERAL.—Part E of title XVIII of the Social
25 Security Act, as added by section 101 and amended by

1 section 103, is further amended by adding at the end the
2 following:

3 **“Subpart 3—Competitive Bidding and Premiums**

4 **“SEC. 1860E-31. APPLICATION OF COMPETITIVE BIDDING IN**
5 **ENROLLMENT.**

6 “(a) IN GENERAL.—Notwithstanding any other pro-
7 vision of this title, the Secretary shall, beginning with plan
8 year 2023, establish a method whereby individuals enroll-
9 ing under this title so enroll through an online process
10 designed to highlight enrollment options for such individ-
11 uals and allow such individuals to compare costs of enroll-
12 ment in such options.

13 “(b) ENROLLMENT OPTIONS.—For purposes of sub-
14 section (a), the Secretary shall make the following options
15 available to individuals for enrollment under this title:

16 “(1) Traditional fee-for-service coverage.

17 “(2) Provider-led risk-bearing plans (also
18 known as ACOs).

19 “(3) Medicare Advantage plans.

20 “(c) MEDICARE ADVANTAGE PLAN ACTUARIAL
21 VALUE REQUIREMENT.—Each Medicare Advantage plan
22 offered through the process described in subsection (a)
23 shall have an actuarial value equal to traditional fee-for-
24 service coverage under parts A and B.

1 “(d) MA DIRECT DEPOSIT OF CERTAIN REBATES.—
2 In the case of an Medicare Advantage plan with a bid for
3 a year that involves a premium differential between such
4 bid and the benchmark for such year and plan, such plan
5 shall provide for a direct deposit of such differential if the
6 applicable enrollee in such plan does not elect any supple-
7 mental coverage under such plan.

8 “(e) ENROLLMENT IN PRESCRIPTION DRUG COV-
9 ERAGE.—As part of the method described in subsection
10 (a), the Secretary shall establish a process to allow an in-
11 dividual to enroll in prescription drug coverage. In the
12 case of an individual who enrolls in a Medicare Advantage
13 plan, such coverage shall be provided under such plan. In
14 a case of an individual who enrolls in an ACO, such cov-
15 erage shall be provided under such network. In the case
16 of an individual who enrolls under traditional fee-for-serv-
17 ice coverage, such drug coverage shall be provided through
18 a prescription drug plan.

19 “(f) SUPPLEMENTAL BENEFITS.—

20 “(1) MA PLANS.—An MA plan is allowed to
21 offer two different packages of supplemental benefits
22 (these packages are available only to individuals who
23 select such plans).

1 “(2) ACOs.—ACOs may limit supplemental op-
2 tions for their enrollees to Medigap plans with con-
3 tractual ties.

4 “(3) FEE-FOR-SERVICE.—Fee-for-service indi-
5 viduals may select supplemental coverage from
6 Medigap policies.

7 **“SEC. 1860E-32. COMPETITION.**

8 “(a) BID AREAS.—Market areas used for bid submis-
9 sions for Medicare Advantage plans, ACOs, and for cal-
10 culation per person fee-for-services costs shall be metro-
11 politan statistical regions plus associated regions.

12 “(b) PREMIUMS.—Medicare payment benchmark by
13 market area shall be calculated based on weighted average
14 (by enrollment in previous year) of the premium bids from
15 MA plans, ACOs, and the per person costs of fee-for-serv-
16 ice, less the statutory part B premium.

17 “(c) BENEFICIARY RESPONSIBILITY.—Beneficiaries
18 shall pay the difference between Medicare payment and
19 required premium of the plan they choose, and get 100
20 percent of the savings by choosing a plan with a premium
21 below the benchmark.

22 “(d) TRANSITION.—For beneficiaries who are in fee-
23 for-service at the time of the enactment of this section,
24 there shall be a limit on the amount of a premium increase
25 allowable by year of no more than \$20 per month com-

1 pared to what such premium would have otherwise been
2 if this subpart had not been enacted for each year through
3 the fifth year.

4 “(e) **MULTIYEAR CONTRACTS.**—A Medicare Advan-
5 tage plan may offer to beneficiaries multiyear contracts
6 with guaranteed premiums over such years, bearing the
7 risk of any change in payments from the Secretary in sub-
8 sequent years. A beneficiary enrolling under such a con-
9 tract shall be exempt from the method described in sub-
10 section (a).”.

11 (b) **CONFORMING AMENDMENTS.**—

12 (1) Section 1853(a)(1)(A) of the Social Security
13 Act is amended by striking “and section 1859(e)(4)”
14 and inserting “, section 1859(e)(4), and subpart 3
15 of part E”.

16 (2) Section 1853(j) of such Act is amended by
17 inserting “and subpart 3 of part E” after “sub-
18 section (o)”.

19 (3) Section 1854 of such Act is amended—

20 (A) in subsection (a), after the heading, by
21 inserting “Subject to subpart 3 of part E.”;

22 (B) in subsection (b), after the heading, by
23 inserting “Subject to subpart 3 of part E.”;

1 (C) in subsection (d), after the heading, by
 2 inserting “Subject to subpart 3 of part E.”;
 3 and

4 (D) in subsection (e), after the heading, by
 5 inserting “Subject to subpart 3 of part E.”.

6 **SEC. 422. NEW UNIFIED ELIGIBILITY AND ENROLLMENT**
 7 **RULES.**

8 (a) IN GENERAL.—Title XVIII of the Social Security
 9 Act is amended—

10 (1) by redesignating part E as part F; and

11 (2) by inserting after part D the following new
 12 part:

13 **“PART E—MEDICARE WITH CHOICE AND**
 14 **COMPETITION**

15 **“Subpart 1—Opt-Out and Auto-Enrollment**

16 **“SEC. 1860E-11. PART A OPT-OUT AND MA AUTO-ENROLL-**
 17 **MENT.**

18 “(a) PERMITTING INDIVIDUALS TO OPT OUT OF
 19 PART A COVERAGE WITHOUT LOSING SOCIAL SECURITY
 20 BENEFITS.—

21 “(1) IN GENERAL.—The Secretary shall estab-
 22 lish—

23 “(A) a process by which an individual oth-
 24 erwise entitled to benefits under part A may
 25 elect (at a time and in a manner specified

1 under the process) to waive such entitlement;
2 and

3 “(B) a process by which an individual who
4 elects to waive such entitlement may revoke (at
5 a time and in a manner specified under the
6 process) such waiver.

7 The process under subparagraph (B) shall be coordi-
8 nated with the enrollment process under section
9 1837 for part B.

10 “(2) APPLICATION OF LATE ENROLLMENT PEN-
11 ALTY.—An individual who revokes a waiver under
12 paragraph (1)(B) shall be subject to a late enroll-
13 ment penalty as applied under section 1860E-
14 32(c)(2)(C).

15 “(3) NO IMPACT ON TITLE II BENEFITS.—Not-
16 withstanding any other provision of law, an election
17 of an individual to waive entitlement to benefits
18 under part A under paragraph (1)(A) shall not re-
19 sult in any loss of benefits under title II.

20 “(4) DEEMED OPT-OUT.—

21 “(A) An election of an individual to waive
22 entitlement to benefits under part A under
23 paragraph (1)(A) is also deemed the filing of a
24 notice of termination of benefits under part B
25 pursuant to section 1838(b)(1).

1 “(B) The termination of benefits under
2 part B pursuant to section 1838(b) is also
3 deemed to be a waiver of any entitlement to
4 benefits under part A.

5 “(b) SPECIAL OPEN ENROLLMENT PERIOD WITH-
6 OUT LATE ENROLLMENT PENALTY FOR CURRENT PART
7 A ONLY OR PART B ONLY ENROLLEES.—Notwith-
8 standing any other provision of law, in the case of an indi-
9 vidual who as of the general effective date, is entitled to
10 benefits under part A but not enrolled under part B, or
11 who is enrolled under part B but not entitled to benefits
12 (or enrolled) under part A, beginning as of such date, such
13 individual shall be deemed to be enrolled under part B
14 or part A, respectively, unless such individual elects to be
15 enrolled (or entitled to benefits) under neither of such
16 parts during a special open enrollment period specified by
17 the Secretary. No increase in the monthly premium of an
18 individual pursuant to section 1839(b) or section 1818(c)
19 shall be effected in the case of any such individual who
20 is deemed enrolled under part B or part A pursuant to
21 the previous sentence with respect to any period prior to
22 the date of such enrollment.

23 “(c) AUTO ENROLLMENT OF DUAL ELIGIBLE INDI-
24 VIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

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

15 “(2) RIGHT TO DISENROLL.—Nothing in para-
16 graph (1) shall prevent such an individual from de-
17 clining enrollment in any such plan (and thereby ob-
18 taining coverage under Medicare fee-for-service) or
19 from changing enrollment in such a plan to another
20 MA–PD plan.

21 **“SEC. 1860E–12. COORDINATION WITH PART D.**

22 “(a) DEEMED ENROLLMENT UNDER PART D.—

23 “(1) IN GENERAL.—The Secretary shall estab-
24 lish a process that, beginning as of the general effec-
25 tive date, provides for the enrollment in a prescrip-

1 tion drug plan that has a monthly base beneficiary
2 premium that does not exceed the weighted average
3 of premiums for such plans that provide standard
4 prescription drug coverage (as defined in section
5 1860D–2(b)) with respect to the area involved (on
6 a random basis among all such plans in the applica-
7 ble PDP region) of each Medicare enrollee (as de-
8 fined in section 1860E–51) who—

9 “(A) failed to enroll in such a prescription
10 drug plan during the applicable enrollment or
11 coverage election period under section 1860D–
12 1(b); and

13 “(B) failed to elect not to enroll in such a
14 prescription drug plan during an applicable opt-
15 out period described in paragraph (2).

16 Nothing in the previous sentence shall prevent such
17 an individual from declining or changing such enroll-
18 ment. Such process shall be carried out in the same
19 manner as the process described in section 1860D–
20 1(b)(1)(C).

21 “(2) OPT-OUT PERIODS.—The process under
22 paragraph (1) shall provide for the opportunity to
23 make an election described in subparagraph (B) of
24 such paragraph during an opt-out period that is co-

1 ordinated with the relevant enrollment or coverage
2 election period under section 1860D–1.

3 “(3) LATE ENROLLMENT PENALTIES.—In the
4 case of an individual who makes an election de-
5 scribed in paragraph (1)(B) and then enrolls in a
6 prescription drug plan, the late enrollment penalty
7 under section 1860D–13(b) shall apply to the
8 monthly beneficiary premium of such individual, ex-
9 cept that in applying such section, any reference to
10 the initial enrollment period of such individual shall
11 be deemed to be a reference to the opt-out period
12 under paragraph (2) during which the individual
13 elected not to enroll in a prescription drug plan.

14 “(4) NO LATE ENROLLMENT PENALTY FOR
15 CURRENT FEE-FOR-SERVICE BENEFICIARIES WITH-
16 OUT DRUG COVERAGE.—In the case of an individual
17 who is a Medicare enrollee before the date of enact-
18 ment of this section and who was not enrolled under
19 a prescription drug plan before being enrolled under
20 such a plan pursuant to paragraph (1), there shall
21 be no increase in the base beneficiary premium of an
22 individual under section 1860D–13 by a late enroll-
23 ment penalty under subsection (b) of such section
24 with respect to any period prior to the date of such
25 enrollment.

1 “(b) REFERENCE TO REQUIRED PRESCRIPTION
2 DRUG COVERAGE UNDER PART C.—For provision requir-
3 ing coverage under MA plans to include prescription drug
4 coverage, see section 1860E–26.”.

5 (b) LIMITATION ON MEDICAID BENEFITS FOR FULL-
6 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Section 1902
7 of the Social Security Act (42 U.S.C. 1396a) is amended
8 by adding at the end the following new subsection:

9 “(ll) LIMITATION ON BENEFITS FOR FULL-BENEFIT
10 DUAL ELIGIBLE INDIVIDUALS.—Effective as of the gen-
11 eral effective date (as specified in section 1860E–62), ex-
12 cept in the case of a State which has elected the option
13 described in section 1944(b)(2), in the case of an indi-
14 vidual described in subparagraph (A)(ii) of section
15 1935(c)(6) (taking into account the application of sub-
16 paragraph (B) of such section), notwithstanding any other
17 provision of law, medical assistance shall not be available
18 under this title for any items and services for which pay-
19 ment may be made under title XVIII.”.

20 (c) MEDICAID MAINTENANCE OF EFFORT AND AL-
21 TERNATIVES.—Title XIX of the Social Security Act is
22 amended by inserting after section 1943 the following new
23 section:

1 “MAINTENANCE OF EFFORT OPTIONS FOR FULL-BENEFIT
2 DUAL ELIGIBLE INDIVIDUALS

3 “SEC. 1944. (a) IN GENERAL.—Effective as of the
4 general effective date (as specified in section 1860E–62),
5 a State shall elect, in a form and manner specified by the
6 Secretary, a maintenance of effort option described in sub-
7 section (b). In the case of a State that fails to make such
8 an election, the State shall be deemed to have elected the
9 option described in subsection (b)(3).

10 “(b) MAINTENANCE OF EFFORT OPTIONS DE-
11 SCRIBED.—The following are maintenance of effort op-
12 tions described in this subsection for a State, which shall
13 apply to all individuals described in subparagraph (A)(ii)
14 of section 1935(c)(6) (taking into account the application
15 of subparagraph (B) of such section) for such State:

16 “(1) ENROLLMENT OF DUAL ELIGIBLES IN
17 COMPREHENSIVE MEDICAID MANAGED CARE PLAN.—

18 “(A) IN GENERAL.—The State enrolls all
19 such individuals in a comprehensive Medicaid
20 managed care plan offered by a managed care
21 entity under section 1932.

22 “(B) PAYMENT OF SUBSIDY AMOUNT TO
23 STATE.—In the case of a State that elects the
24 option under this paragraph with respect to an
25 individual, the Secretary established under sec-

1 tion 1860E–51 shall pay to the State the same
2 amount that the individual would be entitled to
3 have paid as an income-related premium sub-
4 sidy under section 1860E–41(b)(1)(A) plus the
5 amount that the Secretary estimates would
6 have been paid with respect to the individual
7 under part D (including the actuarial value of
8 subsidy payments under sections 1860D–13
9 and 1860D–14). Such payment shall be made
10 in appropriate part from the Federal Hospital
11 Insurance Trust Fund under section 1817 and
12 the Federal Supplementary Medical Insurance
13 Trust Fund under section 1841.

14 “(C) RELATION TO PART D RULES.—In
15 the case of a State that has elected the option
16 under this paragraph, notwithstanding any
17 other provision of law—

18 “(i) the coverage provided under this
19 option shall be in lieu of any coverage that
20 may otherwise be provided under part D;
21 and

22 “(ii) the payment to the State under
23 subparagraph (B) shall be in lieu of any
24 payments otherwise made with respect to
25 such individual under such part.

1 “(2) OTHER INNOVATIVE ALTERNATIVES.—

2 “(A) IN GENERAL.—The State submits to
3 the Secretary, and has approved by the Sec-
4 retary, an innovative alternative proposal relat-
5 ing to coordinating coverage of such individuals
6 under Medicare and the State plan under title
7 XIX.

8 “(B) PROCESS FOR REVIEW.—With re-
9 spect to proposals submitted to the Secretary
10 under subparagraph (A), the Secretary shall ap-
11 prove such a proposal if the State demonstrates
12 with respect to the proposal that—

13 “(i) there would be no increased cost
14 to the Federal Government if it were ap-
15 proved; and

16 “(ii) there would be no reduction in
17 the quality of care provided to such indi-
18 viduals if the proposal were approved.”.

19 (d) CONFORMING AMENDMENTS.—

20 (1) SECTION 226.—Section 226 of the Social
21 Security Act (42 U.S.C. 426) is amended—

22 (A) in subsection (a), in the matter pre-
23 ceeding paragraph (1), by inserting “, subject to
24 section 1860E–11(a)” after “individual who”;

1 (B) in subsection (b), in the matter pre-
2 ceding paragraph (1), by inserting “, subject to
3 section 1860E–11(a)” after “individual who”;
4 and

5 (C) in subsection (c), in the matter pre-
6 ceding paragraph (1), by inserting “, subject to
7 section 1860E–11(a)” after “subsection (a)”.

8 (2) SECTION 226A.—Section 226A(a) of such
9 Act (42 U.S.C. 426–1(a)) is amended, in the matter
10 preceding paragraph (1), by inserting “and subject
11 to section 1860E–11(a)” after “or title XVIII”.

12 (3) SECTION 1932.—Section 1932(a)(2)(B) of
13 the Social Security Act (42 U.S.C. 1396u–
14 2(a)(2)(B)) is amended by striking “A State” and
15 inserting “Except in the case of a State that has
16 elected the maintenance of effort option described in
17 section 1944(b)(2), a State”.

18 **SEC. 423. NEW BENEFIT STRUCTURE UNDER UNIFIED**
19 **MEDICARE.**

20 (a) IN GENERAL.—Part E of title XVIII of the Social
21 Security Act, as added by section 251, is amended by add-
22 ing at the end the following:

“Subpart 2—Out-of-Pocket Limit**2 “SEC. 1860E-21. OUT-OF-POCKET LIMIT.**

3 “(a) IN GENERAL.—Beginning with 2023, in the case
4 of a Medicare enrollee, if the amount of the out-of-pocket
5 cost-sharing of such enrollee for a calendar year equals
6 or exceeds the catastrophic limit under subsection (b) for
7 that year—

8 “(1) the enrollee shall not be responsible for ad-
9 ditional out-of-pocket cost-sharing incurred during
10 that year; and

11 “(2) the Secretary shall establish procedures
12 under which the Secretary shall, in appropriate part
13 from the Part A Medicare FFS Account under sec-
14 tion 1817 and the Part B Medicare FFS Account
15 under section 1841—

16 “(A) pay on behalf of the enrollee the
17 amount of the additional out-of-pocket cost-
18 sharing described in paragraph (1) attributable
19 to deductibles and coinsurance described in sub-
20 section (c)(1); and

21 “(B) reimburse the enrollee the amount of
22 the additional out-of-pocket cost-sharing de-
23 scribed in paragraph (1) attributable to
24 deductibles and coinsurance described in sub-
25 section (c)(2).

1 “(b) CATASTROPHIC LIMIT.—The amount of the cat-
2 astrophic limit under this subsection for a year shall be
3 the dollar amount in effect under section 223(c)(2)(A)(ii)
4 of the Internal Revenue Code of 1986 for self-only cov-
5 erage for taxable years beginning in such year.

6 “(c) OUT-OF-POCKET COST-SHARING DEFINED.—In
7 this section, the term ‘out-of-pocket cost-sharing’ means,
8 with respect to an individual, the amount of costs incurred
9 by the individual that are attributable to—

10 “(1) deductibles and coinsurance imposed under
11 part A or part B; and

12 “(2) deductibles and coinsurance imposed under
13 standard prescription drug coverage pursuant to sec-
14 tion 1860D–2(b) or alternative prescription drug
15 coverage pursuant to section 1860D–2(c) offered by
16 a prescription drug plan.”.

17 (b) APPLICATION OF OUT-OF-POCKET LIMIT TO MA-
18 PD PLANS.—

19 (1) IN GENERAL.—Section 1852(a)(1)(B) of the
20 Social Security Act (42 U.S.C. 1395w–22(a)(1)(B))
21 is amended—

22 (A) in clause (i), by striking “clause (iii)”
23 and inserting “clauses (iii) and (vi)”; and

24 (B) by adding at the end the following new
25 clause:

1 “(vi) OUT-OF-POCKET LIMIT.—The
2 provisions of section 1860E–21—

3 “(I) shall apply to individuals en-
4 rolled under an MA–PD plan in the
5 same manner as such provisions apply
6 to Medicare enrollees under such sec-
7 tion, except that in lieu of the applica-
8 tion of subsection (a)(2) of such sec-
9 tion the MA–PD plan shall establish
10 procedures to provide for payment of
11 any additional out-of-pocket cost-shar-
12 ing described in subsection (a)(1) of
13 such section incurred by individuals
14 enrolled under the MA–PD plan; and

15 “(II) as applied under subclause
16 (I), may not be waived by application
17 of this subparagraph.

18 In applying subsection (b) of section
19 1860E–21 pursuant to the previous sen-
20 tence, an MA–PD plan may substitute a
21 dollar amount that is less than the dollar
22 amount specified under such subsection.”.

23 (2) EXEMPTING MA–PD PLANS OFFERING AL-
24 TERNATIVE PRESCRIPTION DRUG COVERAGE FROM
25 PART D DEDUCTIBLE AND OUT-OF-POCKET LIMIT

1 REQUIREMENTS.—Section 1860D–2(c) of the Social
2 Security Act (42 U.S.C. 1395w–102(e)) is amend-
3 ed—

4 (A) in paragraph (2), by striking “The de-
5 ductible” and inserting “In the case of a pre-
6 scription drug plan, the deductible”; and

7 (B) in paragraph (3), by striking “The
8 coverage provides” and inserting “In the case
9 of a prescription drug plan, the coverage pro-
10 vides”.

11 (c) PRESCRIPTION DRUG PLANS REQUIRED TO RE-
12 PORT ENROLLEES’ OUT-OF-POCKET COST-SHARING.—
13 Section 1860D–12(b) of the Social Security Act (42
14 U.S.C. 1395w–112(b)) is amended by adding at the end
15 the following new paragraph:

16 “(7) OUT-OF-POCKET COST-SHARING RE-
17 PORTS.—Each contract entered into with a PDP
18 sponsor under this part with respect to a prescrip-
19 tion drug plan offered by such sponsor shall require
20 that, with respect to each claim submitted for items
21 or services furnished to an individual enrolled under
22 the plan pursuant to the contract, the sponsor sub-
23 mits to the Secretary information on the amount of
24 out-of-pocket cost-sharing (as defined in section

1 1860E–23(c)) applicable to such enrollee for such
2 items or services.”.

3 (d) CONFORMING AMENDMENTS.—

4 (1) Section 1813 of the Social Security Act (42
5 U.S.C. 1395e) is amended—

6 (A) in subsection (a), by inserting “Subject
7 to subpart 2 of part E:” before paragraph (1);
8 and

9 (B) in subsection (b), by inserting “Sub-
10 ject to subpart 2 of part E:” before paragraph
11 (1).

12 (2) Section 1833 of such Act (42 U.S.C. 1395l)
13 is amended—

14 (A) in subsection (a), in the matter pre-
15 ceding paragraph (1), by inserting “and sub-
16 part 2 of part E” after “succeeding provisions
17 of this section”;

18 (B) in subsection (b), in the first sentence,
19 by striking “Before applying” and inserting
20 “Subject to subpart 2 of part E, before apply-
21 ing”;

22 (C) in subsection (c)(1), in the matter pre-
23 ceding subparagraph (A), by inserting “subject
24 to subpart 2 of part E,” after “this part,”;

1 (D) in subsection (f), by striking “In es-
2 tablishing” and inserting “Subject to subpart 2
3 of part E, in establishing”; and

4 (E) in subsection (g)(1), by inserting “and
5 subpart 2 of part E” and “paragraphs (4) and
6 (5)”.

7 (3) Section 1882(a)(2) of such Act is amended
8 by striking “No medicare” and inserting “Subject to
9 section 1860E–24(c), no medicare”.

10 **SEC. 424. LATE ENROLLMENT PENALTY NOT TO APPLY FOR**
11 **MONTHS OF ANY HEALTH COVERAGE.**

12 (a) IN GENERAL.—Section 1839(b) of the Social Se-
13 curity Act (42 U.S.C. 1395r) is amended in the second
14 sentence, by inserting before the period at the end the fol-
15 lowing: “or months during which the individual has any
16 other health coverage”.

17 (b) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply for months of coverage begin-
19 ning after the date of the enactment of this Act.

20 **SEC. 425. MEDIGAP REFORM.**

21 Notwithstanding any provision of section 1882 of the
22 Social Security Act (42 U.S.C. 1395ss), as of the date
23 of the enactment of this Act, no policy may be offered
24 under such section that does not provide guaranteed cov-
25 erage (without regard to an individual’s preexisting condi-

1 tions, if any) to all individuals eligible to enroll under such
2 policy.

3 **SEC. 426. ACO REVISION.**

4 (a) ENROLLMENT.—Enrollment in such an ACO
5 under such title shall be based on the method established
6 under part E of such title. Such a network shall bear full
7 risk in the event payments under such title do not equal
8 or exceed liabilities under such network.

9 (b) DIRECTION OF PAYMENT.—An ACO may direct
10 that any payments under such title be made to a central-
11 ized entity rather than to an individual provider or sup-
12 plier.

13 (c) BIDS.—The Secretary of Health and Human
14 Services shall establish a process whereby such networks
15 compete using a bidding process similar to that described
16 in part E of such title for Medicare Advantage plans.

17 **SEC. 427. PRIMARY CARE OPTIONS.**

18 (a) SELECTION OF PRIMARY CARE PHYSICIAN.—The
19 Secretary shall establish a mechanism under which an in-
20 dividual enrolled under part B of title XVIII of the Social
21 Security Act may select such individual's primary care
22 physician. Such an individual shall not be liable for more
23 than \$5 for each visit to such selected physician.

24 (b) PAYMENT TO PHYSICIAN.—A physician selected
25 under subsection (a) shall receive a monthly fee in lieu

1 of any other payment under such part B for evaluation
2 and monitoring of such individual. The Secretary shall
3 provide a list of standardized benefits that are included
4 in such payment, including telephone and email commu-
5 nications, office visits, preventive care, and vaccinations.

6 **SEC. 428. GENERAL PROVISIONS; EFFECTIVE DATE.**

7 Part E of title XVIII of the Social Security Act, as
8 inserted by section 101(a)(2) and as previously amended,
9 is further amended by adding at the end the following new
10 subpart:

11 **“Subpart 5.—General Provisions**

12 **“SEC. 1860E-51. APPLICABILITY; DEFINITIONS.**

13 “(a) IN GENERAL.—The provisions of this Act are
14 superseded to the extent inconsistent with the provisions
15 of this part.

16 “(b) TERMINOLOGY.—For purposes of this part:

17 “(1) MEDICARE ENROLLEE.—

18 “(A) IN GENERAL.—The term ‘Medicare
19 enrollee’ means—

20 “(i) an individual entitled to (or en-
21 rolled for benefits) under part A and en-
22 rolled under part B; and

23 “(ii) except as otherwise specified, an
24 individual described in section 1860E-
25 11(a)(3).

1 “(B) TREATMENT.—Any reference in this
2 Act (or any other Act) in effect before the date
3 of the enactment of this part, to an individual
4 entitled to benefits under part A or enrolled
5 under part B shall be deemed a reference to a
6 Medicare enrollee.

7 “(2) MEDICARE FEE-FOR-SERVICE.—The term
8 ‘Medicare fee-for-service’ means the original Medi-
9 care fee-for-service program under parts A and B,
10 as modified by this part, and does not include part
11 C or part D.

12 “(3) MEDICARE FEE-FOR-SERVICE EN-
13 ROLLEE.—The term ‘Medicare fee-for-service en-
14 rollee’ means a Medicare enrollee who is not enrolled
15 under a Medicare Advantage plan under part C.

16 **“SEC. 1860E-61. GENERAL EFFECTIVE DATE.**

17 “Except as otherwise specified, the provisions of this
18 part shall apply to items and services furnished on or after
19 January 1, 2023, and to plan years beginning on or after
20 such date (referred to in this title as the ‘general effective
21 date’).”.

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

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

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

8 (1) by striking “and office” and inserting “of-
9 fice”; and

10 (2) by inserting: “respiratory services, audiology
11 services (as defined in section 1861(ll)), outpatient
12 therapy services (including physical therapy, occupa-
13 tional therapy, and speech-language pathology serv-
14 ices)” after “the Secretary)),”.

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

17 (1) in paragraph (1), by striking “or a practi-
18 tioner (described in section 1842(b)(18)(C))” and
19 inserting “, a practitioner (described in section
20 1842(b)(18)(C)), or an applicable professional (as
21 defined in paragraph (4)(G))”;

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

25 (3) in paragraph (3)(A)—

1 (A) in the heading, by striking “PHYSI-
2 CIAN AND PRACTITIONER” and inserting “PHY-
3 SICIAN, PRACTITIONER, AND APPLICABLE PRO-
4 FESSIONAL”; and

5 (B) by striking “physicians or practi-
6 tioners” and inserting “physicians, practi-
7 tioners, or applicable professionals”; and

8 (4) in paragraph (4), by adding at the end the
9 following new subparagraph:

10 “(G) APPLICABLE PROFESSIONAL.—The
11 term ‘applicable professional’ means, with re-
12 spect to services furnished on or after the date
13 that is 6 months after the date of the enact-
14 ment of this subparagraph, a certified diabetes
15 educator or licensed—

16 “(i) respiratory therapist;

17 “(ii) audiologist;

18 “(iii) occupational therapist;

19 “(iv) physical therapist; or

20 “(v) speech language pathologist.”.

21 (c) HOME-BASED MONITORING SERVICES FOR CON-
22 GESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE
23 PULMONARY DISEASE.—

24 (1) COVERAGE OF REMOTE PATIENT MONI-
25 TORING SERVICES FOR CERTAIN CHRONIC HEALTH

1 CONDITIONS.—Section 1861(s)(2) of the Social Se-
2 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

3 (A) in subparagraph (GG), by striking
4 “and” at the end;

5 (B) in subparagraph (HH), by inserting
6 “and” at the end; and

7 (C) by inserting after subparagraph (HH)
8 the following new subparagraph:

9 “(II) applicable remote patient monitoring
10 services (as defined in paragraph (1)(A) of sub-
11 section (iii));”.

12 (2) SERVICES DESCRIBED.—Section 1861 of
13 the Social Security Act (42 U.S.C. 1395x) is amend-
14 ed by adding at the end the following new sub-
15 section:

16 “(kkk) REMOTE PATIENT MONITORING SERVICES
17 FOR CHRONIC HEALTH CONDITIONS.—

18 “(1)(A) The term ‘applicable remote patient
19 monitoring services’ means remote patient moni-
20 toring services (as defined in subparagraph (B)) fur-
21 nished to provide for the monitoring, evaluation, and
22 management of an individual with a covered chronic
23 condition (as defined in paragraph (2)), insofar as
24 such services are for the management of such chron-
25 ic condition.

1 “(B) The term ‘remote patient monitoring serv-
2 ices’ means services furnished through remote pa-
3 tient monitoring technology (as defined in subpara-
4 graph (C)).

5 “(C) The term ‘remote patient monitoring tech-
6 nology’ means a coordinated system that uses one or
7 more home-based or mobile monitoring devices that
8 automatically transmit vital sign data or information
9 on activities of daily living and may include re-
10 sponses to assessment questions collected on the de-
11 vices wirelessly or through a telecommunications
12 connection to a server that complies with the Fed-
13 eral regulations (concerning the privacy of individ-
14 ually identifiable health information) promulgated
15 under section 264(c) of the Health Insurance Port-
16 ability and Accountability Act of 1996, as part of an
17 established plan of care for that patient that in-
18 cludes the review and interpretation of that data by
19 a health care professional.

20 “(2) For purposes of paragraph (1), the term
21 ‘covered chronic health condition’ means applicable
22 conditions (as defined in and applied under section
23 1886(q)(5)) when under chronic care management
24 (identified as of July 1, 2015, by HCPCS code

1 99490 (and as subsequently modified by the Sec-
2 retary)).

3 “(3)(A) Payment may be made under this part
4 for applicable remote patient monitoring services
5 provided to an individual during a period of up to
6 90 days and such additional period as provided for
7 under subparagraph (B).

8 “(B) The 90-day period described in subpara-
9 graph (A), with respect to an individual, may be re-
10 newed by the physician who provides chronic care
11 management to such individual if the individual con-
12 tinues to qualify for such management.”.

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

16 (A) in subsection (c)—

17 (i) in paragraph (2)(B)—

18 (I) in clause (ii)(II), by striking
19 “and (v)” and inserting “(v), and
20 (vii)”; and

21 (II) by adding at the end the fol-
22 lowing new clause:

23 “(vii) BUDGETARY TREATMENT OF
24 CERTAIN SERVICES.—The additional ex-
25 penditures attributable to services de-

1 scribed in section 1861(s)(2)(II) shall not
2 be taken into account in applying clause
3 (ii)(II).”; and

4 (ii) by adding at the end the following
5 new paragraph:

6 “(7) TREATMENT OF APPLICABLE REMOTE PA-
7 TIENT MONITORING SERVICES.—

8 “(A) In determining relative value units
9 for applicable remote patient monitoring serv-
10 ices (as defined in section 1861(iii)(1)(A)), the
11 Secretary, in consultation with appropriate phy-
12 sician groups, practitioner groups, and supplier
13 groups, shall take into consideration—

14 “(i) physician or practitioner re-
15 sources, including physician or practitioner
16 time and the level of intensity of services
17 provided, based on—

18 “(I) the frequency of evaluation
19 necessary to manage the individual
20 being furnished the services;

21 “(II) the complexity of the eval-
22 uation, including the information that
23 must be obtained, reviewed, and ana-
24 lyzed; and

1 “(III) the number of possible di-
2 agnoses and the number of manage-
3 ment options that must be considered;
4 “(ii) practice expense costs associated
5 with such services, including the direct
6 costs associated with installation and infor-
7 mation transmission, costs of remote pa-
8 tient monitoring technology (including
9 equipment and software), device delivery
10 costs, and resource costs necessary for pa-
11 tient monitoring and followup (but not in-
12 cluding costs of any related item or non-
13 physician service otherwise reimbursed
14 under this title); and

15 “(iii) malpractice expense resources.

16 “(B) Using the relative value units deter-
17 mined in subparagraph (A), the Secretary shall
18 provide for separate payment for such services
19 and shall not adjust the relative value units as-
20 signed to other services that might otherwise
21 have been determined to include such separately
22 paid remote patient monitoring services.”; and

23 (B) in subsection (j)(3), by inserting
24 “(2)(II),” after “health risk assessment),”.

1 **SEC. 432. EXPANDING THE USE OF TELEHEALTH THROUGH**
2 **THE WAIVER OF CERTAIN REQUIREMENTS.**

3 (a) IN GENERAL.—Section 1834(m) of the Social Se-
4 curity Act (42 U.S.C. 1395m(m)) is amended—

5 (1) in paragraph (4)(C)(i), by striking “and
6 (7)” and inserting “(7), and (8)”; and

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

8 “(8) **AUTHORITY TO WAIVE REQUIREMENTS**
9 **AND LIMITATIONS IF CERTAIN CONDITIONS MET.—**

10 “(A) IN GENERAL.—Notwithstanding the
11 preceding provisions of this subsection, in the
12 case of telehealth services furnished on or after
13 January 1, 2023, the Secretary may waive any
14 restriction applicable to payment for telehealth
15 services under this subsection that is described
16 in subparagraph (B), but only if the Secretary
17 determines that such waiver would not deny or
18 limit the coverage or provision of benefits under
19 this title, and—

20 “(i) the Secretary determines that the
21 waiver is expected to reduce spending
22 under this title without reducing the qual-
23 ity of care or improve the quality of pa-
24 tient care without increasing spending; or

25 “(ii) the waiver would apply to tele-
26 health services furnished in originating

1 sites located in a high-need health profes-
2 sional shortage area (as designated pursu-
3 ant to section 332(a)(1)(A) of the Public
4 Health Service Act (42 U.S.C.
5 254e(a)(1)(A))).

6 “(B) RESTRICTIONS DESCRIBED.—For
7 purposes of this paragraph, restrictions applica-
8 ble to payment for telehealth services under
9 paragraph (1) are—

10 “(i) requirements relating to qualifica-
11 tions for an originating site under para-
12 graph (4)(C)(ii);

13 “(ii) any geographic limitations under
14 paragraph (4)(C)(i) (other than applicable
15 State law requirements, including State li-
16 censure requirements);

17 “(iii) any limitation on the type of
18 technology used to furnish telehealth serv-
19 ices;

20 “(iv) any limitation on the type of
21 provider of services or supplier who may
22 furnish telehealth services (other than the
23 requirement that the provider of services
24 or supplier is enrolled under this title);

1 “(v) any limitation on specific services
2 designated as telehealth services pursuant
3 to this subsection (provided the Secretary
4 determines that such services are clinically
5 appropriate to furnish remotely); or

6 “(vi) any other limitation relating to
7 the furnishing of telehealth services under
8 this title identified by the Secretary.

9 “(C) PUBLIC COMMENT.—The Secretary
10 shall establish a process by which stakeholders
11 may (on at least an annual basis) provide public
12 comment for waivers under this paragraph.

13 “(D) PERIODIC REVIEW OF WAIVERS.—
14 The Secretary shall periodically, but not more
15 often than every 3 years, reassess each waiver
16 under this paragraph to determine whether the
17 waiver continues to meet the conditions applica-
18 ble under subparagraph (A).”.

19 (b) POSTING OF INFORMATION.—Not later than 2
20 years after the date on which a waiver under section
21 1834(m)(8) of the Social Security Act, as added by sub-
22 section (a), first becomes effective, and at least biennially
23 thereafter, the Secretary of Health and Human Services
24 shall post on the internet website of the Centers for Medi-
25 care & Medicaid Services—

1 (1) the number of Medicare beneficiaries receiv-
2 ing telehealth services by reason of each waiver
3 under such section;

4 (2) the impact of such waivers on expenditures
5 and utilization under title XVIII of the Social Secu-
6 rity Act (42 U.S.C. 1395 et seq.); and

7 (3) other outcomes, as determined appropriate
8 by the Secretary.

9 **SEC. 433. EXPANDING THE USE OF TELEHEALTH FOR MEN-**
10 **TAL HEALTH SERVICES.**

11 (a) IN GENERAL.—Section 1834(m) of the Social Se-
12 curity Act (42 U.S.C. 1395m(m)), as amended by the pre-
13 ceding sections, is amended—

14 (1) in paragraph (4)(C)(i), by striking “and
15 (8)” and inserting “(8), and (9)”; and

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

17 “(9) TREATMENT OF MENTAL HEALTH SERV-
18 ICES FURNISHED THROUGH TELEHEALTH.—The ge-
19 ographic requirements described in paragraph
20 (4)(C)(i) (other than applicable State law require-
21 ments, including State licensure requirements) shall
22 not apply with respect to telehealth services that are
23 mental health services (as determined by the Sec-
24 retary) furnished on or after January 1, 2023, to an
25 eligible telehealth individual at an originating site

1 described in paragraph (4)(C)(ii) (other than an
2 originating site described in subclause (IX) of such
3 paragraph).”.

4 (b) INCLUSION OF THE HOME AS AN ORIGINATING
5 SITE.—Section 1834(m)(4)(C)(ii)(X) of such Act (42
6 U.S.C. 1395m(m)(4)(C)(ii)(X)) is amended by striking
7 “paragraph (7)” and inserting “paragraphs (7) and (9)”.

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

15 **SEC. 434. USE OF TELEHEALTH IN EMERGENCY MEDICAL**
16 **CARE.**

17 (a) IN GENERAL.—Section 1834(m) of the Social Se-
18 curity Act (42 U.S.C. 1395m(m)), as amended by the pre-
19 ceding sections, is amended—

20 (1) in paragraph (4)(C)(i), by striking “and
21 (9)” and inserting “(9), and (10)”; and

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

23 “(10) TREATMENT OF EMERGENCY MEDICAL
24 CARE FURNISHED THROUGH TELEHEALTH.—The
25 geographic requirements described in paragraph

1 (4)(C)(i) (other than applicable State law require-
2 ments, including State licensure requirements) shall
3 not apply with respect to telehealth services that are
4 services for emergency medical care (as determined
5 by the Secretary) furnished on or after January 1,
6 2023, to an eligible telehealth individual at an origi-
7 nating site described in subclause (II), (V), or (VII)
8 of paragraph (4)(C)(ii).”.

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

16 **SEC. 435. IMPROVEMENTS TO THE PROCESS FOR ADDING**
17 **TELEHEALTH SERVICES.**

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

22 (1) implement revisions to the process so that
23 the criteria to add services prioritizes, as appro-
24 priate, improved access to care through telehealth
25 services; and

1 (2) provide clarification on what requests to
2 add telehealth services under such process should in-
3 clude.

4 **SEC. 436. RURAL HEALTH CLINICS AND FEDERALLY QUALI-**
5 **FIED HEALTH CENTERS.**

6 (a) **EXPANSION OF ORIGINATING SITES.**—Section
7 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
8 1395m(m)(4)(C)), as amended by the preceding sections,
9 is amended—

10 (1) in clause (i), by striking “and (10)” and in-
11 serting “and (10), and subject to clause (iii),”;

12 (2) by adding at the end the following new
13 clause:

14 “(iii) **RURAL HEALTH CLINICS AND**
15 **FEDERALLY QUALIFIED HEALTH CEN-**
16 **TERS.**—The term ‘originating site’ shall
17 also include any Federally qualified health
18 center and any rural health clinic (as such
19 terms are defined in section 1861(aa)) at
20 which the eligible telehealth individual is
21 located at the time the service is furnished
22 via a telecommunications system, whether
23 or not the individual is located in an area
24 described in clause (i), insofar as such
25 sites are not otherwise included in the defi-

1 nition of originating site under such
2 clause, subject to applicable State law re-
3 quirements, including State licensure re-
4 quirements.”.

5 (b) EXPANSION OF DISTANT SITES.—Section
6 1834(m) of the Social Security Act (42 U.S.C. 1395m(m))
7 is amended—

8 (1) in the first sentence of paragraph (1)—

9 (A) by striking “or a practitioner (de-
10 scribed in section 1842(b)(18)(C))” and insert-
11 ing “, a practitioner (described in section
12 1842(b)(18)(C)), a Federally qualified health
13 center, or a rural health clinic”; and

14 (B) by striking “or practitioner” and in-
15 serting “, practitioner, Federally qualified
16 health center, or rural health clinic”;

17 (2) in paragraph (2)(A)—

18 (A) by inserting “or to a Federally quali-
19 fied health center or rural health clinic that
20 serves as a distant site” after “a distant site”;
21 and

22 (B) by striking “such physician or practi-
23 tioner” and inserting “such physician, practi-
24 tioner, Federally qualified health center, or
25 rural health clinic”; and

1 (3) in paragraph (4)—

2 (A) in subparagraph (A), by inserting
3 “and includes a Federally qualified health cen-
4 ter or rural health clinic that furnishes a tele-
5 health service to an eligible individual” before
6 the period at the end; and

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

9 “(iii) INCLUSION OF RURAL HEALTH
10 CLINIC SERVICES AND FEDERALLY QUALI-
11 FIED HEALTH CENTER SERVICES FUR-
12 NISHED USING TELEHEALTH.—For pur-
13 poses of this subparagraph, the term ‘tele-
14 health services’ includes a rural health
15 clinic service or Federally qualified health
16 center service that is furnished using tele-
17 health to the extent that payment codes
18 corresponding to services identified by the
19 Secretary under clause (i) or (ii) are listed
20 on the corresponding claim for such rural
21 health clinic service or Federally qualified
22 health center service.”.

23 (c) EFFECTIVE DATE.—The amendments made by
24 this section shall apply to services furnished on or after
25 January 1, 2023.

1 **SEC. 437. NATIVE AMERICAN HEALTH FACILITIES.**

2 (a) IN GENERAL.—Section 1834(m)(4)(C) of the So-
3 cial Security Act (42 U.S.C. 1395m(m)(4)(C)), as amend-
4 ed by the preceding sections, is amended—

5 (1) in clause (i), by striking “clause (iii)” and
6 inserting “clauses (iii) and (iv)”; and

7 (2) by adding at the end the following new
8 clause:

9 “(iv) NATIVE AMERICAN HEALTH FA-
10 CILITIES.—The originating site require-
11 ments described in clauses (i) and (ii) shall
12 not apply with respect to a facility of the
13 Indian Health Service, whether operated
14 by such Service, or by an Indian tribe (as
15 that term is defined in section 4 of the In-
16 dian Health Care Improvement Act (25
17 U.S.C. 1603)) or a tribal organization (as
18 that term is defined in section 4 of the In-
19 dian Self-Determination and Education
20 Assistance Act (25 U.S.C. 5304)), or a fa-
21 cility of the Native Hawaiian health care
22 systems authorized under the Native Ha-
23 waiian Health Care Improvement Act (42
24 U.S.C. 11701 et seq.).”.

25 (b) NO ORIGINATING SITE FACILITY FEE FOR NEW
26 SITES.—Section 1834(m)(2)(B)(i) of the Social Security

1 Act (42 U.S.C. 1395m(m)(2)(B)(i)) is amended, in the
2 matter preceding subclause (I), by inserting “(other than
3 an originating site that is only described in clause (iv) of
4 paragraph (4)(C), and does not meet the requirement for
5 an originating site under clause (i) of such paragraph)”
6 after “the originating site”.

7 (c) EFFECTIVE DATE.—The amendments made by
8 this section shall apply to services furnished on or after
9 January 1, 2023.

10 **SEC. 438. WAIVER OF TELEHEALTH RESTRICTIONS DURING**
11 **NATIONAL EMERGENCIES.**

12 Section 1135(b) of the Social Security Act (42 U.S.C.
13 1320b–5(b)) is amended—

14 (1) in paragraph (6), by striking “and” after
15 the semicolon;

16 (2) in paragraph (7), by striking the period at
17 the end and inserting “; and”; and

18 (3) by adding at the end the following:

19 “(8) requirements for payment for telehealth
20 services under section 1834(m).”.

21 **SEC. 439. USE OF TELEHEALTH IN RECERTIFICATION FOR**
22 **HOSPICE CARE.**

23 (a) IN GENERAL.—Section 1814(a)(7)(D)(i) of the
24 Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)) is
25 amended by inserting “(including through use of tele-

1 health, notwithstanding the requirements in section
2 1834(m)(4)(C))” after “face-to-face encounter”.

3 (b) GAO REPORT.—Not later than 3 years after the
4 date of enactment of this Act, the Comptroller General
5 of the United States shall submit a report to Congress
6 evaluating the impact of the amendment made by sub-
7 section (a) on—

8 (1) the number and percentage of beneficiaries
9 recertified for the Medicare hospice benefit at 180
10 days and for subsequent benefit periods;

11 (2) the appropriateness for hospice care of the
12 patients recertified through the use of telehealth;
13 and

14 (3) any other factors determined appropriate by
15 the Comptroller General.

16 **SEC. 440. CLARIFICATION FOR FRAUD AND ABUSE LAWS**
17 **REGARDING TECHNOLOGIES PROVIDED TO**
18 **BENEFICIARIES.**

19 Section 1128A(i)(6) of the Social Security Act (42
20 U.S.C. 1320a–7a(i)(6)) is amended—

21 (1) in subparagraph (I), by striking “; or” and
22 inserting a semicolon;

23 (2) in subparagraph (J), by striking the period
24 at the end and inserting “; or”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(K) the provision of technologies (as de-
4 fined by the Secretary) on or after the date of
5 the enactment of this subparagraph, by a pro-
6 vider of services or supplier (as such terms are
7 defined for purposes of title XVIII) directly to
8 an individual who is entitled to benefits under
9 part A of title XVIII, enrolled under part B of
10 such title, or both, for the purpose of furnishing
11 telehealth services, remote patient monitoring
12 services, or other services furnished through the
13 use of technology (as defined by the Secretary),
14 if—

15 “(i) the technologies are not offered
16 as part of any advertisement or sollicita-
17 tion; and

18 “(ii) the provision of the technologies
19 meets any other requirements set forth in
20 regulations promulgated by the Sec-
21 retary.”.

22 **SEC. 441. STUDY AND REPORT ON INCREASING ACCESS TO**
23 **TELEHEALTH SERVICES IN THE HOME.**

24 (a) **MEDPAC STUDY.**—The Medicare Payment Advi-
25 sory Commission (in this section referred to as the “Com-

1 mission”) shall conduct a study on increasing access under
2 the Medicare program under title XVIII of the Social Se-
3 curity Act (42 U.S.C. 1395 et seq.) to telehealth services
4 in the home. Such study shall include an analysis of the
5 following:

6 (1) How different payers allow the home to be
7 an originating site for telehealth services.

8 (2) Particular types of telehealth services or
9 subgroups of beneficiaries with respect to which al-
10 lowing the home to be an originating site under the
11 Medicare program would be suitable.

12 (b) REPORT.—Not later than 24 months after the
13 date of the enactment of this Act, the Commission shall
14 submit to Congress a report containing the results of the
15 study conducted under subsection (a), together with rec-
16 ommendations for such legislation and administrative ac-
17 tion as the Commission determines appropriate.

18 **SEC. 442. ANALYSIS OF TELEHEALTH WAIVERS IN ALTER-**

19 **NATIVE PAYMENT MODELS.**

20 The second sentence of section 1115A(g) of the So-
21 cial Security Act (42 U.S.C. 1315a(g)) is amended by in-
22 serting “an analysis of waivers under section (d)(1) re-
23 lated to telehealth and the impact on quality and spending
24 under the applicable titles of such waivers,” after “sub-
25 section (c),”.

1 **SEC. 443. MODEL TO ALLOW ADDITIONAL HEALTH PROFES-**
2 **SIONALS TO FURNISH TELEHEALTH SERV-**
3 **ICES.**

4 Section 1115A(b)(2)(B) of the Social Security Act
5 (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the
6 end the following new clause:

7 “(xxviii) Allowing health professionals
8 who are not otherwise eligible under sec-
9 tion 1834(m) to furnish telehealth services
10 to furnish such services.”.

11 **SEC. 444. TESTING OF MODELS TO EXAMINE THE USE OF**
12 **TELEHEALTH UNDER THE MEDICARE PRO-**
13 **GRAM.**

14 Section 1115A(b)(2) of the Social Security Act (42
15 U.S.C. 1315a(b)(2)) is amended by adding at the end the
16 following new subparagraph:

17 “(D) TESTING MODELS TO EXAMINE USE
18 OF TELEHEALTH UNDER MEDICARE.—The Sec-
19 retary shall consider testing under this sub-
20 section models to examine the use of telehealth
21 under title XVIII.”.

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