

118TH CONGRESS  
2D SESSION

# H. R. 10409

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

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 12, 2024

Mr. WESTERMAN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and the Workforce, the Judiciary, Oversight and Accountability, 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

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## A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Fair Care Act of 2024”.

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. Conditional approval of new human drugs for individuals with rare, progressive, and serious diseases.
- 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 co-pay contributions.
- Sec. 350. Antitrust exemption for private health insurance issuers to negotiate wholesale acquisition prices of prescription drugs purchased from drug manufacturers.
- Sec. 351. Biological product innovation.
- Sec. 352. Biosimilar biological products.
- Sec. 353. Prompt approval of drugs related to safety information.
- Sec. 354. Congressional review of the Food and Drug Administration rule-making.
- Sec. 355. 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. Market based part B pricing index.
- Sec. 374. Innovation model testing of Medicare drug payments.
- Sec. 375. 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 2025, 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 2024.

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           ficiary'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, 2025, 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 ‘2024’ 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(c)(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 subsection (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 redes-  
 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, 2025, 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 2025 through 2029.

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, 2025, may be made through December  
25               31, 2023.

1           “(3) LIMITATION.—Amounts appropriated  
 2           under paragraph (1) for each of plan years 2025  
 3           through 2029 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 2025, calendar year 2024.”.

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, 2024, 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 during the 3-year period beginning 1  
16    year after the date of the enactment of this Act. A tax-  
17    payer may not elect not more than 1 applicable taxable  
18    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, 2024, 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       COVERAGE.—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-

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

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-

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

“(1) Health status.

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

“(3) Claims experience.

“(4) Receipt of health care.

“(5) Medical history.

“(6) Genetic information.

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

“(8) Disability.

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

“(b) IN PREMIUM CONTRIBUTIONS.—

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

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           quirement under a group health plan for the  
2           costs of certain items or services related to a  
3           health condition (such as prenatal care or well-  
4           baby 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           223(d)(2) of the Internal Revenue Code of  
 2           1986) with respect to essential health benefits  
 3           covered under the plan.

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

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

16       **“SEC. 199C. ENFORCEMENT OF CERTAIN HEALTH INSUR-**  
 17               **ANCE REQUIREMENTS.**

18           “(a) STATE ENFORCEMENT.—

19               “(1) STATE AUTHORITY.—Each State may re-  
 20           quire that health insurance issuers that issue, sell,  
 21           renew, or offer health insurance coverage in the  
 22           State in the individual or group market meet the re-  
 23           quirements of this part with respect to such issuers.

24               “(2) FAILURE TO IMPLEMENT PROVISIONS.—In  
 25           the case of a determination by the Secretary that a

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, 2024, 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, 2025, 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, 2024;

2 “(C) meets the requirements that applied  
3 with respect to such plan before June 21, 2024;  
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, 2025,  
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 2024, 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, 2025.

## 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 Guaran-

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, 2024.

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 2025, 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       2024’ 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, 2024.

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

8           Section 2701(a)(1)(A)(iii) of the Public Health Serv-  
9 ice Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by in-  
10 serting after “(consistent with section 2707(c))” the fol-  
11 lowing: “or, for plan years beginning on or after January  
12 1, 2025, 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           2024, 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 2024,  
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 2024, over  
14                   the rate of growth in the consumer  
15                   price index for calendar year 2024.

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, 2024.

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, 2025.

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 2025, 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 2025, 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 INDIVIDUALS 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 hospitals in  
23                  the hospital referral region.”.

1           (2) EFFECTIVE DATE.—The amendments made  
2       by this subsection shall apply with respect to items  
3       and services furnished on or after January 1, 2025.

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 2025  
20 through 2034. 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 2025, 102, plus 1 percentage  
2 point for each subsequent year through 2033, 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 2025, 102, plus 1 percentage point for each  
8 subsequent year through 2033, 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 2024, 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, 2025.

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 enrollee 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 or 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, 2025,  
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 2026, the advisory board convened under this section  
16 shall—

17 (1) submit to the Secretary of Health and  
18 Human Services recommendations described under  
19 subsection (a) for executive action and any rec-  
20 ommendations for State actions for potential consid-  
21 eration in making grants under section 2(c) to  
22 States; and

23 (2) submit to Congress recommendations de-  
24 scribed under subsection (a) for legislative proposals.

1       (c) MEMBERSHIP.—The advisory board under this  
2 section shall consist of the following members:

3           (1) Three representatives of companies that  
4       have—

5                   (A) geographically distributed workforces;

6                   (B) at least 10,000 employees; and

7                   (C) no more than 10 percent of such em-  
8       ployees in any single State.

9           (2) Three representatives of health insurance  
10       issuers and health plans, consisting of—

11                   (A) one representative of for-profit health  
12       insurance issuers and health plans with at least  
13       20,000,000 enrollees in the employer-sponsored  
14       market;

15                   (B) one representative of non-profit health  
16       insurance issuers and health plans operating in  
17       at least 5 States; and

18                   (C) one representative of non-profit health  
19       insurance issuers and health plans operating in  
20       a rural State (as defined by the Census Bu-  
21       reau).

22           (3) Seven public policy experts in the field of  
23       hospital consolidation.

1 **SEC. 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

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

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

“(4) REPORTS TO CONGRESS.—

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

1 such covered entities, as reported in paragraph  
2 (1)(A).

3 “(B) GAO REPORTS.—

4 “(i) INITIAL REPORT.—Not later than  
5 1 year after the date of the enactment of  
6 this subsection, the Comptroller General of  
7 the United States shall submit to Congress  
8 a report—

9 “(I) analyzing the State and local  
10 government contracts intended to sat-  
11 isfy the requirement under subsection  
12 (a)(4)(L)(i) for a covered entity to  
13 qualify as an entity described in sub-  
14 paragraph (L) of subsection (a)(4);

15 “(II) assessing the amount of  
16 care such contracts obligate such enti-  
17 ty to provide to low-income individuals  
18 ineligible for Medicare under title  
19 XVIII of the Social Security Act and  
20 Medicaid under title XIX of such Act;  
21 and

22 “(III) analyzing how these con-  
23 tracts define low-income individuals  
24 and whether the Secretary reviews  
25 such determinations.

1                   “(ii) SUBSEQUENT REPORT.—Not  
 2                   later than 2 years after the date of the en-  
 3                   actment of this subsection, the Comptroller  
 4                   General of the United States shall submit  
 5                   to Congress a final report on the informa-  
 6                   tion collected under paragraph (1)(B) re-  
 7                   garding the difference between the aggre-  
 8                   gate gross reimbursement and aggregate  
 9                   acquisition costs received by each such cov-  
 10                  ered entity (including child sites of such  
 11                  entity) for drugs subject to an agreement  
 12                  under this section.”.

13 **SEC. 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)”;

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

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

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

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

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

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

1 utilization rate’ has the meaning given the  
2 term ‘low-income utilization rate’ under  
3 paragraph (3) of section 1923(b) of the  
4 Social Security Act, except that—

5 “(I) clauses (i) and (ii) of sub-  
6 paragraph (A) of such paragraph  
7 shall be applied as if—

8 “(aa) each reference to ‘pa-  
9 tient services’ were a reference to  
10 ‘patient services furnished on an  
11 outpatient basis’; and

12 “(bb) for purposes of clause  
13 (i)(II) of this subparagraph, each  
14 reference to ‘hospital’ were a ref-  
15 erence to ‘off-site outpatient fa-  
16 cilities, clinics, eligible off-site lo-  
17 cations, and associated sites of  
18 the hospital that are identified as  
19 child sites of the hospital pursu-  
20 ant to the identification system  
21 under section 340B(d)(2)(B)(iv)  
22 of the Public Health Service Act’;  
23 and

1 “(II) clauses (i) and (ii) of sub-  
2 paragraph (B) of such paragraph  
3 shall be applied as if—

4 “(aa) each reference to ‘in-  
5 patient hospital services’ were a  
6 reference to ‘outpatient hospital  
7 services’; and

8 “(bb) for purposes of clause  
9 (i)(II) each reference to ‘hos-  
10 pital’s charges’ were a reference  
11 to ‘charges of the off-site out-  
12 patient facilities, clinics, eligible  
13 off-site locations, and associated  
14 sites of the hospital that are  
15 identified as child sites of the  
16 hospital pursuant to the identi-  
17 fication system under section  
18 340B(d)(2)(B)(iv) of the Public  
19 Health Service Act’.”.

20 (b) ANNUAL REPORTS.—Not later than 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. 524C. 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 (b), 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 section, 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 that has been ap-  
24           proved under 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) of the  
24          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25          355(j)(5)(B)(iv)) is amended—

1           (1) in subclause (I), by striking “180 days after  
2           the date” and all that follows through “by any first  
3           applicant” and inserting “180 days after the earlier  
4           of the dates described in items (aa) and (bb) of sub-  
5           clause (II)”;

6           (2) by redesignating subclause (II) as subclause  
7           (III); and

8           (3) by inserting after subclause (I) the fol-  
9           lowing:

10                               “(II) DATES DESCRIBED.—

11                               “(aa) FIRST DATE.—The  
12                               date described in this item is the  
13                               date of the first commercial mar-  
14                               keting of the drug (including the  
15                               commercial marketing of the list-  
16                               ed drug) by any first applicant.

17                               “(bb) SECOND DATE.—The  
18                               date described in this item is the  
19                               date on which all of the following  
20                               conditions are first met, provided  
21                               no application submitted by any  
22                               first applicant is approved on or  
23                               before such date:

24                               “(AA) An application  
25                               for the drug submitted by



1           an applicant other than a  
2           first applicant has received  
3           tentative approval and could  
4           receive approval, if no first  
5           applicant were eligible for  
6           180-day exclusivity under  
7           this clause, and such appli-  
8           cant has not entered into an  
9           agreement that would pre-  
10          vent commercial marketing  
11          upon approval and has sub-  
12          mitted a notification to the  
13          Secretary documenting that  
14          it has not entered into an  
15          agreement that would pre-  
16          vent commercial marketing.

17               “(BB)     Thirty-three  
18          months have passed since  
19          the date of submission of an  
20          application for the drug by  
21          one first applicant, if there  
22          is only one first applicant,  
23          or, in the case of more than  
24          one first applicant, 33  
25          months have passed since

1 the date of submission of all  
2 such applications.

3 “(CC) Approval of an  
4 application for the drug sub-  
5 mitted by at least one first  
6 applicant would not be pre-  
7 cluded under clause (iii).”.

8 (b) INFORMATION.—Not later than 60 days after the  
9 date of enactment of this Act, the Secretary of Health and  
10 Human Services (referred to in this subsection as the  
11 “Secretary”) shall publish, as appropriate and available,  
12 information sufficient to allow applicants to assess wheth-  
13 er the conditions described in subitems (AA) through (CC)  
14 of section 505(j)(5)(B)(iv)(II)(bb) of the Federal Food,  
15 Drug, and Cosmetic Act (as amended by subsection (a))  
16 have been or will be satisfied for all applications where  
17 the exclusivity period under (iv)(I) of section 505(j)(5)(B)  
18 of the Federal Food, Drug, and Cosmetic Act (as so  
19 amended) has not expired, and shall provide updates to  
20 reflect the most recent information available to the Sec-  
21 retary.

22 **SEC. 343. ENSURING TIMELY ACCESS TO GENERICS.**

23 Section 505(q) of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 355(q)) is amended—

25 (1) in paragraph (1)—

1 (A) in subparagraph (A)(i), by inserting “,  
2 10.31,” after “10.30”;

3 (B) in subparagraph (E)—

4 (i) by striking “application and” and  
5 inserting “application or”;

6 (ii) by striking “If the Secretary” and  
7 inserting the following:

8 “(i) IN GENERAL.—If the Secretary”;

9 (iii) by striking the second sentence  
10 and inserting the following:

11 “(ii) PRIMARY PURPOSE OF DELAY-  
12 ING.—

13 “(I) IN GENERAL.—In deter-  
14 mining whether a petition was sub-  
15 mitted with the primary purpose of  
16 delaying an application, the Secretary  
17 may consider the following factors:

18 “(aa) Whether the petition  
19 was submitted in accordance with  
20 paragraph (2)(B), based on when  
21 the petitioner knew or reasonably  
22 should have known the relevant  
23 information relied upon to form  
24 the basis of such petition.

1           “(bb) Whether the petitioner  
2           has submitted multiple or serial  
3           petitions or supplements to peti-  
4           tions raising issues that reason-  
5           ably could have been known to  
6           the petitioner at the time of sub-  
7           mission of the earlier petition or  
8           petitions.

9           “(cc) Whether the petition  
10          was submitted close in time to a  
11          known, first date upon which an  
12          application under subsection  
13          (b)(2) or (j) of this section or  
14          section 351(k) of the Public  
15          Health Service Act could be ap-  
16          proved.

17          “(dd) Whether the petition  
18          was submitted without relevant  
19          data or information in support of  
20          the scientific positions forming  
21          the basis of such petition.

22          “(ee) Whether the petition  
23          raises the same or substantially  
24          similar issues as a prior petition  
25          to which the Secretary has re-

1 sponded substantively already, in-  
2 cluding if the subsequent submis-  
3 sion follows such response from  
4 the Secretary closely in time.

5 “(ff) Whether the petition  
6 requests changing the applicable  
7 standards that other applicants  
8 are required to meet, including  
9 requesting testing, data, or label-  
10 ing standards that are more on-  
11 erous or rigorous than the stand-  
12 ards the Secretary has deter-  
13 mined to be applicable to the list-  
14 ed drug, reference product, or pe-  
15 titioner’s version of the same  
16 drug.

17 “(gg) The petitioner’s record  
18 of submitting petitions to the  
19 Food and Drug Administration  
20 that have been determined by the  
21 Secretary to have been submitted  
22 with the primary purpose of  
23 delay.

24 “(hh) Other relevant and  
25 appropriate factors, which the

1 Secretary shall describe in guid-  
2 ance.

3 “(II) GUIDANCE.—The Secretary  
4 may issue or update guidance, as ap-  
5 propriate, to describe factors the Sec-  
6 retary considers in accordance with  
7 subclause (I).”; and

8 (iv) by adding at the end the fol-  
9 lowing:

10 “(iii) REFERRAL TO THE FEDERAL  
11 TRADE COMMISSION.—The Secretary shall  
12 establish procedures for referring to the  
13 Federal Trade Commission any petition or  
14 supplement to a petition that the Secretary  
15 determines was submitted with the primary  
16 purpose of delaying approval of an applica-  
17 tion. Such procedures shall include notifi-  
18 cation to the petitioner by the Secretary.”;

19 (C) by striking subparagraph (F);

20 (D) by redesignating subparagraphs (G)  
21 through (I) as subparagraphs (F) through (H),  
22 respectively; and

23 (E) in subparagraph (H), as so redesign-  
24 nated, by striking “submission of this petition”  
25 and inserting “submission of this document”;

1 (2) in paragraph (2)—

2 (A) by redesignating subparagraphs (A)  
3 through (C) as subparagraphs (C) through (E),  
4 respectively;

5 (B) by inserting before subparagraph (C),  
6 as so redesignated, the following:

7 “(A) IN GENERAL.—A person shall submit  
8 a petition to the Secretary under paragraph (1)  
9 before filing a civil action in which the person  
10 seeks to set aside, delay, rescind, withdraw, or  
11 prevent submission, review, or approval of an  
12 application submitted under subsection (b)(2)  
13 or (j) of this section or section 351(k) of the  
14 Public Health Service Act. Such petition and  
15 any supplement to such a petition shall describe  
16 all information and arguments that form the  
17 basis of the relief requested in any civil action  
18 described in the previous sentence.

19 “(B) TIMELY SUBMISSION OF CITIZEN PE-  
20 TITION.—A petition and any supplement to a  
21 petition shall be submitted not later than 60  
22 days after the date on which the person first  
23 knew, or reasonably should have known, the in-  
24 formation that forms the basis of the request  
25 made in the petition or supplement.”;

1 (C) in subparagraph (C), as so redesignated—  
2

3 (i) in the heading, by striking “WITH-  
4 IN 150 DAYS”;

5 (ii) in clause (i), by striking “during  
6 the 150-day period referred to in para-  
7 graph (1)(F),”; and

8 (iii) by amending clause (ii) to read as  
9 follows:

10 “(ii) on or after the date that is 151  
11 days after the date of submission of the  
12 petition, the Secretary approves or has ap-  
13 proved the application that is the subject  
14 of the petition without having made such a  
15 final decision.”;

16 (D) by amending subparagraph (D), as so  
17 redesignated, to read as follows:

18 “(D) DISMISSAL OF CERTAIN CIVIL AC-  
19 TIONS.—

20 “(i) PETITION.—If a person files a  
21 civil action against the Secretary in which  
22 a person seeks to set aside, delay, rescind,  
23 withdraw, or prevent submission, review, or  
24 approval of an application submitted under  
25 subsection (b)(2) or (j) of this section or



1 section 351(k) of the Public Health Service  
2 Act without complying with the require-  
3 ments of subparagraph (A), the court shall  
4 dismiss without prejudice the action for  
5 failure to exhaust administrative remedies.

6 “(ii) TIMELINESS.—If a person files a  
7 civil action against the Secretary in which  
8 a person seeks to set aside, delay, rescind,  
9 withdraw, or prevent submission, review, or  
10 approval of an application submitted under  
11 subsection (b)(2) or (j) of this section or  
12 section 351(k) of the Public Health Service  
13 Act without complying with the require-  
14 ments of subparagraph (B), the court shall  
15 dismiss with prejudice the action for fail-  
16 ure to timely file a petition.

17 “(iii) FINAL RESPONSE.—If a civil ac-  
18 tion is filed against the Secretary with re-  
19 spect to any issue raised in a petition time-  
20 ly filed under paragraph (1) in which the  
21 petitioner requests that the Secretary take  
22 any form of action that could, if taken, set  
23 aside, delay, rescind, withdraw, or prevent  
24 submission, review, or approval of an appli-  
25 cation submitted under subsection (b)(2)

or (j) of this section or section 351(k) of the Public Health Service Act before the Secretary has taken final agency action on the petition within the meaning of subparagraph (C), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.”; and

(E) in clause (iii) of subparagraph (E), as so redesignated, by striking “as defined under subparagraph (2)(A)” and inserting “within the meaning of subparagraph (C)”;

and

(3) in paragraph (4)—

(A) by striking “EXCEPTIONS” and all that follows through “This subsection does” and inserting “EXCEPTIONS.—This subsection does”;

(B) by striking subparagraph (B); and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly.

**SEC. 344. PREEMPTION OF STATE BARRIERS TO THE SUBSTITUTION OF BIOSIMILAR PRODUCTS.**

No State, or any political subdivision thereof, may, under any circumstances, prohibit a pharmacy or pharmacist from dispensing, in place of a biological reference product, any biosimilar that the Food and Drug Adminis-

1 tration has designated as an interchangeable product for  
2 that biological reference product.

3 **SEC. 345. INCREASING PHARMACEUTICAL OPTIONS TO**  
4 **TREAT AN UNMET MEDICAL NEED.**

5 Subsection (b) of section 506 of the Federal Food,  
6 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by  
7 adding at the end the following:

8 “(4) UNMET MEDICAL NEED.—For purposes of  
9 paragraph (1), a drug to address an unmet medical  
10 need for a disease or condition shall be deemed to  
11 address such medical need if fewer than 3 available  
12 drugs exist for the treatment of such disease or con-  
13 dition.”.

14 **SEC. 346. CONDITIONAL APPROVAL OF NEW HUMAN DRUGS**  
15 **FOR INDIVIDUALS WITH RARE, PROGRES-**  
16 **SIVE, AND SERIOUS DISEASES.**

17 (a) IN GENERAL.—Subchapter A of chapter V of the  
18 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351  
19 et seq.), as amended by section 341, is further amended  
20 by adding at the end of the following:

21 **“SEC. 524D. CONDITIONAL APPROVAL OF HUMAN DRUGS**  
22 **FOR INDIVIDUALS WITH RARE, PROGRES-**  
23 **SIVE, AND SERIOUS DISEASES.**

24 “(a) CONDITIONAL APPROVAL; PRIORITY REVIEW;  
25 OTHER DESIGNATIONS.—

1           “(1) IN GENERAL.—The sponsor of a drug may  
2       file with the Secretary an application for conditional  
3       approval of an eligible drug described in subsection  
4       (b). The Secretary shall approve or deny such appli-  
5       cation in accordance with subsection (c).

6           “(2) PRIORITY REVIEW.—The Secretary shall  
7       give priority review to an application for conditional  
8       approval of an eligible drug described in subsection  
9       (b).

10          “(3) OTHER DESIGNATIONS.—If a drug that is  
11       granted conditional approval under this section is el-  
12       igible for a special designation by the Secretary  
13       under this Act, including as a drug for a rare dis-  
14       ease or condition under section 526, all applicable  
15       benefits of such other designation shall be available  
16       for use under such conditional approval, including  
17       any tax credits and waiving of fees under chapter  
18       VII.

19          “(4) OTHER PROGRAMS.—A sponsor of a drug  
20       seeking conditional approval of such drug under this  
21       section may also seek designation, exclusivity, or ap-  
22       proval, as applicable, of such drug under other appli-  
23       cable provisions of this Act or the Public Health  
24       Service Act, subject to the requirements of such pro-  
25       visions.

1 “(b) ELIGIBILITY.—

2 “(1) IN GENERAL.—A drug may be eligible for  
3 conditional approval under this section if such drug  
4 is intended to treat a disease or condition that is—

5 “(A) rapidly progressive, terminal, and has  
6 substantial unmet medical need, as determined  
7 by the Secretary; or

8 “(B) a rare disease or condition (as de-  
9 fined in section 526(a)(2)) that results in a  
10 substantially shortened lifespan, substantial re-  
11 duction in quality of life, or other substantial  
12 adverse health effects, as determined by the  
13 Secretary.

14 “(2) EXCLUSION FROM ELIGIBILITY.—A drug  
15 that is intended to treat or respond to a material  
16 threat identified by the Secretary of Homeland Secu-  
17 rity under section 319F-2(c)(2)(A)(ii) of the Public  
18 Health Service Act shall not be eligible for condi-  
19 tional approval under this section.

20 “(c) STANDARD OF REVIEW FOR CONDITIONAL AP-  
21 PROVAL.—

22 “(1) REQUIREMENTS.—The Secretary shall  
23 only approve an application for conditional approval  
24 of a drug under this section if—

25 “(A) the Secretary determines that—

1 “(i)(I) evidence of safety for the drug  
2 has been established by—

3 “(aa) the completion of a phase 1  
4 clinical investigation of the drug (as  
5 described in section 312.21 of title 21,  
6 Code of Federal Regulations (or suc-  
7 cessor regulations)); or

8 “(bb) another demonstration of  
9 safety, as determined appropriate by  
10 the Secretary; and

11 “(II) evidence of effectiveness in  
12 treating a given indication (which indica-  
13 tion is congruent with the eligibility re-  
14 quirements of subsection (b)), as estab-  
15 lished by an ongoing or completed phase 2  
16 clinical investigation of the drug (as de-  
17 scribed in section 312.21 of title 21, Code  
18 of Federal Regulations (or successor regu-  
19 lations)); or

20 “(ii) in the case of a drug that is in-  
21 tended to treat a terminal pediatric rare  
22 disease or condition (as defined in section  
23 526(a)(2)) that does not predominately af-  
24 fect adults—

1 “(I) evidence of safety for the  
2 drug has been established in accord-  
3 ance with clause (i)(I); and

4 “(II) the drug shows preliminary  
5 evidence of clinical effectiveness based  
6 upon studies in animal models; and

7 “(B) the sponsor has provided a written  
8 affirmation of the sponsor’s intent to pursue  
9 under section 505 of this Act or section 351 of  
10 the Public Health Service Act approval of the  
11 drug, which affirmation shall include a justifica-  
12 tion and a plan for pursuing such approval.

13 “(2) ROLLING, REAL-TIME REVIEW.—

14 “(A) IN GENERAL.—If the Secretary deter-  
15 mines, after preliminary evaluation of data sub-  
16 mitted by the sponsor, that a drug may meet  
17 the standard for conditional approval, the spon-  
18 sor may submit portions of an application for  
19 conditional approval of a drug under this sec-  
20 tion for evaluation by the Secretary before the  
21 sponsor submits a complete application, which  
22 submission shall include—

23 “(i) a schedule for submission of in-  
24 formation necessary to make the applica-  
25 tion complete; and

1 “(ii) a payment of any fee that may  
2 be required under section 736.

3 “(B) REVIEW.—The Secretary—

4 “(i) shall evaluate each application  
5 submitted under subparagraph (A) to as-  
6 sess whether such application is complete  
7 or ready to be filed; and

8 “(ii) may commence review of portions  
9 of such application for approval.

10 “(3) USE OF REAL-WORLD EVIDENCE.—

11 “(A) IN GENERAL.—The Secretary shall  
12 allow the use of real-world evidence (as defined  
13 in section 505F(b)), including real-world data  
14 used to generate real-world evidence, and of ex-  
15 ternal sources of data, including prospective or  
16 retrospective natural history data, to support an  
17 application for conditional approval under this  
18 section.

19 “(B) DATA INTEGRITY REQUIREMENTS.—

20 In using evidence described in subparagraph  
21 (A) to support an application for conditional  
22 approval under this section, the sponsor shall  
23 consider the guidance of the Food and Drug  
24 Administration entitled ‘Data Standards for  
25 Drug and Biological Product Submissions Con-



1           taining Real-World Data’ and dated December  
2           2023 (or successor guidance).

3           “(d) FDA AUTHORITY TO WITHDRAW CONDITIONAL  
4 APPROVAL.—

5           “(1) IN GENERAL.—The Secretary may with-  
6 draw the conditional approval of a drug under this  
7 section if—

8           “(A) after adequate review of appropriate  
9 safety data, including data from an observa-  
10 tional registry established under subsection (g),  
11 the Secretary determines that such data no  
12 longer supports conditional approval;

13           “(B) the Secretary determines that the ap-  
14 plication for conditional approval submitted  
15 under subsection (a)(1) contained an untrue  
16 statement of material fact; or

17           “(C) the Secretary determines that the  
18 drug is no longer eligible under subsection (b).

19           “(2) FDA EXAMINATION AUTHORITY.—

20           “(A) IN GENERAL.—For purposes of deter-  
21 mining whether to withdraw the conditional ap-  
22 proval of a drug under paragraph (1), the Sec-  
23 retary may—

24           “(i) review any available clinical data  
25 made available through clinical trials or an

1 observational registry under subsection (g),  
2 applicable to such drug; and

3 “(ii) determine whether the sponsor of  
4 such drug is in violation of a requirement  
5 established under paragraph (3) or (4) of  
6 section 505(o) or section 505–1 with re-  
7 spect to the drug.

8 “(B) TRANSPARENCY.—

9 “(i) IN GENERAL.—The Secretary  
10 may require drug sponsors and observa-  
11 tional registries under subsection (g) to  
12 submit the data described in subparagraph  
13 (A) for the purposes of the review under  
14 that subparagraph.

15 “(ii) FINES.—The Secretary may levy  
16 fines on sponsors and observational reg-  
17 istries that do not comply with a request  
18 for data under clause (i) within such rea-  
19 sonable timeframe as is established by the  
20 Secretary.

21 “(3) EFFECT OF WITHDRAWAL.—

22 “(A) AVAILABILITY TO NEW PATIENTS.—

23 “(i) IN GENERAL.—If a conditional  
24 approval is withdrawn under this sub-  
25 section, the sponsor may not make the

1 drug available to any new patients, but  
2 may continue to make such drug available  
3 to patients who started taking the drug  
4 prior to the date of withdrawal.

5 “(ii) EFFECT.—Nothing in this sub-  
6 paragraph shall be construed to require—

7 “(I) a patient to continue taking  
8 a conditionally approved drug if such  
9 patient decides to stop taking such  
10 drug; or

11 “(II) the sponsor to ensure such  
12 drug continues to be manufactured  
13 after the date of withdrawal.

14 “(B) CIVIL MONETARY PENALTY.—Any  
15 sponsor who makes available to new patients a  
16 drug for which conditional approval has been  
17 withdrawn under this subsection shall be sub-  
18 ject to such civil monetary penalty as is deter-  
19 mined by the Secretary.

20 “(4) WITHDRAWAL NOTICE.—Upon deter-  
21 mining to withdraw the conditional approval of a  
22 drug under paragraph (1), the Secretary shall sub-  
23 mit written notice to the sponsor of such drug and  
24 such withdrawal shall be effective on the date that

1 is 14 days after the date of such submission of no-  
2 tice.

3 “(5) APPEALS.—Not later than 180 days after  
4 the date of enactment of this section, the Secretary,  
5 by rule, shall establish a process by which a sponsor  
6 of a drug for which conditional approval was with-  
7 drawn under paragraph (1) may appeal such with-  
8 drawal.

9 “(6) AUTOMATIC WITHDRAWAL.—

10 “(A) IN GENERAL.—If the sponsor of a  
11 drug that receives conditional approval under  
12 this section does not submit an application for  
13 renewal of such conditional approval under sub-  
14 section (f)(2) by the deadline under that sub-  
15 section, such conditional approval shall auto-  
16 matically be withdrawn in accordance with  
17 paragraph (3) on the date on which such condi-  
18 tional approval expires.

19 “(B) MARKETING REQUIREMENT.—If any  
20 drug that receives conditional approval under  
21 this section is not brought to market within 1  
22 year of the date on which the conditional ap-  
23 proval is granted, such conditional approval,  
24 along with any benefits described in subsection

1 (a)(3), shall automatically be withdrawn in ac-  
2 cordance with paragraph (3) on such date.

3 “(C) NO RIGHT TO APPEAL; EFFECT OF  
4 AUTOMATIC WITHDRAWAL.—

5 “(i) IN GENERAL.—A sponsor shall  
6 not have the right to appeal an automatic  
7 withdrawal under this paragraph.

8 “(ii) EFFECT.—The Secretary shall  
9 have no means or power to prevent an  
10 automatic withdrawal under this para-  
11 graph from occurring.

12 “(e) LABELING; REVIEW OF MATERIALS.—

13 “(1) IN GENERAL.—Sponsors may not make  
14 available to patients a drug conditionally approved  
15 under this section, unless—

16 “(A) all labeling and advertising of such  
17 drug contains the statement ‘conditionally ap-  
18 proved for a limited population’ in a prominent  
19 manner and adjacent to, and not more promi-  
20 nent than—

21 “(i) the proprietary name of such  
22 drug, if any; or

23 “(ii) if there is no proprietary name,  
24 the established name of such drug, if any,  
25 as defined in section 502(e)(3), or, in the

1 case of a drug that is a biological product,  
2 the proper name, as defined by regulation;  
3 and

4 “(B) the prescribing information for the  
5 drug required by section 201.57 of title 21,  
6 Code of Federal Regulations (or any successor  
7 regulation) includes the following statement:  
8 ‘This drug is conditionally approved for use in  
9 a limited and specific population. This drug has  
10 not received full approval by the Food and  
11 Drug Administration. Conditional approval of  
12 this drug may be withdrawn at short notice.’.

13 “(2) SUBMISSION.—Not later than 45 days be-  
14 fore such materials are distributed, all promotional,  
15 educational, and marketing materials for such drug  
16 shall be submitted to the Secretary for review.

17 “(3) PUBLIC LIST.—The Secretary shall main-  
18 tain a list of all drugs conditionally approved under  
19 this section on a publicly accessible website. Such  
20 website shall briefly describe what each conditionally  
21 approved drug is and list the 1 or more diseases or  
22 conditions for which the drug is indicated.

23 “(f) RENEWAL OF CONDITIONAL APPROVAL; RE-  
24 QUIREMENT TO BRING DRUG TO MARKET.—

1           “(1) DURATION; RENEWALS.—The conditional  
2           approval for a drug under this section is effective for  
3           a 2-year period. The sponsor may request renewal of  
4           such conditional approval for up to 3 subsequent 2-  
5           year periods. Conditional approval with respect to a  
6           drug shall not exceed a total of 8 years from the ini-  
7           tial date the drug was granted conditional approval.

8           “(2) APPLICATIONS FOR RENEWAL OF CONDI-  
9           TIONAL APPROVAL.—

10           “(A) IN GENERAL.—Except as provided in  
11           subparagraph (C), the sponsor of a drug seek-  
12           ing a renewal of conditional approval for such  
13           drug under this subsection shall submit to the  
14           Secretary, not later than 180 days before the  
15           date on which such conditional approval expires,  
16           an application that contains the applicable in-  
17           formation described in paragraph (3) in a  
18           standardized format determined by the Sec-  
19           retary.

20           “(B) PROCESS FOR GRANTING RENEW-  
21           ALS.—Not later than 180 days after the date of  
22           enactment of this section, the Secretary, by  
23           rule, shall establish the process for granting a  
24           renewal under this subsection.

1                   “(C) EXEMPTION FOR SMALL POPULATION  
2                   DISEASES.—

3                   “(i) IN GENERAL.—The Secretary  
4                   shall exempt from the requirements of sub-  
5                   paragraph (A) and paragraph (3) an appli-  
6                   cation for a renewal of conditional approval  
7                   for a drug under this subsection if the Sec-  
8                   retary determines that the population af-  
9                   fected by the disease or condition that the  
10                  drug is intended to treat does not support  
11                  additional preliminary evidence of effective-  
12                  ness (as defined in paragraph (3)(D)).

13                  “(ii) APPLICATION FOR EXEMP-  
14                  TION.—Sponsors may submit an applica-  
15                  tion for exemption under this subpara-  
16                  graph not later than 180 days before the  
17                  date on which the conditional approval ex-  
18                  pires.

19                  “(iii) APPLICATION PROCESS.—Not  
20                  later than 180 days after the date of en-  
21                  actment of this section, the Secretary shall  
22                  establish a standardized application proc-  
23                  ess for purposes of this subparagraph.

24                  “(iv) DEADLINE.—The Secretary shall  
25                  approve or deny an application under this



1           subparagraph before the date on which the  
2           conditional approval expires.

3           “(v) APPEALS.—Not later than 180  
4           days after the date of enactment of this  
5           section, the Secretary shall establish a  
6           process under which a sponsor may appeal  
7           a denial of an application under this sub-  
8           paragraph.

9           “(3) ADDITIONAL PRELIMINARY EVIDENCE OF  
10          EFFECTIVENESS.—The information described in this  
11          paragraph is the following:

12           “(A) FOR THE FIRST APPROVAL RE-  
13          NEWAL.—With respect to an application under  
14          paragraph (2) for the first renewal of condi-  
15          tional approval for a drug under this sub-  
16          section, additional preliminary evidence of effec-  
17          tiveness of the drug, as compared to the evi-  
18          dence provided in the initial application for con-  
19          ditional approval for the drug under subsection  
20          (c).

21           “(B) FOR THE SECOND APPROVAL RE-  
22          NEWAL.—With respect to an application under  
23          paragraph (2) for the second renewal of condi-  
24          tional approval for a drug under this sub-  
25          section, additional preliminary evidence of effec-

1           tiveness of the drug, as compared to the evi-  
2           dence provided in the renewal application de-  
3           scribed in subparagraph (A).

4           “(C) FOR THE FINAL APPROVAL RE-  
5           NEWAL.—With respect to an application under  
6           paragraph (2) for the third renewal of condi-  
7           tional approval for a drug under this sub-  
8           section, a written affirmation from the head of  
9           the drug’s review division of the Office of New  
10          Drugs or the Office of Therapeutic Products  
11          asserting that a third renewal is necessary—

12               “(i) for patients who have benefitted  
13               from such drug to retain access to such  
14               drug; and

15               “(ii) to generate additional prelimi-  
16               nary evidence of effectiveness for the pur-  
17               poses of attaining approval under section  
18               505 of this Act or section 351 of the Pub-  
19               lic Health Service Act.

20          “(D) DEFINITION.—In this paragraph, the  
21          term ‘preliminary evidence of effectiveness’  
22          means—

23               “(i) clinical evidence generated by an  
24               ongoing or completed clinical trial con-  
25               ducted in accordance with section 11.22 of

1 title 42, Code of Federal Regulations (or  
2 successor regulations);

3 “(ii) real-world evidence (as defined in  
4 section 505F(b)); or

5 “(iii) evidence from an observational  
6 registry under subsection (g).

7 “(4) DENIAL OF RENEWAL ON THE BASIS OF  
8 DATA FRAUD.—The Secretary may deny the applica-  
9 tion for renewal of conditional approval for a drug  
10 under this subsection if the Secretary, in conducting  
11 a review under subsection (d)(2), finds that the evi-  
12 dence provided in such application under subpara-  
13 graph (A) or (B) of paragraph (3) was fraudulently  
14 manipulated by the applicable observational registry  
15 and that such application substantially relies on  
16 such data.

17 “(g) OBSERVATIONAL REGISTRIES.—

18 “(1) ESTABLISHMENT.—

19 “(A) IN GENERAL.—Subject to subpara-  
20 graph (C), the sponsor of a drug conditionally  
21 approved under this section shall establish an  
22 observational registry, for patients who are or  
23 will be treated with such drug, that pertains to  
24 the disease or condition that the drug is in-  
25 tended to treat.

1           “(B) REGISTRIES.—In establishing an ob-  
2           servational registry for a drug under subpara-  
3           graph (A), the sponsor may—

4                   “(i) establish a new observational reg-  
5           istry;

6                   “(ii) use an existing observational reg-  
7           istry that pertains to the disease or condi-  
8           tion such drug is intended to treat;

9                   “(iii) combine 1 or more existing ob-  
10          servational registries that pertain to the  
11          disease or condition such drug is intended  
12          to treat with a new observational registry;  
13          or

14                  “(iv) combine 2 or more existing ob-  
15          servational registries that pertain to the  
16          disease or condition such drug is intended  
17          to treat.

18           “(C) APPROVAL OF REGISTRY AND RIGHT  
19          TO APPEAL.—Not later than 180 days after the  
20          date of enactment of this section, the Secretary  
21          shall establish—

22                  “(i) a process to approve or deny the  
23          establishment of an observational registry  
24          under subparagraph (A); and

1                   “(ii) a process for sponsors that re-  
2                   ceived such a denial to appeal the denial.

3                   “(2) REQUIREMENT FOR PATIENTS TO ENROLL  
4                   IN OBSERVATIONAL REGISTRY.—

5                   “(A) IN GENERAL.—A drug conditionally  
6                   approved under this section shall not be made  
7                   available to a patient unless such patient is en-  
8                   rolled in the applicable observational registry  
9                   described in paragraph (1).

10                  “(B) INFORMED CONSENT.—

11                  “(i) IN GENERAL.—Prior to enrolling  
12                  in an observational registry under subpara-  
13                  graph (A), a patient shall provide informed  
14                  consent in accordance with clause (ii).

15                  “(ii) APPLICATION OF CERTAIN RE-  
16                  QUIREMENTS.—The requirements for in-  
17                  formed consent under part 50 of sub-  
18                  chapter A of chapter I of title 21, Code of  
19                  Federal Regulations (or successor regula-  
20                  tions), shall apply to enrollment an obser-  
21                  vational registry under this paragraph.

22                  “(3) SUBMISSION OF PATIENT DATA.—

23                  “(A) IN GENERAL.—The sponsor of a drug  
24                  conditionally approved under this section shall  
25                  be responsible for obtaining and submitting pa-

1           tient data to the applicable observational reg-  
2           istry described in paragraph (1).

3           “(B) SUBMISSION STANDARDS.—Not later  
4           than 180 days after the date of enactment of  
5           this section, the Secretary shall establish data  
6           submission standards for sponsors to comply  
7           with for purposes of subparagraph (A) to en-  
8           sure that registry data is consistent and clini-  
9           cally informed.

10          “(4) REQUIREMENTS FOR REGISTRIES.—An ob-  
11          servational registry described in paragraph (1) for a  
12          drug conditionally approved under this section may  
13          be operated by the sponsor of such drug or, at the  
14          sponsor’s discretion, a third party, for-profit organi-  
15          zation, or nonprofit organization.

16          “(5) RISK AND BENEFIT DATA.—

17               “(A) IN GENERAL.—The sponsor of a drug  
18               conditionally approved under this section shall  
19               submit relevant risk and benefit data to the ap-  
20               plicable observational registry described in  
21               paragraph (1).

22               “(B) ONLINE PORTAL.—The Secretary  
23               shall operate an online portal on an existing  
24               website of the Secretary for sponsors to submit  
25               data described in subparagraph (A).

1 “(6) ACCESSIBILITY.—

2 “(A) IN GENERAL.—An observational reg-  
3 istry described in paragraph (1) shall—

4 “(i) not later than 30 days after re-  
5 ceipt of a request, provide patients (or  
6 their designated representatives) with ac-  
7 cess to such patient’s personal registry in-  
8 formation; and

9 “(ii) provide approved researchers and  
10 medical professionals access to de-identi-  
11 fied and aggregated data from the registry  
12 for the purposes of indication- and disease-  
13 specific and translational research into  
14 conditions and diseases relating to the dis-  
15 ease or condition that the drug tracked by  
16 the observational registry is intended to  
17 treat.

18 “(B) APPROVED RESEARCHERS AND MED-  
19 ICAL PROFESSIONALS.—Not later than 180  
20 days after the date of enactment of this section,  
21 the Secretary, by rule, shall establish a process  
22 for approving researchers and medical profes-  
23 sionals for purposes of subparagraph (A)(ii).

24 “(7) EFFECT.—Nothing in this section shall be  
25 construed to modify or limit the Secretary’s author-

1       ity to require for a drug conditionally approved  
2       under this section any type of postapproval study  
3       under any other provision of law, including sections  
4       505(o)(3), 505B, and 506.

5       “(h) PURSUIT OF A DIFFERENT INDICATION.—

6               “(1) IN GENERAL.—In the case of a drug con-  
7       ditionally approved under this section for which such  
8       approval was withdrawn under subsection (d), ex-  
9       pired under subsection (f)(1), or was denied for re-  
10      newal under subsection (f)(4), not later than 2 years  
11      after the date of withdrawal, expiration, or denial, as  
12      applicable, the sponsor of such drug shall have the  
13      opportunity to petition the Secretary to receive con-  
14      ditional approval of such drug, in accordance with  
15      this section, for a different indication.

16             “(2) PROCESS.—Not later than 180 days after  
17      the date of enactment of this section, the Secretary  
18      shall establish a process for petitions under para-  
19      graph (1).

20      “(i) TRANSITION TO OTHER FORMS OF APPROVAL.—

21             “(1) IN GENERAL.—A drug that receives condi-  
22      tional approval under this section may be granted  
23      approval under section 505 of this Act or section  
24      351 of the Public Health Service Act during the pe-  
25      riod in which such conditional approval is in effect.



1 Effective on the date on which approval for such  
2 drug is granted under section 505 of this Act or sec-  
3 tion 351 of the Public Health Service Act, such con-  
4 ditional approval shall be automatically withdrawn in  
5 accordance with subsection (d)(3).

6 “(2) CONSIDERATION OF CERTAIN EVI-  
7 DENCE.—In determining whether to approve under  
8 section 505 of this Act or section 351 of the Public  
9 Health Service Act a drug that has received condi-  
10 tional approval under this section, the Secretary may  
11 consider evidence from the observational registry for  
12 the drug under subsection (g).

13 “(j) INFORMED CONSENT.—

14 “(1) IN GENERAL.—Prior to being prescribed a  
15 drug conditionally approved under this section, a pa-  
16 tient shall provide informed consent in accordance  
17 with paragraph (2).

18 “(2) APPLICATION OF CERTAIN REQUIRE-  
19 MENTS.—The requirements for informed consent  
20 under part 50 of subchapter A of chapter I of title  
21 21, Code of Federal Regulations (or successor regu-  
22 lations), shall apply to drugs conditionally approved  
23 under this section.

24 “(3) OBSERVATIONAL REGISTRIES.—An obser-  
25 vational registry established for a drug in accord-

1       ance with subsection (g) may obtain, and maintain  
2       records of, informed consent of a patient on behalf  
3       of the drug sponsor, in accordance with paragraph  
4       (2).

5               “(4) COMMON RULE.—Drugs conditionally ap-  
6       proved under this section shall comply with subpart  
7       A of part 46 of title 45, Code of Federal Regulations  
8       (commonly known as the ‘Common Rule’) (or suc-  
9       cessor regulations), if applicable.

10              “(k) LIMITATION ON LIABILITY.—With respect to  
11      any claim under State law relating to a drug made avail-  
12      able pursuant to a grant of conditional approval under this  
13      section, no liability shall lie against a sponsor or manufac-  
14      turer of the drug, or any health care provider who pre-  
15      scribes or administers the drug, absent intentional wrong-  
16      doing.

17              “(l) REPORT TO CONGRESS.—

18               “(1) IN GENERAL.—Not later than 2 years  
19      after the date of enactment of this section, and once  
20      every 2 years thereafter, the Secretary, in collabora-  
21      tion with drug sponsors, shall submit a report to  
22      Congress on all drugs granted conditional approval  
23      under this section. Such report shall include—

24                   “(A) an estimated number of patients  
25                   treated with each such drug, and the number of

1 patients tracked in an observational registry  
2 under subsection (g) with respect to each such  
3 drug, if applicable;

4 “(B) a discussion, at an aggregate level, of  
5 the types and amounts of data obtained  
6 through observational registries under sub-  
7 section (g), such as patient treatments and  
8 uses, length of use, side effects encountered,  
9 relevant biomarkers, scan results, cause of  
10 death and how long the patient lived, and ad-  
11 verse drug effects;

12 “(C) a list of all such drugs for which an  
13 application for approval under this section, or  
14 an application for an extension of conditional  
15 approval under this section, has been sub-  
16 mitted; and

17 “(D) the number of all applications grant-  
18 ed and denied conditional approval under this  
19 section.

20 “(2) SPONSOR PARTICIPATION.—Not later than  
21 180 days before the date on which the Secretary  
22 submits a report under paragraph (1), the sponsor  
23 of a drug conditionally approved under this section  
24 shall provide to the Secretary the information de-

1       scribed in subparagraphs (A) and (B) of paragraph  
2       (1), as applicable.

3               “(3) NOTICE AUTHORITY.—The Secretary may  
4       notify sponsors of drugs conditionally approved  
5       under this section and observational registries under  
6       subsection (g) as necessary to complete a report  
7       under paragraph (1).”.

8       (b) CONFORMING AMENDMENT.—Section 505(a) of  
9       the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
10      355(a)) is amended by inserting “, or there is in effect  
11     a conditional approval under section 524C with respect to  
12     such drug” before the period.

13      (c) REIMBURSEMENT.—

14              (1) PRIVATE HEALTH INSURERS.—Section  
15      2719A of the Public Health Service Act (42 U.S.C.  
16      300gg–19a) is amended by adding at the end the  
17      following:

18              “(f) COVERAGE OF CERTAIN DRUGS.—A group  
19      health plan or health insurance issuer offering group or  
20      individual health insurance coverage shall provide coverage  
21      for, and shall not impose any cost sharing requirements  
22      for, drugs conditionally approved under section 524D of  
23      the Federal Food, Drug, and Cosmetic Act for patients  
24      who have the disease or condition the drug is intended  
25      to treat.”.

1           (2) FEDERAL HEALTH CARE PROGRAMS.—The  
 2           requirement under subsection (f) 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           (f).

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 condi-  
 16                   tionally approved under section 524D of such  
 17                   Act” before the semicolon.

18 **SEC. 347. CONSOLIDATING EXCLUSIVITY PERIODS FOR**  
 19 **DRUGS TREATING RARE DISEASES AND CON-**  
 20 **DITIONS.**

21           (a) IN GENERAL.—Section 527(a) of the Federal  
 22           Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is  
 23           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 “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 section and the amend-  
4 ments made by this section apply only with respect to a  
5 biological product for which the reference product (as such  
6 term is used in section 351 of the Public Health Service  
7 Act (42 U.S.C. 262)) is licensed under subsection (a) of  
8 such section on or after the date of enactment of this Act.

9 **SEC. 349. REGULATION OF MANUFACTURER-SPONSORED**  
10 **CO-PAY 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 **INSURANCE 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 insurance  
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 such term in subsection  
8 (a) of the 1st section of the Clayton Act (15 U.S.C.  
9 12(a)), except that such term includes section 5 of  
10 the Federal Trade Commission Act (15 U.S.C. 45)  
11 to the extent such section 5 applies to unfair meth-  
12 ods of 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) which  
17 is licensed to engage in the business of insurance in  
18 a State and which is subject to State law which reg-  
19 ulates insurance (within the meaning of section  
20 514(b)(2) of the Employee Retirement Income Secu-  
21 rity Act of 1974 (29 U.S.C. 1144(b)(2))). Such term  
22 does not include a group health plan.

23 (3) HEALTH MAINTENANCE ORGANIZATION.—  
24 The term “health maintenance organization”  
25 means—

1 (A) a health maintenance organization (as  
2 defined in section 1301(a) of the Public Health  
3 Service Act (42 U.S.C. 300e(a));

4 (B) an organization recognized under State  
5 law as a health maintenance organization; or

6 (C) a similar organization regulated under  
7 State law for solvency in the same manner and  
8 to the same extent as such a health mainte-  
9 nance organization.

10 (4) MANUFACTURER.—The term “manufac-  
11 turer” means any person who is engaged in manu-  
12 facturing, preparing, propagating, compounding,  
13 processing, packaging, repackaging, or labeling of a  
14 prescription drug.

15 (5) PRESCRIPTION DRUG.—The term “prescrip-  
16 tion drug” means any human drug required by Fed-  
17 eral law or regulation to be dispensed only by a pre-  
18 scription, including finished dosage forms and active  
19 ingredients subject to section 503(b) of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).

21 (c) EFFECTIVE DATE.—This section shall not apply  
22 with respect to any conduct that occurs before the date  
23 of enactment of this Act.

1 **SEC. 351. BIOLOGICAL PRODUCT INNOVATION.**

2 Section 351(j) of the Public Health Service Act (42  
3 U.S.C. 262(j)) is amended—

4 (1) by striking “except that a product” and in-  
5 serting “except that—

6 “(1) a product”;

7 (2) by striking “Act.” and inserting “Act; and”;  
8 and

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

10 “(2) no requirement under such Act regarding  
11 an official compendium (as defined in section 201(j)  
12 of such Act), or other reference in such Act to an  
13 official compendium (as so defined), shall apply with  
14 respect to a biological product subject to regulation  
15 under this section.”.

16 **SEC. 352. BIOSIMILAR BIOLOGICAL PRODUCTS.**

17 (a) IN GENERAL.—Section 351(k) of the Public  
18 Health Service Act (42 U.S.C. 262(k)) is amended—

19 (1) in the subsection heading, by striking “OR  
20 INTERCHANGEABLE”;

21 (2) in paragraph (2)—

22 (A) by striking subparagraph (B);

23 (B) by redesignating clauses (ii) and (iii)  
24 of subparagraph (A) as subparagraphs (B) and  
25 (C), respectively, and adjusting the margins ac-  
26 cordingly;

1 (C) in subparagraph (A)—

2 (i) in clause (i), by redesignating sub-  
3 clauses (I) through (V) as clauses (i)  
4 through (v), respectively, and adjusting the  
5 margins accordingly;

6 (ii) in clause (i), as so redesignated by  
7 clause (i) of this subparagraph, by redesign-  
8 ating items (aa) through (cc) as sub-  
9 clauses (I) through (III), respectively, and  
10 adjusting the margins accordingly; and

11 (iii) by striking “(A) IN GENERAL”  
12 and all that follows through “An applica-  
13 tion submitted under this subsection shall  
14 include information” and inserting the fol-  
15 lowing:

16 “(A) IN GENERAL.—An application sub-  
17 mitted under this subsection shall include infor-  
18 mation”;

19 (D) in subparagraph (B), as so redesign-  
20 ated by subparagraph (B) of this paragraph,  
21 by striking “clause (i)(I)” and inserting “sub-  
22 paragraph (A)(i)”;

23 (E) in subparagraph (C), as so redesign-  
24 ated by subparagraph (B) of this paragraph,  
25 by redesignating subclauses (I) through (III) as

1 clauses (i) through (iii), respectively, and by ad-  
2 justing the margins accordingly;

3 (3) by amending paragraph (4) to read as fol-  
4 lows:

5 “(4) INTERCHANGEABILITY.—

6 “(A) IN GENERAL.—A biological product  
7 licensed under this subsection shall be deemed  
8 to be interchangeable with the reference prod-  
9 uct.

10 “(B) CONGRESSIONAL BRIEFING PRIOR TO  
11 CERTAIN STUDY REQUIREMENTS.—The Sec-  
12 retary may require the sponsor of an applica-  
13 tion submitted under this section to conduct a  
14 study to evaluate the risk, in terms of safety,  
15 purity, or potency, of alternating or switching  
16 between the use of the biological product that  
17 is the subject of the application and the ref-  
18 erence product, if, before requiring such a  
19 study, the Secretary first holds a private brief-  
20 ing with the chair and ranking member of the  
21 Committee on Health, Education, Labor, and  
22 Pensions of the Senate and the chair and the  
23 ranking member of the Committee on Energy  
24 and Commerce of the House of Representatives,  
25 to explain why such a study is necessary for the

1 biological product, what information the Sec-  
2 retary expects such a study to reveal, what al-  
3 ternatives to such study have been considered,  
4 and why those alternatives are not sufficient.”;  
5 (4) by striking paragraph (6);  
6 (5) in paragraph (8)(D)—

7 (A) in clause (i), by striking “class; and”  
8 and inserting “class.”;

9 (B) by striking clause (ii); and

10 (C) by striking “description of—” and all  
11 that follows through “criteria that the Sec-  
12 retary” and inserting “description of the cri-  
13 teria that the Secretary”; and

14 (6) in paragraph (9)(A)(iv), by striking “para-  
15 graph (6) or”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) Section 351(i)(3) of the Public Health Serv-  
18 ice Act (42 U.S.C. 262(i)(3)) is amended by striking  
19 “that is shown to meet the standards described in  
20 subsection (k)(4)” and inserting “licensed under  
21 subsection (k)”.

22 (2) Section 352A of the Public Health Service  
23 Act (42 U.S.C. 263–1) is amended by striking “and  
24 interchangeable biosimilar biological products” each  
25 place it appears.

1           (3) Section 744G(14) of the Federal Food,  
2       Drug, and Cosmetic Act (21 U.S.C. 379j–51(14)) is  
3       amended by striking “, including a supplement re-  
4       questing that the Secretary determine that the bio-  
5       similar biological product meets the standards for  
6       interchangeability described in section 351(k)(4) of  
7       the Public Health Service Act”.

8           (4) Section 505B(l) of the Federal Food, Drug,  
9       and Cosmetic Act (21 U.S.C. 355c(l)) is amended to  
10      read as follows:

11      “(l) BIOSIMILAR BIOLOGICAL PRODUCTS.—A biologi-  
12     cal product for which an application is submitted under  
13     section 351(k) of the Public Health Service Act shall be  
14     considered to have a new active ingredient for purposes  
15     of this section, except that a pediatric assessment shall  
16     not be required for a claimed indication in a relevant pedi-  
17     atric population if the assessment would involve—

18           “(1) a condition of use that has not been pre-  
19       viously approved for the reference product; or

20           “(2) a dosage form, strength, or route of ad-  
21       ministration that differs from that of the reference  
22       product.”.

23      (c) APPLICATION.—The amendment made by sub-  
24     section (a)(4) to section 351(k)(6) of the Public Health  
25     Service Act (42 U.S.C. 262(k)(6)) shall apply only with



1 respect to applications approved under section 351(k) of  
2 such Act on or after the date of enactment of this Act.  
3 Any period of exclusivity granted under section 351(k)(6)  
4 of such Act with respect to an application approved under  
5 such section 351(k) before the date of enactment of this  
6 Act shall apply in accordance with such section 351(k)(6),  
7 as in effect on the day before the date of enactment of  
8 this Act.

9 **SEC. 353. PROMPT APPROVAL OF DRUGS RELATED TO**  
10 **SAFETY INFORMATION.**

11 Section 505 of the Federal Food, Drug, and Cosmetic  
12 Act (21 U.S.C. 355) is amended by adding at the end the  
13 following:

14 “(aa) PROMPT APPROVAL OF DRUGS WHEN SAFETY  
15 INFORMATION IS ADDED TO LABELING.—

16 “(1) GENERAL RULE.—A drug for which an ap-  
17 plication has been submitted or approved under sub-  
18 section (b)(2) or (j) shall not be considered ineligible  
19 for approval under this section or misbranded under  
20 section 502 on the basis that the labeling of the  
21 drug omits safety information, including contra-  
22 indications, warnings, precautions, dosing, adminis-  
23 tration, or other information pertaining to safety,  
24 when the omitted safety information is protected by  
25 exclusivity under clause (iii) or (iv) of subsection

1 (j)(5)(F), clause (iii) or (iv) of subsection (c)(3)(E),  
2 or section 527(a), or by an extension of such exclu-  
3 sivity under section 505A or 505E.

4 “(2) LABELING.—Notwithstanding clauses (iii)  
5 and (iv) of subsection (j)(5)(F), clauses (iii) and (iv)  
6 of subsection (c)(3)(E), or section 527, the Sec-  
7 retary shall require that the labeling of a drug ap-  
8 proved pursuant to an application submitted under  
9 subsection (b)(2) or (j) that omits safety information  
10 described in paragraph (1) include a statement of  
11 any appropriate safety information that the Sec-  
12 retary considers necessary to assure safe use.

13 “(3) AVAILABILITY AND SCOPE OF EXCLU-  
14 SIVITY.—This subsection does not affect—

15 “(A) the availability or scope of exclusivity  
16 or an extension of exclusivity described in sub-  
17 paragraph (A) or (B) of section 505A(o)(3);

18 “(B) the question of the eligibility for ap-  
19 proval under this section of any application de-  
20 scribed in subsection (b)(2) or (j) that omits  
21 any other aspect of labeling protected by exclu-  
22 sivity under—

23 “(i) clause (iii) or (iv) of subsection  
24 (j)(5)(F);

1 “(ii) clause (iii) or (iv) of subsection  
 2 (c)(3)(E); or  
 3 “(iii) section 527(a); or  
 4 “(C) except as expressly provided in para-  
 5 graphs (1) and (2), the operation of this section  
 6 or section 527.”.

7 **SEC. 354. CONGRESSIONAL REVIEW OF THE FOOD AND**  
 8 **DRUG ADMINISTRATION RULEMAKING.**

9 (a) CONGRESSIONAL REVIEW.—Part I of title 5,  
 10 United States Code, is amended by inserting after chapter  
 11 8 the following:

12 **“CHAPTER 8a—CONGRESSIONAL REVIEW**  
 13 **OF FOOD AND DRUG ADMINISTRATION**  
 14 **RULEMAKING**

“Sec.

“810. Applicability.

“811. Congressional review.

“812. Congressional approval procedure for major rules.

“813. Congressional disapproval procedure for nonmajor rules.

“814. Definitions.

“815. Judicial review.

“816. Exemption for monetary policy.

“817. Effective date of certain rules.

“818. Regulatory cut-go requirement.

“819. Review of rules currently in effect.

15 **“§ 810. Applicability**

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

18 **“§ 811. Congressional review**

19 “(a)(1)(A) Before a rule may take effect, the Food  
 20 and Drug Administration shall satisfy the requirements

1 of section 818 and shall publish in the Federal Register  
2 a list of information on which the rule is based, including  
3 data, scientific and economic studies, and cost-benefit  
4 analyses, and identify how the public can access such in-  
5 formation online, and shall submit to each House of the  
6 Congress and to the Comptroller General a report con-  
7 taining—

8 “(i) a copy of the rule;

9 “(ii) a concise general statement relating to the  
10 rule;

11 “(iii) a classification of the rule as a major or  
12 nonmajor rule, including an explanation of the clas-  
13 sification specifically addressing each criteria for a  
14 major rule contained within sections 814(2)(A),  
15 814(2)(B), and 814(2)(C);

16 “(iv) a list of any other related regulatory ac-  
17 tions intended to implement the same statutory pro-  
18 vision or regulatory objective as well as the indi-  
19 vidual and aggregate economic effects of those ac-  
20 tions; and

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

22 “(B) On the date of the submission of the report  
23 under subparagraph (A), the Food and Drug Administra-  
24 tion shall submit to the Comptroller General and make  
25 available to each House of Congress—

1           “(i) a complete copy of the cost-benefit analysis  
2           of the rule, if any, including an analysis of any jobs  
3           added or lost, differentiating between public and pri-  
4           vate sector jobs;

5           “(ii) the Food and Drug Administration’s ac-  
6           tions pursuant to sections 603, 604, 605, 607, and  
7           609 of this title;

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

11          “(iv) any other relevant information or require-  
12          ments under any other Act and any relevant Execu-  
13          tive orders.

14          “(C) Upon receipt of a report submitted under sub-  
15          paragraph (A), each House shall provide copies of the re-  
16          port to the chairman and ranking member of each stand-  
17          ing committee with jurisdiction under the rules of the  
18          House of Representatives or the Senate to report a bill  
19          to amend the provision of law under which the rule is  
20          issued.

21          “(2)(A) The Comptroller General shall provide a re-  
22          port on each major rule to the committees of jurisdiction  
23          by the end of 15 calendar days after the submission or  
24          publication date. The report of the Comptroller General  
25          shall include an assessment of the Food and Drug Admin-

1   istration’s compliance with procedural steps required by  
2   paragraph (1)(B) and an assessment of whether the major  
3   rule imposes any new limits or mandates on private-sector  
4   activity.

5       “(B) The Food and Drug Administration shall co-  
6   operate with the Comptroller General by providing infor-  
7   mation relevant to the Comptroller General’s report under  
8   subparagraph (A).

9       “(3) A major rule relating to a report submitted  
10   under paragraph (1) shall take effect upon enactment of  
11   a joint resolution of approval described in section 812 or  
12   as provided for in the rule following enactment of a joint  
13   resolution of approval described in section 812, whichever  
14   is later.

15       “(4) A nonmajor rule shall take effect as provided  
16   by section 813 after submission to Congress under para-  
17   graph (1).

18       “(5) If a joint resolution of approval relating to a  
19   major rule is not enacted within the period provided in  
20   subsection (b)(2), then a joint resolution of approval relat-  
21   ing to the same rule may not be considered under this  
22   chapter in the same Congress by either the House of Rep-  
23   resentatives or the Senate.

1       “(b)(1) A major rule shall not take effect unless the  
2 Congress enacts a joint resolution of approval described  
3 under section 812.

4       “(2) If a joint resolution described in subsection (a)  
5 is not enacted into law by the end of 70 session days or  
6 legislative days, as applicable, beginning on the date on  
7 which the report referred to in section 811(a)(1)(A) is re-  
8 ceived by Congress (excluding days either House of Con-  
9 gress is adjourned for more than 3 days during a session  
10 of Congress), then the rule described in that resolution  
11 shall be deemed not to be approved and such rule shall  
12 not take effect.

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

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

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

24               “(B) necessary for the enforcement of criminal  
25 laws;

1           “(C) necessary for national security; or

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

4       “(3) An exercise by the President of the authority  
5       under this subsection shall have no effect on the proce-  
6       dures under section 812.

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

12           “(A) in the case of the Senate, 60 session days;  
13      or

14           “(B) in the case of the House of Representa-  
15      tives, 60 legislative days,

16      before the date the Congress is scheduled to adjourn a  
17      session of Congress through the date on which the same  
18      or succeeding Congress first convenes its next session, sec-  
19      tions 812 and 813 shall apply to such rule in the suc-  
20      ceeding session of Congress.

21       “(2)(A) In applying sections 812 and 813 for pur-  
22      poses of such additional review, a rule described under  
23      paragraph (1) shall be treated as though—

24           “(i) such rule were published in the Federal  
25      Register on—



1 “(I) in the case of the Senate, the 15th  
2 session day; or

3 “(II) in the case of the House of Rep-  
4 resentatives, the 15th legislative day,  
5 after the succeeding session of Congress first con-  
6 venes; and

7 “(ii) a report on such rule were submitted to  
8 Congress under subsection (a)(1) on such date.

9 “(B) Nothing in this paragraph shall be construed  
10 to affect the requirement under subsection (a)(1) that a  
11 report shall be submitted to Congress before a rule can  
12 take effect.

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

16 **“§ 812. Congressional approval procedure for major**  
17 **rules**

18 “(a)(1) For purposes of this section, the term ‘joint  
19 resolution’ means only a joint resolution addressing a re-  
20 port classifying a rule as major pursuant to section  
21 811(a)(1)(A)(iii) that—

22 “(A) bears no preamble;

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

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

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

6       “(2) After a House of Congress receives a report  
7       classifying a rule as major pursuant to section  
8       811(a)(1)(A)(iii), the majority leader of that House (or  
9       his or her respective designee) shall introduce (by request,  
10      if appropriate) a joint resolution described in paragraph  
11      (1)—

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

14           “(B) in the case of the Senate, within 3 session  
15      days.

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

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

23       “(c) In the Senate, if the committee or committees  
24      to which a joint resolution described in subsection (a) has  
25      been referred have not reported it at the end of 15 session

1 days after its introduction, such committee or committees  
2 shall be automatically discharged from further consider-  
3 ation of the resolution and it shall be placed on the cal-  
4 endar. A vote on final passage of the resolution shall be  
5 taken on or before the close of the 15th session day after  
6 the resolution is reported by the committee or committees  
7 to which it was referred, or after such committee or com-  
8 mittees have been discharged from further consideration  
9 of the resolution.

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

1 main the unfinished business of the Senate until disposed  
2 of.

3 “(2) In the Senate, debate on the joint resolution,  
4 and on all debatable motions and appeals in connection  
5 therewith, shall be limited to not more than 2 hours, which  
6 shall be divided equally between those favoring and those  
7 opposing the joint resolution. A motion to further limit  
8 debate is in order and not debatable. An amendment to,  
9 or a motion to postpone, or a motion to proceed to the  
10 consideration of other business, or a motion to recommit  
11 the joint resolution is not in order.

12 “(3) In the Senate, immediately following the conclu-  
13 sion of the debate on a joint resolution described in sub-  
14 section (a), and a single quorum call at the conclusion of  
15 the debate if requested in accordance with the rules of the  
16 Senate, the vote on final passage of the joint resolution  
17 shall occur.

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

22 “(e) In the House of Representatives, if any com-  
23 mittee to which a joint resolution described in subsection  
24 (a) has been referred has not reported it to the House  
25 at the end of 15 legislative days after its introduction,

1 such committee shall be discharged from further consider-  
2 ation of the joint resolution, and it shall be placed on the  
3 appropriate calendar. On the second and fourth Thursdays  
4 of each month it shall be in order at any time for the  
5 Speaker to recognize a Member who favors passage of a  
6 joint resolution that has appeared on the calendar for at  
7 least 5 legislative days to call up that joint resolution for  
8 immediate consideration in the House without intervention  
9 of any point of order. When so called up a joint resolution  
10 shall be considered as read and shall be debatable for 1  
11 hour equally divided and controlled by the proponent and  
12 an opponent, and the previous question shall be considered  
13 as ordered to its passage without intervening motion. It  
14 shall not be in order to reconsider the vote on passage.  
15 If a vote on final passage of the joint resolution has not  
16 been taken by the third Thursday on which the Speaker  
17 may recognize a Member under this subsection, such vote  
18 shall be taken on that day.

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

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

24 “(B) the procedure in the receiving House shall  
25 be the same as if no joint resolution had been re-

1       ceived from the other House until the vote on pas-  
2       sage, when the joint resolution received from the  
3       other House shall supplant the joint resolution of  
4       the receiving House.

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

8       “(g) If either House has not taken a vote on final  
9       passage of the joint resolution by the last day of the period  
10      described in section 811(b)(2), then such vote shall be  
11      taken on that day.

12      “(h) This section and section 813 are enacted by  
13      Congress—

14           “(1) as an exercise of the rulemaking power of  
15      the Senate and House of Representatives, respec-  
16      tively, and as such is deemed to be part of the rules  
17      of each House, respectively, but applicable only with  
18      respect to the procedure to be followed in that  
19      House in the case of a joint resolution described in  
20      subsection (a) and superseding other rules only  
21      where explicitly so; and

22           “(2) with full recognition of the Constitutional  
23      right of either House to change the rules (so far as  
24      they relate to the procedure of that House) at any

1       time, in the same manner and to the same extent as  
2       in the case of any other rule of that House.

3   **“§ 813. Congressional disapproval procedure for**  
4       **nonmajor rules**

5       “(a) For purposes of this section, the term ‘joint res-  
6   olution’ means only a joint resolution introduced in the  
7   period beginning on the date on which the report referred  
8   to in section 811(a)(1)(A) is received by Congress and  
9   ending 60 days thereafter (excluding days either House  
10   of Congress is adjourned for more than 3 days during a  
11   session of Congress), the matter after the resolving clause  
12   of which is as follows: ‘That Congress disapproves the  
13   nonmajor rule submitted by the \_\_\_\_\_ relating to  
14   \_\_\_\_\_, and such rule shall have no force or effect.’ (The  
15   blank spaces being appropriately filled in).

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

19       “(c) In the Senate, if the committee to which is re-  
20   ferred a joint resolution described in subsection (a) has  
21   not reported such joint resolution (or an identical joint  
22   resolution) at the end of 15 session days after the date  
23   of introduction of the joint resolution, such committee may  
24   be discharged from further consideration of such joint res-  
25   olution upon a petition supported in writing by 30 Mem-

1 bers of the Senate, and such joint resolution shall be  
2 placed on the calendar.

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

20       “(2) In the Senate, debate on the joint resolution,  
21 and on all debatable motions and appeals in connection  
22 therewith, shall be limited to not more than 10 hours,  
23 which shall be divided equally between those favoring and  
24 those opposing the joint resolution. A motion to further  
25 limit debate is in order and not debatable. An amendment



1 to, or a motion to postpone, or a motion to proceed to  
2 the consideration of other business, or a motion to recom-  
3 mit the joint resolution is not in order.

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

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

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

17 “(1) after the expiration of the 60 session days  
18 beginning with the applicable submission or publica-  
19 tion date; or

20 “(2) if the report under section 811(a)(1)(A)  
21 was submitted during the period referred to in sec-  
22 tion 811(d)(1), after the expiration of the 60 session  
23 days beginning on the 15th session day after the  
24 succeeding session of Congress first convenes.

1       “(f) If, before the passage by one House of a joint  
2 resolution of that House described in subsection (a), that  
3 House receives from the other House a joint resolution  
4 described in subsection (a), then the following procedures  
5 shall apply:

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

8           “(2) With respect to a joint resolution described  
9 in subsection (a) of the House receiving the joint  
10 resolution—

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

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

16 **“§ 814. Definitions**

17       “For purposes of this chapter:

18           “(1) The term ‘major rule’ means any rule of  
19 the Food and Drug Administration, including an in-  
20 terim final rule, that the Administrator of the Office  
21 of Information and Regulatory Affairs of the Office  
22 of Management and Budget finds has resulted in or  
23 is likely to result in—

1           “(A) an annual cost on the economy of  
2           \$100,000,000 or more, adjusted annually for  
3           inflation;

4           “(B) a major increase in costs or prices for  
5           consumers, individual industries, Federal,  
6           State, or local government agencies, or geo-  
7           graphic regions; or

8           “(C) significant adverse effects on competi-  
9           tion, employment, investment, productivity, in-  
10          novation, or on the ability of United States-  
11          based enterprises to compete with foreign-based  
12          enterprises in domestic and export markets.

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

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

19                 “(A) any rule of particular applicability;

20                 “(B) any rule relating to agency manage-  
21                 ment or personnel; or

22                 “(C) any rule of agency organization, pro-  
23                 cedure, or practice that does not substantially  
24                 affect the rights or obligations of non-agency  
25                 parties.

1           “(4) The term ‘submission date or publication  
2           date’, except as otherwise provided in this chapter,  
3           means—

4                   “(A) in the case of a major rule, the date  
5                   on which the Congress receives the report sub-  
6                   mitted under section 811(a)(1); and

7                   “(B) in the case of a nonmajor rule, the  
8                   later of—

9                           “(i) the date on which the Congress  
10                          receives the report submitted under section  
11                          811(a)(1); and

12                           “(ii) the date on which the nonmajor  
13                          rule is published in the Federal Register, if  
14                          so published.

15   **“§ 815. Judicial review**

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

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

22           “(c) The enactment of a joint resolution of approval  
23           under section 812 shall not be interpreted to serve as a  
24           grant or modification of statutory authority by Congress  
25           for the promulgation of a rule, shall not extinguish or af-

1   fect any claim, whether substantive or procedural, against  
2   any alleged defect in a rule, and shall not form part of  
3   the record before the court in any judicial proceeding con-  
4   cerning a rule except for purposes of determining whether  
5   or not the rule is in effect.

6   **“§ 816. Exemption for monetary policy**

7         “Nothing in this chapter shall apply to rules that con-  
8   cern monetary policy proposed or implemented by the  
9   Board of Governors of the Federal Reserve System or the  
10  Federal Open Market Committee.

11  **“§ 817. Effective date of certain rules**

12         “Notwithstanding section 811, any rule other than a  
13  major rule which the Food and Drug Administration for  
14  good cause finds (and incorporates the finding and a brief  
15  statement of reasons therefore in the rule issued) that no-  
16  tice and public procedure thereon are impracticable, un-  
17  necessary, or contrary to the public interest, shall take ef-  
18  fect at such time as the Food and Drug Administration  
19  determines.

20  **“§ 818. Regulatory cut-go requirement**

21         “In making any new rule, the Food and Drug Admin-  
22  istration shall identify a rule or rules that may be amend-  
23  ed or repealed to completely offset any annual costs of  
24  the new rule to the United States economy. Before the  
25  new rule may take effect, the Food and Drug Administra-

tion shall make each such repeal or amendment. In making such an amendment or repeal, the Food and Drug Administration shall comply with the requirements of subchapter II of chapter 5, but the Food and Drug Administration may consolidate proceedings under subchapter II (of chapter 5) with proceedings on the new rule.

**“§ 819. Review of rules currently in effect**

“(a) ANNUAL REVIEW.—Beginning on the date that is 6 months after the date of enactment of this section and annually thereafter for the 9 years following, the Food and Drug Administration shall designate not less than 10 percent of eligible rules made by the Food and Drug Administration for review, and shall submit a report including each such eligible rule in the same manner as a report under section 811(a)(1). Section 811, section 812, and section 813 shall apply to each such rule, subject to subsection (c) of this section. No eligible rule previously designated may be designated again.

“(b) SUNSET FOR ELIGIBLE RULES NOT EXTENDED.—Beginning after the date that is 10 years after the date of enactment of this section, if Congress has not enacted a joint resolution of approval for that eligible rule, that eligible rule shall not continue in effect.

1       “(c) CONSOLIDATION; SEVERABILITY.—In applying  
2 sections 811, 812, and 813 to eligible rules under this sec-  
3 tion, the following shall apply:

4           “(1) The words ‘take effect’ shall be read as  
5 ‘continue in effect’.

6           “(2) Except as provided in paragraph (3), a  
7 single joint resolution of approval shall apply to all  
8 eligible rules in a report designated for a year, and  
9 the matter after the resolving clause of that joint  
10 resolution is as follows: ‘That Congress approves the  
11 rules submitted by the \_\_\_\_ for the year \_\_\_\_.’ (The  
12 blank spaces being appropriately filled in).

13           “(3) It shall be in order to consider any amend-  
14 ment that provides for specific conditions on which  
15 the approval of a particular eligible rule included in  
16 the joint resolution is contingent.

17           “(4) A member of either House may move that  
18 a separate joint resolution be required for a specified  
19 rule.

20       “(d) DEFINITION.—In this section, the term ‘eligible  
21 rule’ means a rule that is in effect as of the date of enact-  
22 ment of this section.”.

23       (b) BUDGETARY EFFECTS OF RULES SUBJECT TO  
24 SECTION 922 OF TITLE 5, UNITED STATES CODE.—Sec-  
25 tion 257(b)(2) of the Balanced Budget and Emergency

1 Deficit Control Act of 1985 is amended by adding at the  
2 end the following new subparagraph:

3           “(E) BUDGETARY EFFECTS OF RULES  
4           SUBJECT TO SECTION 922 OF TITLE 5, UNITED  
5           STATES CODE.—Any rules subject to the con-  
6           gressional approval procedure set forth in sec-  
7           tion 922 of chapter 8 of title 5, United States  
8           Code, affecting budget authority, outlays, or re-  
9           ceipts shall be assumed to be effective unless it  
10          is not approved in accordance with such sec-  
11          tion.”.

12          (c) GOVERNMENT ACCOUNTABILITY OFFICE STUDY  
13 OF RULES.—

14           (1) IN GENERAL.—The Comptroller General of  
15          the United States shall conduct a study to deter-  
16          mine, as of the date of the enactment of this Act—

17           (A) how many rules (as such term is de-  
18           fined in section 814 of title 5, United States  
19           Code) of the Food and Drug Administration  
20           were in effect;

21           (B) how many major rules (as such term  
22           is defined in section 814 of title 5, United  
23           States Code) of the Food and Drug Administra-  
24           tion were in effect; and



1 (C) the total estimated economic cost im-  
2 posed by all such rules.

3 (2) REPORT.—Not later than 1 year after the  
4 date of the enactment of this Act, the Comptroller  
5 General of the United States shall submit a report  
6 to Congress that contains the findings of the study  
7 conducted under paragraph (1).

8 (d) EFFECTIVE DATE.—Subsections (a) and (b), and  
9 the amendments made by such sections, shall take effect  
10 beginning on the date that is 1 year after the date of en-  
11 actment of this Act.

12 **SEC. 355. GOVERNMENT ACCOUNTABILITY OFFICE STUDY**  
13 **OF RULES.**

14 (a) IN GENERAL.—The Comptroller General of the  
15 United States shall conduct a study to determine, as of  
16 the date of the enactment of this Act—

17 (1) how many rules (as such term is defined in  
18 section 804 of title 5, United States Code) were in  
19 effect;

20 (2) how many major rules (as such term is de-  
21 fined in section 804 of title 5, United States Code)  
22 were in effect; and

23 (3) the total estimated economic cost imposed  
24 by all such rules.

1 (b) REPORT.—Not later than 1 year after the date  
2 of the enactment of this Act, the Comptroller General of  
3 the United States shall submit a report to Congress that  
4 contains the findings of the study conducted under sub-  
5 section (a).

6 **Subtitle D—Prescription Drug and**  
7 **Pharmacy Benefit Manager**  
8 **Transparency**

9 **SEC. 361. PATENT DISCLOSURE REQUIREMENTS.**

10 (a) IN GENERAL.—Section 351 of the Public Health  
11 Service Act (42 U.S.C. 262) is amended by adding at the  
12 end the following:

13 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT  
14 TO PATENTS.—

15 “(1) APPROVED APPLICATION HOLDER LISTING  
16 REQUIREMENTS.—

17 “(A) IN GENERAL.—Beginning on the date  
18 of enactment of this subsection, within 30 days  
19 of approval of an application under subsection  
20 (a) or (k), the holder of such approved applica-  
21 tion shall submit to the Secretary a list of each  
22 patent required to be disclosed (as described in  
23 paragraph (3)).

24 “(B) PREVIOUSLY APPROVED OR LI-  
25 CENSED BIOLOGICAL PRODUCTS.—

1                   “(i) PRODUCTS APPROVED UNDER  
2                   SECTION 351 OF THE PHSA.—Not later  
3                   than 30 days after the date of enactment  
4                   of the Fair Care Act of 2024, the holder  
5                   of a biological product license that was ap-  
6                   proved under subsection (a) or (k) before  
7                   the date of enactment of such Act shall  
8                   submit to the Secretary a list of each pat-  
9                   ent required to be disclosed (as described  
10                  in paragraph (3)).

11                  “(ii) PRODUCTS APPROVED UNDER  
12                  SECTION 505 OF THE FFDCA.—Not later  
13                  than 30 days after March 23, 2021, the  
14                  holder of an approved application for a bio-  
15                  logical product under section 505 of the  
16                  Federal Food, Drug, and Cosmetic Act  
17                  that is deemed to be a license for the bio-  
18                  logical product under this section on  
19                  March 23, 2021, shall submit a list of each  
20                  patent required to be disclosed (as de-  
21                  scribed in paragraph (3)).

22                  “(C) UPDATES.—The holder of a biological  
23                  product license approved under subsection (a)  
24                  or (k) shall submit to the Secretary a list that  
25                  includes—

1 “(i) any patent first required to be  
2 disclosed (as described in paragraph (3))  
3 after the submission under subparagraph  
4 (A) or (B), as applicable, within 30 days of  
5 the earlier of—

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

9 “(II) the date of approval of a  
10 supplemental application for the bio-  
11 logical product; and

12 “(ii) any patent, or any claim with re-  
13 spect to a patent, included on the list pur-  
14 suant to this paragraph with respect to the  
15 biological product subsequently determined  
16 to be invalid or unenforceable, within 30  
17 days of a determination of patent inva-  
18 lidity.

19 “(2) PUBLICATION OF INFORMATION.—

20 “(A) IN GENERAL.—Within 1 year of the  
21 date of enactment of the Fair Care Act of  
22 2024, the Secretary shall publish and make  
23 available to the public a single, easily search-  
24 able, list that includes—

1 “(i) the official and proprietary name  
2 of each biological product licensed under  
3 subsection (a) or (k), and of each biological  
4 product application approved under section  
5 505 of the Federal Food, Drug, and Cos-  
6 metic Act and deemed to be a license for  
7 the biological product under this section on  
8 March 23, 2021;

9 “(ii) with respect to each biological  
10 product described in clause (i), each patent  
11 submitted in accordance with paragraph  
12 (1);

13 “(iii) the date of licensure and appli-  
14 cation number for each such biological  
15 product;

16 “(iv) the marketing status, dosage  
17 form, route of administration, strength,  
18 and, if applicable, reference product, for  
19 each such biological product;

20 “(v) the licensure status for each such  
21 biological product, including whether the li-  
22 cense at the time of listing is approved,  
23 withdrawn, or revoked;

24 “(vi) any period of any exclusivity  
25 under subsection (k)(7)(A) or subsection

1 (k)(7)(B) of this section or section 527 of  
2 the Federal Food, Drug, and Cosmetic  
3 Act, and any extension of such period in  
4 accordance with subsection (m) of this sec-  
5 tion with respect to each such biological  
6 product, and the date on which such exclu-  
7 sivity expires;

8 “(vii) information regarding any de-  
9 termination related to biosimilarity or  
10 interchangeability for each such biological  
11 product; and

12 “(viii) information regarding approved  
13 indications for each such biological prod-  
14 uct, in such manner as the Secretary de-  
15 termines appropriate.

16 “(B) UPDATES.—Every 30 days after the  
17 publication of the first list under subparagraph  
18 (A), the Secretary shall revise the list to in-  
19 clude—

20 “(i)(I) each biological product licensed  
21 under subsection (a) or (k) during the 30-  
22 day period; and

23 “(II) with respect to each biological  
24 product described in subclause (I), the in-

1 formation described in clauses (i) through  
2 (viii) of subparagraph (A); and

3 “(ii) any updates to information pre-  
4 viously published in accordance with sub-  
5 paragraph (A).

6 “(3) PATENTS REQUIRED TO BE DISCLOSED.—

7 In this section, a ‘patent required to be disclosed’ is  
8 any patent for which the holder of a biological prod-  
9 uct license approved under subsection (a) or (k), or  
10 a biological product application approved under sec-  
11 tion 505 of the Federal Food, Drug, and Cosmetic  
12 Act and deemed to be a license for a biological prod-  
13 uct under this section on March 23, 2021, believes  
14 a claim of patent infringement could reasonably be  
15 asserted by the holder, or by a patent owner that  
16 has granted an exclusive license to the holder with  
17 respect to the biological product that is the subject  
18 of such license, if a person not licensed by the holder  
19 engaged in the making, using, offering to sell, sell-  
20 ing, or importing into the United States of the bio-  
21 logical product that is the subject of such license.”.

22 (b) DISCLOSURE OF PATENTS.—Section  
23 351(l)(3)(A)(i) of the Public Health Service Act (42  
24 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included

1 in the list provided by the reference product sponsor under  
2 subsection (o)(1)” after “a list of patents”.

3 (c) RESTRICTION ON CLAIMS OF PATENT INFRINGE-  
4 MENT.—Section 271(e) of title 35, United States Code,  
5 is amended by adding at the end the following:

6 “(7) The owner of a patent that should have  
7 been included in the list described in section  
8 351(o)(1) of the Public Health Service Act (42  
9 U.S.C. 262(o)(1)), including any updates required  
10 under subparagraph (C) of that section, but was not  
11 timely included in such list, may not bring an action  
12 under this section for infringement of the patent.”.

13 (d) REGULATIONS.—The Secretary of Health and  
14 Human Services may promulgate regulations to carry out  
15 subsection (o) of section 351 of the Public Health Service  
16 Act (42 U.S.C. 262), as added by subsection (a).

17 (e) RULE OF CONSTRUCTION.—Nothing in this Act,  
18 including an amendment made by this Act, shall be con-  
19 strued to require or allow the Secretary of Health and  
20 Human Services to delay the licensing of a biological prod-  
21 uct under section 351 of the Public Health Service Act  
22 (42 U.S.C. 262).



1 **SEC. 362. REQUIREMENTS WITH RESPECT TO PRESCRIP-**  
2 **TION DRUG BENEFITS.**

3 (a) IN GENERAL.—Subpart II of part A of title  
4 XXVII of the Public Health Service Act (42 U.S.C.  
5 300gg–11 et seq.) is amended by adding at the end the  
6 following:

7 **“SEC. 2729A. REQUIREMENTS WITH RESPECT TO PRESCRIP-**  
8 **TION DRUG BENEFITS.**

9 “A group health plan or a health insurance issuer of-  
10 fering group or individual health insurance coverage shall  
11 not, and shall ensure that any entity that provides phar-  
12 macy benefits management services under a contract with  
13 any such health plan or health insurance coverage does  
14 not, receive from a drug manufacturer a reduction in price  
15 or other remuneration with respect to any prescription  
16 drug received by an enrollee in the plan or coverage and  
17 covered by the plan or coverage, unless—

18 “(1) any such reduction in price is reflected at  
19 the point of sale to the enrollee; and

20 “(2) any such other remuneration is a flat fee-  
21 based service fee that a manufacturer of prescription  
22 drugs pays to a pharmacy benefit manager for serv-  
23 ices rendered to the manufacturer that relate to ar-  
24 rangements by the pharmacy benefit manager to  
25 provide pharmacy benefit management services to a  
26 health plan or health insurance issuer, if certain

1 conditions established by the Secretary are met, in-  
 2 cluding requirements that the fees are transparent  
 3 to the health plan or health insurance issuer.”.

4 (b) EFFECTIVE DATE.—Section 2729A of the Public  
 5 Health Service Act, as added by subsection (a), shall take  
 6 effect on January 1, 2025.

7 **SEC. 363. PBM TRANSPARENCY AND ELIMINATION OF DIR**  
 8 **FEES.**

9 (a) PROHIBITING MEDICARE PDP SPONSORS AND  
 10 MA–PD ORGANIZATIONS FROM RETROACTIVELY REDUC-  
 11 ING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHAR-  
 12 MACIES.—

13 (1) IN GENERAL.—Section 1860D–12(b)(4)(A)  
 14 of the Social Security Act (42 U.S.C. 1395w–  
 15 112(b)(4)(A)) is amended by adding at the end the  
 16 following new clause:

17 “(iv) PROHIBITING RETROACTIVE RE-  
 18 DUCTIONS IN PAYMENTS ON CLEAN  
 19 CLAIMS.—Each contract entered into with  
 20 a PDP sponsor under this part with re-  
 21 spect to a prescription drug plan offered  
 22 by such sponsor shall provide that after  
 23 the date of receipt of a clean claim sub-  
 24 mitted by a pharmacy, the PDP sponsor  
 25 (or an agent of the PDP sponsor) may not

1 retroactively reduce payment on such claim  
2 directly or indirectly through aggregated  
3 effective rate or otherwise except in the  
4 case such claim is found to not be a clean  
5 claim (such as in the case of a claim lack-  
6 ing required substantiating documentation)  
7 during the course of a routine audit as  
8 permitted pursuant to written agreement  
9 between the PDP sponsor (or such an  
10 agent) and such pharmacy. The previous  
11 sentence shall not prohibit any retroactive  
12 increase in payment to a pharmacy pursu-  
13 ant to a written agreement between a PDP  
14 sponsor (or an agent of such sponsor) and  
15 such pharmacy.”.

16 (2) EFFECTIVE DATE.—The amendment made  
17 by subsection (a) shall apply with respect to con-  
18 tracts entered into on or after January 1, 2025.

19 (b) ELIMINATION OF DIR FEES.—

20 (1) PHARMACY BENEFITS MANAGER STAND-  
21 ARDS UNDER THE MEDICARE PROGRAM FOR PRE-  
22 SCRIPTIION DRUG PLANS AND MA–PD PLANS.—

23 (A) IN GENERAL.—Section 1860D–12(b)  
24 of the Social Security Act (42 U.S.C. 1395w–

1           112(b)) is amended by adding at the end the  
2           following new paragraph:

3           “(7) PHARMACY BENEFITS MANAGER TRANS-  
4           PARENCY REQUIREMENTS.—Each contract entered  
5           into with a PDP sponsor under this part with re-  
6           spect to a prescription drug plan offered by such  
7           sponsor or with an MA organization offering an  
8           MA–PD plan under part C shall provide that the  
9           sponsor or organization, respectively, may not enter  
10          into a contract with any pharmacy benefits manager  
11          (referred to in this paragraph as a ‘PBM’) to man-  
12          age the prescription drug coverage provided under  
13          such plan, or to control the costs of the prescription  
14          drug coverage under such plan, unless the PBM ad-  
15          heres to the following criteria when handling person-  
16          ally identifiable utilization and claims data or other  
17          sensitive patient data:

18                 “(A) The PBM may not transmit any per-  
19                 sonally identifiable utilization, protected health  
20                 information, or claims data, with respect to a  
21                 plan enrollee, to a pharmacy owned by a PBM  
22                 if the plan enrollee has not voluntarily elected  
23                 in writing or via secure electronic means to fill  
24                 that particular prescription at the PBM-owned  
25                 pharmacy.

1           “(B) The PBM may not require that a  
2           plan enrollee use a retail pharmacy, mail order  
3           pharmacy, specialty pharmacy, or other phar-  
4           macy entity providing pharmacy services in  
5           which the PBM has an ownership interest or  
6           that has an ownership interest in the PBM, or  
7           provide an incentive to a plan enrollee to en-  
8           courage the enrollee to use a retail pharmacy,  
9           mail order pharmacy, specialty pharmacy, or  
10          other pharmacy entity providing pharmacy serv-  
11          ices in which the PBM has an ownership inter-  
12          est or that has an ownership interest in the  
13          PBM, if the incentive is applicable only to such  
14          pharmacies.”.

15                 (B) REGULAR UPDATE OF PRESCRIPTION  
16          DRUG PRICING STANDARD.—Paragraph (6) of  
17          section 1860D–12(b) of the Social Security Act  
18          (42 U.S.C. 1395w–112(b)) is amended to read  
19          as follows:

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

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

1 (B)) of pharmacies based on the cost of a drug,  
2 each contract entered into with such sponsor  
3 under this part (or organization under part C)  
4 with respect to the plan shall provide that the  
5 sponsor (or organization) shall—

6 “(i) update such standard not less fre-  
7 quently than once every 7 days, beginning  
8 with an initial update on January 1 of  
9 each year, to accurately reflect the market  
10 price of acquiring the drug;

11 “(ii) disclose to applicable pharmacies  
12 and the contracting entities of such phar-  
13 macies the sources used for making any  
14 such update immediately without require-  
15 ment of request;

16 “(iii) if the source for such a standard  
17 for reimbursement is not publicly available,  
18 disclose to the applicable pharmacies and  
19 the respective contracting entities of such  
20 pharmacies all individual drug prices to be  
21 so updated in advance of the use of such  
22 prices for the reimbursement of claims;

23 “(iv) establish a process to appeal, in-  
24 vestigate, and resolve disputes regarding  
25 individual drug prices that are less than

1 the pharmacy acquisition price for such  
2 drug, which must be adjudicated within 7  
3 days of the pharmacy filing its appeal; and

4 “(v) provide all such pricing data in  
5 an .xml spreadsheet format or a com-  
6 parable easily accessible and complete  
7 spreadsheet format.

8 “(B) PRESCRIPTION DRUG PRICING  
9 STANDARD DEFINED.—For purposes of sub-  
10 paragraph (A), a standard for reimbursement  
11 of a pharmacy is any methodology or formula  
12 for varying the pricing of a drug or drugs dur-  
13 ing the term of the pharmacy reimbursement  
14 contract that is based on the cost of the drug  
15 involved, including drug pricing references and  
16 amounts that are based upon average wholesale  
17 price, wholesale average cost, average manufac-  
18 turer price, average sales price, maximum al-  
19 lowable cost (MAC), or other costs, whether  
20 publicly available or not.”.

21 (C) EFFECTIVE DATE.—The amendments  
22 made by this section shall apply to plan years  
23 beginning on or after January 1, 2025.

24 (2) REGULAR UPDATE OF PRESCRIPTION DRUG  
25 PRICING STANDARD UNDER TRICARE RETAIL PHAR-

1       MACY PROGRAM.—Section 1074g(d) of title 10,  
2       United States Code, is amended by adding at the  
3       end the following new paragraph:

4       “(3) To the extent practicable, with respect to the  
5       TRICARE retail pharmacy program described in sub-  
6       section (a)(2)(E)(ii), the Secretary shall ensure that a con-  
7       tract entered into with a TRICARE managed care support  
8       contractor includes requirements described in section  
9       1860D–12(b)(6) of the Social Security Act (42 U.S.C.  
10      1395w–112(b)(6)) to ensure the provision of information  
11      regarding the pricing standard for prescription drugs.”.

12               (3) PRESCRIPTION DRUG TRANSPARENCY IN  
13      THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-  
14      GRAM.—

15               (A) IN GENERAL.—Section 8902 of title 5,  
16      United States Code, is amended by adding at  
17      the end the following new subsections:

18      “(p) A contract may not be made or a plan approved  
19      under this chapter under which a carrier has an agree-  
20      ment with a pharmacy benefits manager (in this sub-  
21      section referred to as a ‘PBM’) to manage prescription  
22      drug coverage or to control the costs of the prescription  
23      drug coverage unless the carrier and PBM adhere to the  
24      following criteria:



1           “(1) The PBM may not transmit any personally  
2           identifiable utilization, protected health information,  
3           or claims data with respect to an individual enrolled  
4           under such contract or plan to a pharmacy owned by  
5           the PBM if the individual has not voluntarily elected  
6           in writing or via secure electronic means to fill that  
7           particular prescription at such a pharmacy.

8           “(2) The PBM may not require that an indi-  
9           vidual enrolled under such contract or plan use a re-  
10          tail pharmacy, mail order pharmacy, specialty phar-  
11          macy, or other pharmacy entity providing pharmacy  
12          services in which the PBM has an ownership interest  
13          or that has an ownership interest in the PBM or  
14          provide an incentive to a plan enrollee to encourage  
15          the enrollee to use a retail pharmacy, mail order  
16          pharmacy, specialty pharmacy, or other pharmacy  
17          entity providing pharmacy services in which the  
18          PBM has an ownership interest or that has an own-  
19          ership interest in the PBM, if the incentive is appli-  
20          cable only to such pharmacies.

21          “(q)(1) If a contract made or plan approved under  
22          this chapter provides for a standard for reimbursement  
23          (as described in paragraph (2)) with respect to a prescrip-  
24          tion drug plan, such contract or plan shall provide that  
25          the applicable carrier—

1           “(A) update such standard not less frequently  
2           than once every 7 days, beginning with an initial up-  
3           date on January 1 of each year, to accurately reflect  
4           the market price of acquiring the drug;

5           “(B) disclose to applicable pharmacies and the  
6           contracting entities of such pharmacies the sources  
7           used for making any such update immediately with-  
8           out requirement of request;

9           “(C) if the source for such a standard for reim-  
10          bursement is not publicly available, disclose to the  
11          applicable pharmacies and contracting entities of  
12          such pharmacies all individual drug prices to be so  
13          updated in advance of the use of such prices for the  
14          reimbursement of claims;

15          “(D) establish a process to appeal, investigate,  
16          and resolve disputes regarding individual drug prices  
17          that are less than the pharmacy acquisition price for  
18          such drug, which must be adjudicated within 7 days  
19          of the pharmacy filing its appeal; and

20          “(E) provide all such pricing data in an .xml  
21          spreadsheet format or a comparable easily accessible  
22          and complete spreadsheet format.

23          “(2) For purposes of paragraph (1), a standard for  
24          reimbursement of a pharmacy is any methodology or for-  
25          mula for varying the pricing of a drug or drugs during

1 the term of the pharmacy reimbursement contract that is  
 2 based on the cost of the drug involved, including drug pric-  
 3 ing references and amounts that are based upon average  
 4 wholesale price, wholesale average cost, average manufac-  
 5 turer price, average sales price, maximum allowable cost,  
 6 or other costs, whether publicly available or not.”.

7 (B) APPLICATION.—The amendment made  
 8 by subparagraph (A) shall apply to any contract  
 9 entered into under section 8902 of title 5,  
 10 United States Code, on or after the date of en-  
 11 actment of this section.

12 **SEC. 364. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**  
 13 **EFIT MANAGER SERVICES.**

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

18 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**  
 19 **BENEFIT MANAGER SERVICES.**

20 “(a) IN GENERAL.—A group health plan or health  
 21 insurance issuer offering group health insurance coverage  
 22 or an entity or subsidiary providing pharmacy benefits  
 23 management services shall not enter into a contract with  
 24 a drug manufacturer, distributor, wholesaler, subcon-  
 25 tractor, rebate aggregator, or any associated third party

1 that limits the disclosure of information to plan sponsors  
2 in such a manner that prevents the plan or coverage, or  
3 an entity or subsidiary providing pharmacy benefits man-  
4 agement services on behalf of a plan or coverage from  
5 making the reports described in subsection (b).

6 “(b) REPORTS TO GROUP PLAN SPONSORS.—

7 “(1) IN GENERAL.—Beginning with the first  
8 plan year that begins after the date of enactment of  
9 the Fair Care Act of 2024, not less frequently than  
10 once every 6 months, a health insurance issuer offer-  
11 ing group health insurance coverage or an entity  
12 providing pharmacy benefits management services  
13 on behalf of a group health plan shall submit to the  
14 plan sponsor (as defined in section 3(16)(B) of the  
15 Employee Retirement Income Security Act of 1974)  
16 of such group health plan or health insurance cov-  
17 erage a report in accordance with this subsection  
18 and make such report available to the plan sponsor  
19 in a machine-readable format. Each such report  
20 shall include, with respect to the applicable group  
21 health plan or health insurance coverage—

22 “(A) information collected from drug man-  
23 ufacturers by such issuer or entity on the total  
24 amount of copayment assistance dollars paid, or  
25 copayment cards applied, that were funded by

1 the drug manufacturer with respect to the en-  
2 rollees in such plan or coverage;

3 “(B) a list of each covered drug dispensed  
4 during the reporting period, including, with re-  
5 spect to each such drug during the reporting  
6 period—

7 “(i) the brand name, chemical entity,  
8 and National Drug Code;

9 “(ii) the number of enrollees for  
10 whom the drug was filled during the plan  
11 year, the total number of prescription fills  
12 for the drug (including original prescrip-  
13 tions and refills), and the total number of  
14 dosage units of the drug dispensed across  
15 the plan year, including whether the dis-  
16 pensing channel was by retail, mail order,  
17 or specialty pharmacy;

18 “(iii) the wholesale acquisition cost,  
19 listed as cost per days supply and cost per  
20 pill, or in the case of a drug in another  
21 form, per dose;

22 “(iv) the total out-of-pocket spending  
23 by enrollees on such drug, including en-  
24 rollee spending through copayments, coin-  
25 surance, and deductibles; and

1 “(v) for any drug for which gross  
2 spending of the group health plan or  
3 health insurance coverage exceeded  
4 \$10,000 during the reporting period—

5 “(I) a list of all other available  
6 drugs in the same therapeutic cat-  
7 egory or class, including brand name  
8 drugs and biological products and ge-  
9 neric drugs or biosimilar biological  
10 products that are in the same thera-  
11 peutic category or class; and

12 “(II) the rationale for preferred  
13 formulary placement of a particular  
14 drug or drugs in that therapeutic cat-  
15 egory or class;

16 “(C) a list of each therapeutic category or  
17 class of drugs that were dispensed under the  
18 health plan or health insurance coverage during  
19 the reporting period, and, with respect to each  
20 such therapeutic category or class of drugs,  
21 during the reporting period—

22 “(i) total gross spending by the plan,  
23 before manufacturer rebates, fees, or other  
24 manufacturer remuneration;

1           “(ii) the number of enrollees who  
2           filled a prescription for a drug in that cat-  
3           egory or class;

4           “(iii) if applicable to that category or  
5           class, a description of the formulary tiers  
6           and utilization mechanisms (such as prior  
7           authorization or step therapy) employed  
8           for drugs in that category or class;

9           “(iv) the total out-of-pocket spending  
10          by enrollees, including enrollee spending  
11          through copayments, coinsurance, and  
12          deductibles; and

13          “(v) for each therapeutic category or  
14          class under which 3 or more drugs are in-  
15          cluded on the formulary of such plan or  
16          coverage—

17               “(I) the amount received, or ex-  
18               pected to be received, from drug man-  
19               ufacturers in rebates, fees, alternative  
20               discounts, or other remuneration—

21                       “(aa) to be paid by drug  
22                       manufacturers for claims in-  
23                       curred during the reporting pe-  
24                       riod; or

1                   “(bb) that is related to utili-  
2                   zation of drugs, in such thera-  
3                   peutic category or class;

4                   “(II) the total net spending, after  
5                   deducting rebates, price concessions,  
6                   alternative discounts or other remu-  
7                   neration from drug manufacturers, by  
8                   the health plan or health insurance  
9                   coverage on that category or class of  
10                  drugs; and

11                  “(III) the net price per course of  
12                  treatment or 30-day supply incurred  
13                  by the health plan or health insurance  
14                  coverage and its enrollees, after man-  
15                  ufacturer rebates, fees, and other re-  
16                  muneration for drugs dispensed within  
17                  such therapeutic category or class  
18                  during the reporting period;

19                  “(D) total gross spending on prescription  
20                  drugs by the plan or coverage during the re-  
21                  porting period, before rebates and other manu-  
22                  facturer fees or remuneration;

23                  “(E) total amount received, or expected to  
24                  be received, by the health plan or health insur-  
25                  ance coverage in drug manufacturer rebates,



1 fees, alternative discounts, and all other remuneration received from the manufacturer or any  
2 third party, other than the plan sponsor, related to utilization of drug or drug spending  
3 under that health plan or health insurance coverage during the reporting period;  
4  
5

6 “(F) the total net spending on prescription  
7 drugs by the health plan or health insurance  
8 coverage during the reporting period; and  
9

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

16 “(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of  
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1 such information according to such privacy regula-  
2 tions.

3 “(3) DISCLOSURE AND REDISCLOSURE.—

4 “(A) LIMITATION TO BUSINESS ASSOCI-  
5 ATES.—A group health plan receiving a report  
6 under paragraph (1) may disclose such informa-  
7 tion only to business associates of such plan as  
8 defined in section 160.103 of title 45, Code of  
9 Federal Regulations (or successor regulations).

10 “(B) CLARIFICATION REGARDING PUBLIC  
11 DISCLOSURE OF INFORMATION.—Nothing in  
12 this section prevents a health insurance issuer  
13 offering group health insurance coverage or an  
14 entity providing pharmacy benefits management  
15 services on behalf of a group health plan from  
16 placing reasonable restrictions on the public dis-  
17 closure of the information contained in a report  
18 described in paragraph (1), except that such  
19 issuer or entity may not restrict disclosure of  
20 such report to governmental agencies pursuant  
21 to an investigation or enforcement action.

22 “(C) LIMITED FORM OF REPORT.—The  
23 Secretary shall define through rulemaking a  
24 limited form of the report under paragraph (1)  
25 required of plan sponsors who are drug manu-

1           facturers, drug wholesalers, or other direct par-  
2           ticipants in the drug supply chain, in order to  
3           prevent anti-competitive behavior.

4           “(c) LIMITATIONS ON SPREAD PRICING.—

5           “(1) PRESCRIPTION DRUG TRANSACTIONS WITH  
6           PHARMACIES INDEPENDENT OF THE ISSUER OR  
7           PHARMACY BENEFITS MANAGER.—If the pharmacy  
8           that dispenses a prescription drug to an enrollee in  
9           a group health plan or group or individual health in-  
10          surance coverage is not wholly or partially owned by  
11          such plan, such issuer, or an entity providing phar-  
12          macy benefit management services under such plan  
13          or coverage, such plan, issuer, or entity shall not  
14          charge the plan, issuer, or enrollee a price for such  
15          prescription drug that exceeds the price paid to the  
16          pharmacy.

17          “(2) INTRA-COMPANY PRESCRIPTION DRUG  
18          TRANSACTIONS.—If the mail order, specialty, or re-  
19          tail pharmacy that dispenses a prescription drug to  
20          an enrollee in a group health plan or health insur-  
21          ance coverage is wholly or partially owned by, and  
22          submits claims to, such health insurance issuer or  
23          an entity providing pharmacy benefit management  
24          services under a group health plan or group or indi-  
25          vidual health insurance coverage, the price charged

1 for such drug by such pharmacy to such group  
2 health plan or health insurance issuer offering group  
3 or individual health insurance coverage may not ex-  
4 ceed the lesser of—

5 “(A) the amount paid to the pharmacy for  
6 acquisition of the drug; or

7 “(B) the median price charged to the  
8 group health plan or health insurance issuer  
9 when the same drug is dispensed to enrollees in  
10 the plan or coverage by other similarly situated  
11 pharmacies not wholly or partially owned by the  
12 health insurance issuer or entity providing  
13 pharmacy benefits management services, as de-  
14 scribed in paragraph (1).

15 “(3) SUPPLEMENTARY REPORTING FOR INTRA-  
16 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A  
17 health insurance issuer of group health insurance  
18 coverage or an entity providing pharmacy benefits  
19 management services under a group health plan or  
20 group health insurance coverage that conducts  
21 transactions with a wholly or partially owned phar-  
22 macy, as described in paragraph (2), shall submit,  
23 together with the report under subsection (b), a sup-  
24 plementary report every 6 months to the plan spon-  
25 sor that includes—

1           “(A) an explanation of any benefit design  
2           parameters that encourage enrollees in the plan  
3           or coverage to fill prescriptions at mail order,  
4           specialty, or retail pharmacies that are wholly  
5           or partially owned by that issuer or entity;

6           “(B) the percentage of total prescriptions  
7           charged to the plan, coverage, or enrollees in  
8           the plan or coverage, that were dispensed by  
9           mail order, specialty, or retail pharmacies that  
10          are wholly or partially owned by the issuer or  
11          entity providing pharmacy benefits management  
12          services; and

13          “(C) a list of all drugs dispensed by such  
14          wholly or partially-owned pharmacy and  
15          charged to the plan or coverage, or enrollees of  
16          the plan or coverage, during the applicable  
17          quarter, and, with respect to each drug—

18                 “(i) the amount charged per course of  
19                 treatment or 30-day supply with respect to  
20                 enrollees in the plan or coverage, including  
21                 amounts charged to the plan or coverage  
22                 and amounts charged to the enrollee;

23                 “(ii) the median amount charged to  
24                 the plan or coverage, per course of treat-  
25                 ment or 30-day supply, including amounts

1           paid by the enrollee, when the same drug  
2           is dispensed by other pharmacies that are  
3           not wholly or partially owned by the issuer  
4           or entity and that are included in the  
5           pharmacy network of that plan or cov-  
6           erage;

7           “(iii) the interquartile range of the  
8           costs, per course of treatment or 30-day  
9           supply, including amounts paid by the en-  
10          rollee, when the same drug is dispensed by  
11          other pharmacies that are not wholly or  
12          partially owned by the issuer or entity and  
13          that are included in the pharmacy network  
14          of that plan or coverage; and

15          “(iv) the lowest cost per course of  
16          treatment or 30-day supply, for such drug,  
17          including amounts charged to the plan or  
18          issuer and enrollee, that is available from  
19          any pharmacy included in the network of  
20          the plan or coverage.

21          “(d) FULL REBATE PASS-THROUGH TO PLAN.—

22                 “(1) IN GENERAL.—A pharmacy benefits man-  
23          ager, a third-party administrator of a group health  
24          plan, a health insurance issuer offering group health  
25          insurance coverage, or an entity providing pharmacy

1       benefits management services under such health  
2       plan or health insurance coverage shall remit 100  
3       percent of rebates, fees, alternative discounts, and  
4       all other remuneration received from a pharma-  
5       ceutical manufacturer, distributor or any other third  
6       party, that are related to utilization of drugs under  
7       such health plan or health insurance coverage, to the  
8       group health plan.

9               “(2) FORM AND MANNER OF REMITTANCE.—  
10       Such rebates, fees, alternative discounts, and other  
11       remuneration shall be—

12               “(A) remitted to the group health plan in  
13       a timely fashion after the period for which such  
14       rebates, fees, or other remuneration is cal-  
15       culated, and in no case later than 90 days after  
16       the end of such period;

17               “(B) fully disclosed and enumerated to the  
18       group health plan sponsor, as described in  
19       (b)(1);

20               “(C) available for audit by the plan spon-  
21       sor, or a third party designated by a plan spon-  
22       sor no less than once per plan year; and

23               “(D) returned to the issuer or entity pro-  
24       viding pharmaceutical benefit management  
25       services by the group health plan if audits by

1           such issuer or entity indicate that the amounts  
2           received are incorrect after such amounts have  
3           been paid to the group health plan.

4           “(3) AUDIT OF REBATE CONTRACTS.—A phar-  
5           macy benefits manager, a third-party administrator  
6           of a group health plan, a health insurance issuer of-  
7           fering group health insurance coverage, or an entity  
8           providing pharmacy benefits management services  
9           under such health plan or health insurance coverage  
10          shall make rebate contracts with drug manufactur-  
11          ers available for audit by such plan sponsor or des-  
12          ignated third party, subject to confidentiality agree-  
13          ments to prevent re-disclosure of such contracts.

14          “(e) ENFORCEMENT.—

15                 “(1) IN GENERAL.—The Secretary, in consulta-  
16                 tion with the Secretary of Labor and the Secretary  
17                 of the Treasury, shall enforce this section.

18                 “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
19                 TION.—A health insurance issuer or an entity pro-  
20                 viding pharmacy benefit management services that  
21                 violates subsection (a), fails to provide information  
22                 required under subsection (b), engages in spread  
23                 pricing as defined in subsection (c), or fails to com-  
24                 ply with the requirements of subsection (d), or a  
25                 drug manufacturer that fails to provide information



1 under subsection (b)(1)(A), in a timely manner shall  
2 be subject to a civil monetary penalty in the amount  
3 of \$10,000 for each day during which such violation  
4 continues or such information is not disclosed or re-  
5 ported.

6 “(3) FALSE INFORMATION.—A health insurance  
7 issuer, entity providing pharmacy benefit manage-  
8 ment services, or drug manufacturer that knowingly  
9 provides false information under this section shall be  
10 subject to a civil money penalty in an amount not  
11 to exceed \$100,000 for each item of false informa-  
12 tion. Such civil money penalty shall be in addition to  
13 other penalties as may be prescribed by law.

14 “(4) PROCEDURE.—The provisions of section  
15 1128A of the Social Security Act, other than sub-  
16 section (a) and (b) and the first sentence of sub-  
17 section (c)(1) of such section shall apply to civil  
18 monetary penalties under this subsection in the  
19 same manner as such provisions apply to a penalty  
20 or proceeding under section 1128A of the Social Se-  
21 curity Act.

22 “(5) SAFE HARBOR.—The Secretary may waive  
23 penalties under paragraph (2), or extend the period  
24 of time for compliance with a requirement of this  
25 section, for an entity in violation of this section that

1       has made a good-faith effort to comply with this sec-  
2       tion.

3       “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
4       tion shall be construed to prohibit payments to entities  
5       offering pharmacy benefits management services for bona  
6       fide services using a fee structure not contemplated by this  
7       section, provided that such fees are transparent to group  
8       health plans and health insurance issuers.

9       “(g) DEFINITIONS.—In this section—

10           “(1) the term ‘similarly situated pharmacy’  
11       means, with respect to a particular pharmacy, an-  
12       other pharmacy that is approximately the same size  
13       (as measured by the number of prescription drugs  
14       dispensed), and that serves patients in the same geo-  
15       graphical area, whether through physical locations or  
16       mail order; and

17           “(2) the term ‘wholesale acquisition cost’ has  
18       the meaning given such term in section  
19       1847A(c)(6)(B) of the Social Security Act.”.

20       **SEC. 365. STUDY BY COMPTROLLER GENERAL OF UNITED**  
21           **STATES.**

22       (a) IN GENERAL.—The Comptroller General of the  
23       United States (referred to in this section as the “Comp-  
24       troller General”) shall, in consultation with appropriate

1 stakeholders, conduct a study on the role of pharmacy  
2 benefit managers.

3 (b) PERMISSIBLE EXAMINATION.—In conducting the  
4 study required under subsection (a), the Comptroller Gen-  
5 eral may examine various qualitative and quantitative as-  
6 pects of the role of pharmacy benefit managers, such as  
7 the following:

8 (1) The role that pharmacy benefit managers  
9 play in the pharmaceutical supply chain.

10 (2) The state of competition among pharmacy  
11 benefit managers, including the market share for the  
12 Nation's largest pharmacy benefit managers.

13 (3) The use of rebates and fees by pharmacy  
14 benefit managers, including—

15 (A) the extent to which rebates are passed  
16 on to health plans and whether such rebates are  
17 passed on to individuals enrolled in such plans;

18 (B) the extent to which rebates are kept by  
19 such pharmacy benefit managers; and

20 (C) the role of any fees charged by such  
21 pharmacy benefit managers.

22 (4) Whether pharmacy benefit managers struc-  
23 ture their formularies in favor of high-rebate pre-  
24 scription drugs over lower-cost, lower-rebate alter-  
25 natives.

1           (5) The average prior authorization approval  
2           time for pharmacy benefit managers.

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

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

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

### 15       **SEC. 371. MEDICARE PART D MODERNIZATION REDESIGN.**

16          (a) BENEFIT STRUCTURE REDESIGN.—Section  
17       1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
18       102(b)) is amended—

19               (1) in paragraph (2)—

20                       (A) in subparagraph (A), in the matter  
21               preceding clause (i), by inserting “for a year  
22               preceding 2025 and for costs above the annual  
23               deductible specified in paragraph (1) and up to  
24               the annual out-of-pocket threshold specified in

paragraph (4)(B) for 2025 and each subsequent year” after “paragraph (3)”;

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting “for a year preceding 2025,” after “paragraph (4),”; and

(ii) in clause (ii)(III), by striking “and each subsequent year” and inserting “, 2021, 2022, 2023, and 2024”; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2025,” after “paragraph (4),”; and

(II) in subclause (I)(bb), by striking “a year after 2018” and inserting “each of years 2018 through 2024”; and

(ii) in clause (ii)(V), by striking “2019 and each subsequent year” and inserting “each of years 2019 through 2024”;

(2) in paragraph (3)(A)—

1 (A) in the matter preceding clause (i), by  
2 inserting “for a year preceding 2025,” after  
3 “and (4),”; and

4 (B) in clause (ii), by striking “for a subse-  
5 quent year” and inserting “for each of years  
6 2007 through 2024”;

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

10 (I) by redesignating subclauses  
11 (I) and (II) as items (aa) and (bb),  
12 respectively, and indenting appro-  
13 priately;

14 (II) in the matter preceding item  
15 (aa), as redesignated by subclause (I),  
16 by striking “is equal to the greater  
17 of—” and inserting “is equal to—

18 “(I) for a year preceding 2025,  
19 the greater of—”;

20 (III) by striking the period at the  
21 end of item (bb), as redesignated by  
22 subclause (I), and inserting “; and”;  
23 and

24 (IV) by adding at the end the fol-  
25 lowing:

1 “(II) for 2025 and each suc-  
2 ceeding year, \$0.”; and

3 (ii) in clause (ii)—

4 (I) by striking “clause (i)(I)” and  
5 inserting “clause (i)(I)(aa)”; and

6 (II) by adding at the end the fol-  
7 lowing new sentence: “The Secretary  
8 shall continue to calculate the dollar  
9 amounts specified in clause (i)(I)(aa),  
10 including with the adjustment under  
11 this clause, after 2024 for purposes of  
12 section 1860D–14(a)(1)(D)(iii).”;

13 (B) in subparagraph (B)—

14 (i) in clause (i)—

15 (I) in subclause (V), by striking  
16 “or” at the end;

17 (II) in subclause (VI)—

18 (aa) by striking “for a sub-  
19 sequent year” and inserting “for  
20 2021 through 2024”; and

21 (bb) by striking the period  
22 at the end and inserting a semi-  
23 colon; and

24 (III) by adding at the end the  
25 following new subclauses:

1 “(VII) for 2025, is equal to  
2 \$3,100; or

3 “(VIII) for a subsequent year, is  
4 equal to the amount specified in this  
5 subparagraph for the previous year,  
6 increased by the annual percentage in-  
7 crease described in paragraph (6) for  
8 the year involved.”; and

9 (ii) in clause (ii), by striking “clause  
10 (i)(II)” and inserting “clause (i)”;

11 (C) in subparagraph (C)(i), by striking  
12 “and for amounts” and inserting “and for a  
13 year preceding 2025 for amounts”; and

14 (D) in subparagraph (E), by striking “In  
15 applying” and inserting “For each of 2011  
16 through 2024, in applying”.

17 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

18 (1) IN GENERAL.—Section 1860D–2(b)(2)(A)  
19 of the Social Security Act (42 U.S.C. 1395w–  
20 102(b)(2)(A)), as amended by subsection (a), is  
21 amended—

22 (A) by redesignating clauses (i) and (ii) as  
23 subclauses (I) and (II) and moving such sub-  
24 clauses 2 ems to the right;



1 (B) by striking “25 PERCENT COINSUR-  
 2 ANCE.—Subject to” and inserting “COINSUR-  
 3 ANCE.—

4 “(i) IN GENERAL.—Subject to”;

5 (C) in each of subclauses (I) and (II), as  
 6 redesignated by subparagraph (A), by striking  
 7 “25 percent” and inserting “the applicable per-  
 8 centage (as defined in clause (ii))”; and

9 (D) by adding at the end the following new  
 10 clause:

11 “(ii) APPLICABLE PERCENTAGE DE-  
 12 FINED.—For purposes of clause (i), the  
 13 term ‘applicable percentage’ means—

14 “(I) for a year preceding 2025,  
 15 25 percent; and

16 “(II) for 2025 and each subse-  
 17 quent year, 20 percent.”.

18 (2) CONFORMING AMENDMENT.—Section  
 19 1860D–14(a)(2)(D) of the Social Security Act (42  
 20 U.S.C. 1395w–114(a)(2)(D)) is amended by striking  
 21 “25 percent” and inserting “the applicable percent-  
 22 age”.

23 (c) DECREASING REINSURANCE PAYMENT  
 24 AMOUNT.—Section 1860D–15(b) of the Social Security  
 25 Act (42 U.S.C. 1395w–115(b)) is amended—

1 (1) in paragraph (1)—

2 (A) by striking “equal to 80 percent” and  
3 inserting “equal to—

4 “(A) for a year preceding 2025, 80 per-  
5 cent”;

6 (B) in subparagraph (A), as added by  
7 paragraph (1), by striking the period at the end  
8 and inserting “; and”; and

9 (C) by adding at the end the following new  
10 subparagraph:

11 “(B) for 2025 and each subsequent year,  
12 the sum of—

13 “(i) an amount equal to the applicable  
14 percentage specified in paragraph (5)(A) of  
15 such allowable reinsurance costs attrib-  
16 utable to that portion of gross prescription  
17 drug costs as specified in paragraph (3) in-  
18 curred in the coverage year after such indi-  
19 vidual has incurred costs that exceed the  
20 annual out-of-pocket threshold specified in  
21 section 1860D–2(b)(4)(B) with respect to  
22 applicable drugs (as defined in section  
23 1860D–14B(g)(2)); and

24 “(ii) an amount equal to the applica-  
25 ble percentage specified in paragraph

1 (5)(B) of allowable reinsurance costs at-  
2 tributable to that portion of gross prescrip-  
3 tion drug costs as specified in paragraph  
4 (3) incurred in the coverage year after  
5 such individual has incurred costs that ex-  
6 ceed the annual out-of-pocket threshold  
7 specified in section 1860D–2(b)(4)(B) with  
8 respect to covered part D drugs that are  
9 not applicable drugs (as so defined).”; and  
10 (2) by adding at the end the following new  
11 paragraph:

12 “(5) APPLICABLE PERCENTAGE SPECIFIED.—  
13 For purposes of paragraph (1)(B), the applicable  
14 percentage specified in this paragraph is—

15 “(A) with respect to applicable drugs (as  
16 defined in section 1860D–14B(g)(2))—

17 “(i) for 2025, 60 percent;

18 “(ii) for 2026, 40 percent; and

19 “(iii) for 2027 and each subsequent  
20 year, 20 percent; and

21 “(B) with respect to covered part D drugs  
22 that are not applicable drugs (as so defined)—

23 “(i) for 2025, 80 percent;

24 “(ii) for 2026, 60 percent; and

1 “(iii) for 2027 and each subsequent  
2 year, 40 percent.”.

3 (d) MANUFACTURER DISCOUNT PROGRAM DURING  
4 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

5 (1) IN GENERAL.—Part D of title XVIII of the  
6 Social Security Act is amended by inserting after  
7 section 1860D–14A (42 U.S.C. 1495w–114) the fol-  
8 lowing new section:

9 **“SEC. 1860D–14B. MANUFACTURER DISCOUNT PROGRAM.**

10 “(a) ESTABLISHMENT.—The Secretary shall estab-  
11 lish a manufacturer discount program (in this section re-  
12 ferred to as the ‘program’). Under the program, the Sec-  
13 retary shall enter into agreements described in subsection  
14 (b) with manufacturers and provide for the performance  
15 of the duties described in subsection (c). The Secretary  
16 shall establish a model agreement for use under the pro-  
17 gram by not later than January 1, 2025, in consultation  
18 with manufacturers, and allow for comment on such model  
19 agreement.

20 “(b) TERMS OF AGREEMENT.—

21 “(1) IN GENERAL.—

22 “(A) AGREEMENT.—An agreement under  
23 this section shall require the manufacturer to  
24 provide applicable beneficiaries access to dis-  
25 counted prices for applicable drugs of the man-

1 manufacturer that are dispensed on or after Janu-  
2 ary 1, 2025.

3 “(B) PROVISION OF DISCOUNTED PRICES  
4 AT THE POINT-OF-SALE.—The discounted prices  
5 described in subparagraph (A) shall be provided  
6 to the applicable beneficiary at the pharmacy or  
7 by the mail order service at the point-of-sale of  
8 an applicable drug.

9 “(2) PROVISION OF APPROPRIATE DATA.—Each  
10 manufacturer with an agreement in effect under this  
11 section shall collect and have available appropriate  
12 data, as determined by the Secretary, to ensure that  
13 it can demonstrate to the Secretary compliance with  
14 the requirements under the program.

15 “(3) COMPLIANCE WITH REQUIREMENTS FOR  
16 ADMINISTRATION OF PROGRAM.—Each manufac-  
17 turer with an agreement in effect under this section  
18 shall comply with requirements imposed by the Sec-  
19 retary or a third party with a contract under sub-  
20 section (d)(3), as applicable, for purposes of admin-  
21 istering the program, including any determination  
22 under subparagraph (A) of subsection (c)(1) or pro-  
23 cedures established under such subsection (c)(1).

24 “(4) LENGTH OF AGREEMENT.—

1           “(A) IN GENERAL.—An agreement under  
2           this section shall be effective for an initial pe-  
3           riod of not less than 12 months and shall be  
4           automatically renewed for a period of not less  
5           than 1 year unless terminated under subpara-  
6           graph (B).

7           “(B) TERMINATION.—

8           “(i) BY THE SECRETARY.—The Sec-  
9           retary may provide for termination of an  
10          agreement under this section for a knowing  
11          and willful violation of the requirements of  
12          the agreement or other good cause shown.  
13          Such termination shall not be effective ear-  
14          lier than 30 days after the date of notice  
15          to the manufacturer of such termination.  
16          The Secretary shall provide, upon request,  
17          a manufacturer with a hearing concerning  
18          such a termination, and such hearing shall  
19          take place prior to the effective date of the  
20          termination with sufficient time for such  
21          effective date to be repealed if the Sec-  
22          retary determines appropriate.

23          “(ii) BY A MANUFACTURER.—A man-  
24          ufacturer may terminate an agreement  
25          under this section for any reason. Any

1 such termination shall be effective, with re-  
2 spect to a plan year—

3 “(I) if the termination occurs be-  
4 fore January 30 of a plan year, as of  
5 the day after the end of the plan year;  
6 and

7 “(II) if the termination occurs on  
8 or after January 30 of a plan year, as  
9 of the day after the end of the suc-  
10 ceeding plan year.

11 “(iii) EFFECTIVENESS OF TERMI-  
12 NATION.—Any termination under this sub-  
13 paragraph shall not affect discounts for  
14 applicable drugs of the manufacturer that  
15 are due under the agreement before the ef-  
16 fective date of its termination.

17 “(iv) NOTICE TO THIRD PARTY.—The  
18 Secretary shall provide notice of such ter-  
19 mination to a third party with a contract  
20 under subsection (d)(3) within not less  
21 than 30 days before the effective date of  
22 such termination.

23 “(5) EFFECTIVE DATE OF AGREEMENT.—An  
24 agreement under this section shall take effect on a

1 date determined appropriate by the Secretary, which  
2 may be at the start of a calendar quarter.

3 “(c) DUTIES DESCRIBED.—The duties described in  
4 this subsection are the following:

5 “(1) ADMINISTRATION OF PROGRAM.—Admin-  
6 istering the program, including—

7 “(A) the determination of the amount of  
8 the discounted price of an applicable drug of a  
9 manufacturer;

10 “(B) the establishment of procedures  
11 under which discounted prices are provided to  
12 applicable beneficiaries at pharmacies or by  
13 mail order service at the point-of-sale of an ap-  
14 plicable drug;

15 “(C) the establishment of procedures to  
16 ensure that, not later than the applicable num-  
17 ber of calendar days after the dispensing of an  
18 applicable drug by a pharmacy or mail order  
19 service, the pharmacy or mail order service is  
20 reimbursed for an amount equal to the dif-  
21 ference between—

22 “(i) the negotiated price of the appli-  
23 cable drug; and

24 “(ii) the discounted price of the appli-  
25 cable drug;



1           “(D) the establishment of procedures to  
2           ensure that the discounted price for an applica-  
3           ble drug under this section is applied before any  
4           coverage or financial assistance under other  
5           health benefit plans or programs that provide  
6           coverage or financial assistance for the pur-  
7           chase or provision of prescription drug coverage  
8           on behalf of applicable beneficiaries as the Sec-  
9           retary may specify; and

10           “(E) providing a reasonable dispute resolu-  
11           tion mechanism to resolve disagreements be-  
12           tween manufacturers, applicable beneficiaries,  
13           and the third party with a contract under sub-  
14           section (d)(3).

15           “(2) MONITORING COMPLIANCE.—

16           “(A) IN GENERAL.—The Secretary shall  
17           monitor compliance by a manufacturer with the  
18           terms of an agreement under this section.

19           “(B) NOTIFICATION.—If a third party  
20           with a contract under subsection (d)(3) deter-  
21           mines that the manufacturer is not in compli-  
22           ance with such agreement, the third party shall  
23           notify the Secretary of such noncompliance for  
24           appropriate enforcement under subsection (e).

1           “(3) COLLECTION OF DATA FROM PRESCRIP-  
2           TION DRUG PLANS AND MA-PD PLANS.—The Sec-  
3           retary may collect appropriate data from prescrip-  
4           tion drug plans and MA-PD plans in a timeframe  
5           that allows for discounted prices to be provided for  
6           applicable drugs under this section.

7           “(d) ADMINISTRATION.—

8           “(1) IN GENERAL.—Subject to paragraph (2),  
9           the Secretary shall provide for the implementation of  
10          this section, including the performance of the duties  
11          described in subsection (c).

12          “(2) LIMITATION.—In providing for the imple-  
13          mentation of this section, the Secretary shall not re-  
14          ceive or distribute any funds of a manufacturer  
15          under the program.

16          “(3) CONTRACT WITH THIRD PARTIES.—The  
17          Secretary shall enter into a contract with 1 or more  
18          third parties to administer the requirements estab-  
19          lished by the Secretary in order to carry out this  
20          section. At a minimum, the contract with a third  
21          party under the preceding sentence shall require  
22          that the third party—

23                 “(A) receive and transmit information be-  
24                 tween the Secretary, manufacturers, and other

1 individuals or entities the Secretary determines  
2 appropriate;

3 “(B) receive, distribute, or facilitate the  
4 distribution of funds of manufacturers to ap-  
5 propriate individuals or entities in order to  
6 meet the obligations of manufacturers under  
7 agreements under this section;

8 “(C) provide adequate and timely informa-  
9 tion to manufacturers, consistent with the  
10 agreement with the manufacturer under this  
11 section, as necessary for the manufacturer to  
12 fulfill its obligations under this section; and

13 “(D) permit manufacturers to conduct  
14 periodic audits, directly or through contracts, of  
15 the data and information used by the third  
16 party to determine discounts for applicable  
17 drugs of the manufacturer under the program.

18 “(4) PERFORMANCE REQUIREMENTS.—The  
19 Secretary shall establish performance requirements  
20 for a third party with a contract under paragraph  
21 (3) and safeguards to protect the independence and  
22 integrity of the activities carried out by the third  
23 party under the program under this section.

1           “(5) ADMINISTRATION.—Chapter 35 of title 44,  
2       United States Code, shall not apply to the program  
3       under this section.

4           “(6) FUNDING.—For purposes of carrying out  
5       this section, the Secretary shall provide for the  
6       transfer, from the Federal Supplementary Medical  
7       Insurance Trust Fund under section 1841 to the  
8       Centers for Medicare & Medicaid Services Program  
9       Management Account, of \$4,000,000 for each of fis-  
10      cal years 2024 through 2027, to remain available  
11      until expended.”.

12       “(e) ENFORCEMENT.—

13           “(1) AUDITS.—Each manufacturer with an  
14      agreement in effect under this section shall be sub-  
15      ject to periodic audit by the Secretary.

16           “(2) CIVIL MONEY PENALTY.—

17           “(A) IN GENERAL.—The Secretary shall  
18      impose a civil money penalty on a manufacturer  
19      that fails to provide applicable beneficiaries dis-  
20      counts for applicable drugs of the manufacturer  
21      in accordance with such agreement for each  
22      such failure in an amount the Secretary deter-  
23      mines is commensurate with the sum of—

24           “(i) the amount that the manufac-  
25      turer would have paid with respect to such

1 discounts under the agreement, which will  
2 then be used to pay the discounts which  
3 the manufacturer had failed to provide;  
4 and

5 “(ii) 25 percent of such amount.

6 “(B) APPLICATION.—The provisions of  
7 section 1128A (other than subsections (a) and  
8 (b)) shall apply to a civil money penalty under  
9 this paragraph in the same manner as such  
10 provisions apply to a penalty or proceeding  
11 under section 1128A(a).

12 “(f) CLARIFICATION REGARDING AVAILABILITY OF  
13 OTHER COVERED PART D DRUGS.—Nothing in this sec-  
14 tion shall prevent an applicable beneficiary from pur-  
15 chasing a covered part D drug that is not an applicable  
16 drug (including a generic drug or a drug that is not on  
17 the formulary of the prescription drug plan or MA–PD  
18 plan that the applicable beneficiary is enrolled in).

19 “(g) DEFINITIONS.—In this section:

20 “(1) APPLICABLE BENEFICIARY.—The term  
21 ‘applicable beneficiary’ means an individual who, on  
22 the date of dispensing a covered part D drug—

23 “(A) is enrolled in a prescription drug plan  
24 or an MA–PD plan;

1 “(B) is not enrolled in a qualified retiree  
2 prescription drug plan; and

3 “(C) has incurred costs for covered part D  
4 drugs in the year that are above the annual de-  
5 ductible specified in section 1860D–2(b)(1) for  
6 such year.

7 “(2) APPLICABLE DRUG.—The term ‘applicable  
8 drug’ means, with respect to an applicable bene-  
9 ficiary, a covered part D drug—

10 “(A) approved under a new drug applica-  
11 tion under section 505(c) of the Federal Food,  
12 Drug, and Cosmetic Act or, in the case of a bio-  
13 logic product, licensed under section 351 of the  
14 Public Health Service Act (including a product  
15 licensed under subsection (k) of such section  
16 351); and

17 “(B)(i) if the PDP sponsor of the prescrip-  
18 tion drug plan or the MA organization offering  
19 the MA–PD plan uses a formulary, which is on  
20 the formulary of the prescription drug plan or  
21 MA–PD plan that the applicable beneficiary is  
22 enrolled in;

23 “(ii) if the PDP sponsor of the prescrip-  
24 tion drug plan or the MA organization offering  
25 the MA–PD plan does not use a formulary, for

1 which benefits are available under the prescrip-  
2 tion drug plan or MA–PD plan that the appli-  
3 cable beneficiary is enrolled in; or

4 “(iii) is provided through an exception or  
5 appeal.

6 “(3) APPLICABLE NUMBER OF CALENDAR  
7 DAYS.—The term ‘applicable number of calendar  
8 days’ means—

9 “(A) with respect to claims for reimburse-  
10 ment submitted electronically, 14 days; and

11 “(B) with respect to claims for reimburse-  
12 ment submitted otherwise, 30 days.

13 “(4) DISCOUNTED PRICE.—

14 “(A) IN GENERAL.—The term ‘discounted  
15 price’ means—

16 “(i) with respect to an applicable drug  
17 dispensed for an applicable beneficiary who  
18 has incurred costs that are below the an-  
19 nual out-of-pocket threshold specified in  
20 section 1860D–2(b)(4)(B) for the year, 93  
21 percent of the negotiated price of the ap-  
22 plicable drug of a manufacturer; and

23 “(ii) with respect to an applicable  
24 drug dispensed for an applicable bene-  
25 ficiary who has incurred costs for covered

1 part D drugs in the year that are equal to  
2 or exceed the annual out-of-pocket thresh-  
3 old specified in section 1860D–2(b)(4)(B)  
4 for the year, 86 percent of the negotiated  
5 price of the applicable drug of a manufac-  
6 turer.

7 “(B) CLARIFICATION.—Nothing in this  
8 section shall be construed as affecting the re-  
9 sponsibility of an applicable beneficiary for pay-  
10 ment of a dispensing fee for an applicable drug.

11 “(C) CLARIFICATION FOR CERTAIN  
12 CLAIMS.—With respect to the amount of the ne-  
13 gotiated price of an individual claim for an ap-  
14 plicable drug with respect to an applicable bene-  
15 ficiary, the manufacturer of the applicable drug  
16 shall provide—

17 “(i) the discounted price under clause  
18 (i) of subparagraph (A) only on the portion  
19 of the negotiated price of the applicable  
20 drug that falls above the deductible speci-  
21 fied in section 1860D–2(b)(1) for the year  
22 and below the annual out-of-pocket thresh-  
23 old specified in section 1860D–2(b)(4)(B)  
24 for the year; and



1                   “(ii) the discounted price under clause  
2                   (ii) of subparagraph (A) only on the por-  
3                   tion of the negotiated price of the applica-  
4                   ble drug that falls at or above such annual  
5                   out-of-pocket threshold.

6                   “(5) MANUFACTURER.—The term ‘manufac-  
7                   turer’ means any entity which is engaged in the pro-  
8                   duction, preparation, propagation, compounding,  
9                   conversion, or processing of prescription drug prod-  
10                  ucts, either directly or indirectly by extraction from  
11                  substances of natural origin, or independently by  
12                  means of chemical synthesis, or by a combination of  
13                  extraction and chemical synthesis. Such term does  
14                  not include a wholesale distributor of drugs or a re-  
15                  tail pharmacy licensed under State law.

16                  “(6) NEGOTIATED PRICE.—The term ‘nego-  
17                  tiated price’ has the meaning given such term in sec-  
18                  tion 1860D–2(d)(1)(B), except that such negotiated  
19                  price shall not include any dispensing fee for the ap-  
20                  plicable drug.

21                  “(7) QUALIFIED RETIREE PRESCRIPTION DRUG  
22                  PLAN.—The term ‘qualified retiree prescription drug  
23                  plan’ has the meaning given such term in section  
24                  1860D–22(a)(2).”.

1           (2) SUNSET OF MEDICARE COVERAGE GAP DIS-  
2           COUNT PROGRAM.—Section 1860D–14A of the So-  
3           cial Security Act (42 U.S.C. 1395–114a) is amend-  
4           ed—

5                     (A) in subsection (a), in the first sentence,  
6                     by striking “The Secretary” and inserting  
7                     “Subject to subsection (h), the Secretary”; and

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

10          “(h) SUNSET OF PROGRAM.—

11                     “(1) IN GENERAL.—The program shall not  
12                     apply to applicable drugs dispensed on or after Jan-  
13                     uary 1, 2025, and, subject to paragraph (2), agree-  
14                     ments under this section shall be terminated as of  
15                     such date.

16                     “(2) CONTINUED APPLICATION FOR APPLICA-  
17                     BLE DRUGS DISPENSED PRIOR TO SUNSET.—The  
18                     provisions of this section (including all responsibil-  
19                     ities and duties) shall continue to apply after Janu-  
20                     ary 1, 2025, with respect to applicable drugs dis-  
21                     pensed prior to such date.”.

22           (3) INCLUSION OF ACTUARIAL VALUE OF MANU-  
23           FACTURER DISCOUNTS IN BIDS.—Section 1860D–11  
24           of the Social Security Act (42 U.S.C. 1395w–111)  
25           is amended—

1 (A) in subsection (b)(2)(C)(iii)—

2 (i) by striking “assumptions regarding  
3 the reinsurance” and inserting “assump-  
4 tions regarding—

5 “(I) the reinsurance”; and

6 (ii) by adding at the end the fol-  
7 lowing:

8 “(II) for 2025 and each subse-  
9 quent year, the manufacturer dis-  
10 counts provided under section 1860D–  
11 14B subtracted from the actuarial  
12 value to produce such bid; and”; and

13 (B) in subsection (c)(1)(C)—

14 (i) by striking “an actuarial valuation  
15 of the reinsurance” and inserting “an ac-  
16 tuarial valuation of—

17 “(i) the reinsurance”;

18 (ii) in clause (i), as added by clause  
19 (i) of this subparagraph, by adding “and”  
20 at the end; and

21 (iii) by adding at the end the fol-  
22 lowing:

23 “(ii) for 2025 and each subsequent  
24 year, the manufacturer discounts provided  
25 under section 1860D–14B;”.

1           (4) CLARIFICATION REGARDING EXCLUSION OF  
2       MANUFACTURER DISCOUNTS FROM TROOP.—Section  
3       1860D–2(b)(4) of the Social Security Act (42  
4       U.S.C. 1395w–102(b)(4)) is amended—

5           (A) in subparagraph (C), by inserting “and  
6       subject to subparagraph (F)” after “subpara-  
7       graph (E)”; and

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

10           “(F) CLARIFICATION REGARDING EXCLU-  
11       SION OF MANUFACTURER DISCOUNTS.—In ap-  
12       plying subparagraph (A), incurred costs shall  
13       not include any manufacturer discounts pro-  
14       vided under section 1860D–14B.”.

15       (e) DETERMINATION OF ALLOWABLE REINSURANCE  
16       COSTS.—Section 1860D–15(b) of the Social Security Act  
17       (42 U.S.C. 1395w–115(b)) is amended—

18           (1) in paragraph (2)—

19           (A) by striking “COSTS.—For purposes”  
20       and inserting “COSTS.—

21           “(A) IN GENERAL.—Subject to subpara-  
22       graph (B), for purposes”; and

23           (B) by adding at the end the following new  
24       subparagraph:

1                   “(B) INCLUSION OF MANUFACTURER DIS-  
 2                   COUNTS ON APPLICABLE DRUGS.—For purposes  
 3                   of applying subparagraph (A), the term ‘allow-  
 4                   able reinsurance costs’ shall include the portion  
 5                   of the negotiated price (as defined in section  
 6                   1860D–14B(g)(6)) of an applicable drug (as  
 7                   defined in section 1860D–14B(g)(2)) that was  
 8                   paid by a manufacturer under the manufacturer  
 9                   discount program under section 1860D–14B.”;  
 10                  and  
 11                  (2) in paragraph (3)—

12                   (A) in the first sentence, by striking “For  
 13                   purposes” and inserting “Subject to paragraph  
 14                   (2)(B), for purposes”; and

15                   (B) in the second sentence, by inserting  
 16                   “or, in the case of an applicable drug, by a  
 17                   manufacturer” after “by the individual or  
 18                   under the plan”.

19                  (f) UPDATING RISK ADJUSTMENT METHODOLOGIES  
 20                  TO ACCOUNT FOR PART D MODERNIZATION REDE-  
 21                  SIGN.—Section 1860D–15(c) of the Social Security Act  
 22                  (42 U.S.C. 1395w–115(c)) is amended by adding at the  
 23                  end the following new paragraph:

24                   “(3) UPDATING RISK ADJUSTMENT METH-  
 25                   ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-

1 TION REDESIGN.—The Secretary shall update the  
2 risk adjustment methodologies used to adjust bid  
3 amounts pursuant to this subsection as appropriate  
4 to take into account changes in benefits under this  
5 part pursuant to the amendments made by section  
6 371 of the Fair Care Act of 2024.”.

7 (g) CONDITIONS FOR COVERAGE OF DRUGS UNDER  
8 THIS PART.—Section 1860D–43 of the Social Security  
9 Act (42 U.S.C. 1395w–153) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (2), by striking “and” at  
12 the end;

13 (B) in paragraph (3), by striking the pe-  
14 riod at the end and inserting a semicolon; and

15 (C) by adding at the end the following new  
16 paragraphs:

17 “(4) participate in the manufacturer discount  
18 program under section 1860D–14B;

19 “(5) have entered into and have in effect an  
20 agreement described in subsection (b) of such sec-  
21 tion 1860D–14B with the Secretary; and

22 “(6) have entered into and have in effect, under  
23 terms and conditions specified by the Secretary, a  
24 contract with a third party that the Secretary has

1 entered into a contract with under subsection (d)(3)  
2 of such section 1860D–14B.”;

3 (2) by striking subsection (b) and inserting the  
4 following:

5 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)  
6 of subsection (a) shall apply to covered part D drugs dis-  
7 pensed under this part on or after January 1, 2011, and  
8 before January 1, 2025, and paragraphs (4) through (6)  
9 of such subsection shall apply to covered part D drugs  
10 dispensed on or after January 1, 2025.”; and

11 (3) in subsection (c), by striking paragraph (2)  
12 and inserting the following:

13 “(2) the Secretary determines that in the period  
14 beginning on January 1, 2011, and ending on De-  
15 cember 31, 2011 (with respect to paragraphs (1)  
16 through (3) of subsection (a)), or the period begin-  
17 ning on January 1, 2025, and ending December 31,  
18 2025 (with respect to paragraphs (4) through (6) of  
19 such subsection), there were extenuating cir-  
20 cumstances.”.

21 (h) CONFORMING AMENDMENTS.—

22 (1) Section 1860D–2 of the Social Security Act  
23 (42 U.S.C. 1395w–102) is amended—

24 (A) in subsection (a)(2)(A)(i)(I), by strik-  
25 ing “, or an increase in the initial” and insert-

1           ing “or for a year preceding 2025 an increase  
2           in the initial”;

3           (B) in subsection (c)(1)(C)—

4                 (i) in the subparagraph heading, by  
5                 striking “AT INITIAL COVERAGE LIMIT”;  
6                 and

7                 (ii) by inserting “for a year preceding  
8                 2025 or the annual out-of-pocket threshold  
9                 specified in subsection (b)(4)(B) for the  
10                year for 2025 and each subsequent year”  
11                after “subsection (b)(3) for the year” each  
12                place it appears; and

13           (C) in subsection (d)(1)(A), by striking “or  
14           an initial” and inserting “or for a year pre-  
15           ceding 2025 an initial”.

16           (2) Section 1860D–4(a)(4)(B)(i) of the Social  
17           Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is  
18           amended by striking “the initial” and inserting “for  
19           a year preceding 2025, the initial”.

20           (3) Section 1860D–14(a) of the Social Security  
21           Act (42 U.S.C. 1395w–114(a)) is amended—

22                 (A) in paragraph (1)—

23                 (i) in subparagraph (C), by striking  
24                 “The continuation” and inserting “For a  
25                 year preceding 2025, the continuation”;



1 (ii) in subparagraph (D)(iii), by strik-  
 2 ing “1860D–2(b)(4)(A)(i)(I)” and insert-  
 3 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

4 (iii) in subparagraph (E), by striking  
 5 “The elimination” and inserting “For a  
 6 year preceding 2025, the elimination”; and  
 7 (B) in paragraph (2)—

8 (i) in subparagraph (C), by striking  
 9 “The continuation” and inserting “For a  
 10 year preceding 2025, the continuation”;  
 11 and

12 (ii) in subparagraph (E)—

13 (I) by inserting “for a year pre-  
 14 ceding 2025,” after “subsection (c)”;  
 15 and

16 (II) by striking “1860D–  
 17 2(b)(4)(A)(i)(I)” and inserting  
 18 “1860D–2(b)(4)(A)(i)(I)(aa)”.

19 (4) Section 1860D–21(d)(7) of the Social Secu-  
 20 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended  
 21 by striking “section 1860D–2(b)(B)(4)(B)(i)” and  
 22 inserting “section 1860D–2(b)(B)(4)(C)(i)”.

23 (5) Section 1860D–22(a)(2)(A) of the Social  
 24 Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is  
 25 amended—

1 (A) by striking “the value of any discount”  
2 and inserting the following: “the value of—

3 “(i) for years prior to 2025, any dis-  
4 count”;

5 (B) in clause (i), as inserted by subpara-  
6 graph (A) of this paragraph, by striking the pe-  
7 riod at the end and inserting “; and”; and

8 (C) by adding at the end the following new  
9 clause:

10 “(ii) for 2025 and each subsequent  
11 year, any discount provided pursuant to  
12 section 1860D–14B.”.

13 (6) Section 1860D–41(a)(6) of the Social Secu-  
14 rity Act (42 U.S.C. 1395w–151(a)(6)) is amended—

15 (A) by inserting “for a year before 2025”  
16 after “1860D–2(b)(3)”; and

17 (B) by inserting “for such year” before the  
18 period.

19 (i) EFFECTIVE DATE.—The amendments made by  
20 this section shall apply to plan year 2025 and subsequent  
21 plan years.

1 **SEC. 372. MAXIMUM MONTHLY CAP ON COST-SHARING PAY-**  
2 **MENTS UNDER PRESCRIPTION DRUG PLANS**  
3 **AND MA-PD PLANS.**

4 (a) IN GENERAL.—Section 1860D–2(b) of the Social  
5 Security Act (42 U.S.C. 1395w–102(b)), as amended by  
6 section 121, is amended—

7 (1) in paragraph (2)—

8 (A) in subparagraph (A), by striking “and  
9 (D)” and inserting “, (D), and (E)”; and

10 (B) by adding at the end the following new  
11 subparagraph:

12 “(E) MAXIMUM MONTHLY CAP ON COST-  
13 SHARING PAYMENTS.—

14 “(i) IN GENERAL.—For plan years be-  
15 ginning on or after January 1, 2025, the  
16 Secretary shall, through notice and com-  
17 ment rulemaking, establish a process under  
18 which each PDP sponsor offering a pre-  
19 scription drug plan and each MA organiza-  
20 tion offering an MA–PD plan shall provide  
21 to any enrollee, including an enrollee who  
22 is a subsidy eligible individual (as defined  
23 in paragraph (3) of section 1860D–14(a)),  
24 the option to elect with respect to a plan  
25 year to have their monthly cost-sharing

1 payments under the plan capped in accord-  
2 ance with this subparagraph.

3 “(ii) DETERMINATION OF MAXIMUM  
4 MONTHLY CAP.—For each month in the  
5 plan year after an enrollee in a prescrip-  
6 tion drug plan or an MA–PD plan has  
7 made an election pursuant to clause (i),  
8 the PDP sponsor or MA organization shall  
9 determine a maximum monthly cap (as de-  
10 fined in clause (iv)) for such enrollee.

11 “(iii) BENEFICIARY MONTHLY PAY-  
12 MENTS.—With respect to an enrollee who  
13 has made an election pursuant to clause  
14 (i), for each month described in clause (ii),  
15 the PDP sponsor or MA organization shall  
16 bill such enrollee an amount (not to exceed  
17 the maximum monthly cap) for the out-of-  
18 pocket costs of such enrollee in such  
19 month.

20 “(iv) MAXIMUM MONTHLY CAP DE-  
21 FINED.—In this subparagraph, the term  
22 ‘maximum monthly cap’ means, with re-  
23 spect to an enrollee—

1 “(I) for the first month in which  
2 this subparagraph applies, an amount  
3 determined by calculating—

4 “(aa) the annual out-of-  
5 pocket threshold specified in  
6 paragraph (4)(B) minus the in-  
7 curred costs of the enrollee as de-  
8 scribed in paragraph (4)(C); di-  
9 vided by

10 “(bb) the number of months  
11 remaining in the plan year; and

12 “(II) for a subsequent month, an  
13 amount determined by calculating—

14 “(aa) the sum of any re-  
15 maining out-of-pocket costs owed  
16 by the enrollee from a previous  
17 month that have not yet been  
18 billed to the enrollee and any ad-  
19 ditional costs incurred by the en-  
20 rollee; divided by

21 “(bb) the number of months  
22 remaining in the plan year.

23 “(v) ADDITIONAL REQUIREMENTS.—

24 The following requirements shall apply  
25 with respect to the option to make an elec-

tion pursuant to clause (i) under this subparagraph:

“(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1804(a).

“(II) TIMING OF ELECTION.—An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

“(aa) prior to the beginning of the plan year; or

“(bb) in any month during the plan year.

“(III) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

“(aa) may not limit the option for an enrollee to make such

1 an election to certain covered  
2 part D drugs;

3 “(bb) shall, prior to the plan  
4 year, notify prospective enrollees  
5 of the option to make such an  
6 election in promotional materials;

7 “(cc) shall include informa-  
8 tion on such option in enrollee  
9 educational materials;

10 “(dd) shall have in place a  
11 mechanism to notify a pharmacy  
12 during the plan year when an en-  
13 rollee incurs out-of-pocket costs  
14 with respect to covered part D  
15 drugs that make it likely the en-  
16 rollee may benefit from making  
17 such an election;

18 “(ee) shall provide that a  
19 pharmacy, after receiving a noti-  
20 fication described in item (dd)  
21 with respect to an enrollee, in-  
22 forms the enrollee of such notifi-  
23 cation;

24 “(ff) shall ensure that such  
25 an election by an enrollee has no

1 effect on the amount paid to  
2 pharmacies (or the timing of  
3 such payments) with respect to  
4 covered part D drugs dispensed  
5 to the enrollee; and

6 “(gg) shall have in place a  
7 financial reconciliation process to  
8 correct inaccuracies in payments  
9 made by an enrollee under this  
10 subparagraph with respect to  
11 covered part D drugs during the  
12 plan year.

13 “(IV) FAILURE TO PAY AMOUNT  
14 BILLED.—If an enrollee fails to pay  
15 the amount billed for a month as re-  
16 quired under this subparagraph, the  
17 election of the enrollee pursuant to  
18 clause (i) shall be terminated and en-  
19 rollee shall pay the cost-sharing other-  
20 wise applicable for any covered part D  
21 drugs subsequently dispensed to the  
22 enrollee up to the annual out-of-pock-  
23 et threshold specified in paragraph  
24 (4)(B).



1 “(V) CLARIFICATION REGARDING  
2 PAST DUE AMOUNTS.—Nothing in this  
3 subparagraph shall be construed as  
4 prohibiting a PDP sponsor or an MA  
5 organization from billing an enrollee  
6 for an amount owed under this sub-  
7 paragraph.

8 “(VI) TREATMENT OF UNSET-  
9 TLED BALANCES.—Any unsettled bal-  
10 ances with respect to amounts owed  
11 under this subparagraph shall be  
12 treated as plan losses and the Sec-  
13 retary shall not be liable for any such  
14 balances outside of those assumed as  
15 losses estimated in plan bids.”; and

16 (2) in paragraph (4)—

17 (A) in subparagraph (C), by striking “and  
18 subject to subparagraph (F)” and inserting  
19 “and subject to subparagraphs (F) and (G)”;  
20 and

21 (B) by adding at the end the following new  
22 subparagraph:

23 “(G) INCLUSION OF COSTS PAID UNDER  
24 MAXIMUM MONTHLY CAP OPTION.—In applying  
25 subparagraph (A), with respect to an enrollee

1           who has made an election pursuant to clause (i)  
2           of paragraph (2)(E), costs shall be treated as  
3           incurred if such costs are paid by a PDP spon-  
4           sor or an MA organization under the process  
5           provided under such paragraph.”.

6           (b) APPLICATION TO ALTERNATIVE PRESCRIPTION  
7 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-  
8 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-  
9 ing at the end the following new paragraph:

10           “(4) SAME MAXIMUM MONTHLY CAP ON COST-  
11 SHARING.—For plan years beginning on or after  
12 January 1, 2025, the maximum monthly cap on  
13 cost-sharing payments under the process provided  
14 under subsection (b)(2)(E) shall apply to such cov-  
15 erage.”.

16 **SEC. 373. MARKET BASED PART B PRICING INDEX.**

17           Notwithstanding any provision of part B of title  
18 XVIII of the Social Security Act, the Secretary of Health  
19 and Human Services may make payments for drugs pay-  
20 able under such part based on an international pricing  
21 index. In using such an index, the Secretary shall take  
22 into account whether the market of each country included  
23 in such index is a price-controlled or free market and give  
24 more weight under such index to countries with market-  
25 based drug policies.

1 **SEC. 374. INNOVATION MODEL TESTING OF MEDICARE**  
2 **DRUG PAYMENTS.**

3 Notwithstanding any provision of section 1115A, the  
4 Secretary of Health and Human Services may, under such  
5 section, test a model to integrate benefits provided for  
6 drugs under parts A, B, and D of title XVIII of the Social  
7 Security Act.

8 **SEC. 375. MODIFICATION OF MAXIMUM REBATE AMOUNT**  
9 **UNDER MEDICAID DRUG REBATE PROGRAM.**

10 (a) IN GENERAL.—Subparagraph (D) of section  
11 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–  
12 8(c)(2)) is amended to read as follows:

13 “(D) MAXIMUM REBATE AMOUNT.—

14 “(i) IN GENERAL.—Except as pro-  
15 vided in clause (ii), in no case shall the  
16 sum of the amounts applied under para-  
17 graph (1)(A)(ii) and this paragraph with  
18 respect to each dosage form and strength  
19 of a single source drug or an innovator  
20 multiple source drug for a rebate period  
21 exceed—

22 “(I) for rebate periods beginning  
23 after December 31, 2009, and before  
24 September 30, 2025, 100 percent of  
25 the average manufacturer price of the  
26 drug; and

1 “(II) for rebate periods beginning  
2 on or after October 1, 2025, 125 per-  
3 cent of the average manufacturer  
4 price of the drug.

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

8 “(I) IN GENERAL.—If the aver-  
9 age manufacturer price with respect  
10 to each dosage form and strength of  
11 a single source drug or an innovator  
12 multiple source drug increases on or  
13 after October 1, 2025, and such in-  
14 creased average manufacturer price  
15 exceeds the inflation-adjusted average  
16 manufacturer price determined with  
17 respect to such drug under subclause  
18 (II) for the rebate period, clause (i)  
19 shall not apply and there shall be no  
20 limitation on the sum of the amounts  
21 applied under paragraph (1)(A)(ii)  
22 and this paragraph for the rebate pe-  
23 riod with respect to each dosage form  
24 and strength of the single source drug  
25 or innovator multiple source drug.

1                   “(II) INFLATION-ADJUSTED AV-  
2                   ERAGE MANUFACTURER PRICE DE-  
3                   FINED.—In this clause, the term ‘in-  
4                   flation-adjusted average manufacturer  
5                   price’ means, with respect to a single  
6                   source drug or an innovator multiple  
7                   source drug and a rebate period, the  
8                   average manufacturer price for each  
9                   dosage form and strength of the drug  
10                  for the calendar quarter beginning  
11                  July 1, 1990 (without regard to  
12                  whether or not the drug has been sold  
13                  or transferred to an entity, including  
14                  a division or subsidiary of the manu-  
15                  facturer, after the 1st day of such  
16                  quarter), increased by the percentage  
17                  by which the consumer price index for  
18                  all urban consumers (United States  
19                  city average) for the month before the  
20                  month in which the rebate period be-  
21                  gins exceeds such index for September  
22                  1990.”.

23           (b) TREATMENT OF SUBSEQUENTLY APPROVED  
24   DRUGS.—Section 1927(c)(2)(B) of the Social Security Act  
25   (42 U.S.C. 1396r–8(c)(2)(B)) is amended by inserting

1 “and clause (ii)(II) of subparagraph (D)” after “clause  
2 (ii)(II) of subparagraph (A)”.

3 (c) TECHNICAL AMENDMENTS.—Section  
4 1927(c)(3)(C)(ii)(IV) of the Social Security Act (42  
5 U.S.C. 1396r–9(c)(3)(C)(ii)(IV)) is amended—

6 (1) by striking “subparagraph (A)” and insert-  
7 ing “paragraph (3)(A)”; and

8 (2) by striking “this subparagraph” and insert-  
9 ing “paragraph (3)(C)”.

## 10 **Subtitle F—Medical Malpractice** 11 **Reform**

### 12 **SEC. 381. DEFINITIONS.**

13 In this Act:

14 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-  
15 TEM; ADR.—The term “alternative dispute resolution  
16 system” or “ADR” means a system that provides  
17 for the resolution of health care lawsuits in a man-  
18 ner other than through a civil action brought in a  
19 State or Federal court.

20 (2) CLAIMANT.—The term “claimant” means  
21 any person who brings a health care lawsuit, includ-  
22 ing a person who asserts or claims a right to legal  
23 or equitable contribution, indemnity, or subrogation,  
24 arising out of a health care liability claim or action,  
25 and any person on whose behalf such a claim is as-

1       serted or such an action is brought, whether de-  
2       ceased, incompetent, or a minor.

3           (3) COLLATERAL SOURCE BENEFITS.—The  
4       term “collateral source benefits” means any amount  
5       paid or reasonably likely to be paid in the future to  
6       or on behalf of the claimant, or any service, product,  
7       or other benefit provided or reasonably likely to be  
8       provided in the future to or on behalf of the claim-  
9       ant, as a result of the injury or wrongful death, pur-  
10      suant to—

11           (A) any State or Federal health, sickness,  
12       income-disability, accident, or workers’ com-  
13       pensation law;

14           (B) any health, sickness, income-disability,  
15       or accident insurance that provides health bene-  
16       fits or income-disability coverage;

17           (C) any contract or agreement of any  
18       group, organization, partnership, or corporation  
19       to provide, pay for, or reimburse the cost of  
20       medical, hospital, dental, or income-disability  
21       benefits; and

22           (D) any other publicly or privately funded  
23       program.

24           (4) CONTINGENT FEE.—The term “contingent  
25       fee” includes all compensation to any person or per-

1        sons which is payable only if a recovery is effected  
2        on behalf of one or more claimants.

3            (5) ECONOMIC DAMAGES.—The term “economic  
4        damages” means objectively verifiable monetary  
5        losses incurred as a result of the provision or use of  
6        (or failure to provide or use) health care services or  
7        medical products, such as past and future medical  
8        expenses, loss of past and future earnings, cost of  
9        obtaining domestic services, loss of employment, and  
10       loss of business or employment opportunities, unless  
11       otherwise defined under applicable State law. In no  
12       circumstances shall damages for health care services  
13       or medical products exceed the amount actually paid  
14       or incurred by or on behalf of the claimant.

15           (6) FUTURE DAMAGES.—The term “future  
16        damages” means any damages that are incurred  
17        after the date of judgment, settlement, or other reso-  
18        lution (including mediation, or any other form of al-  
19        ternative dispute resolution).

20           (7) HEALTH CARE LAWSUIT.—The term  
21        “health care lawsuit” means any health care liability  
22        claim concerning the provision of goods or services  
23        for which coverage was provided in whole or in part  
24        via a Federal program, subsidy or tax benefit, or  
25        any health care liability action concerning the provi-



1 sion of goods or services for which coverage was pro-  
2 vided in whole or in part via a Federal program,  
3 subsidy or tax benefit, brought in a State or Federal  
4 court or pursuant to an alternative dispute resolu-  
5 tion system, against a health care provider regard-  
6 less of the theory of liability on which the claim is  
7 based, or the number of claimants, plaintiffs, de-  
8 fendants, or other parties, or the number of claims  
9 or causes of action, in which the claimant alleges a  
10 health care liability claim. Such term does not in-  
11 clude a claim or action which is based on criminal  
12 liability; which seeks civil fines or penalties paid to  
13 Federal, State, or local government; or which is  
14 grounded in antitrust.

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

24 (9) HEALTH CARE LIABILITY CLAIM.—The  
25 term “health care liability claim” means a demand

1 by any person, whether or not pursuant to ADR,  
2 against a health care provider, including, but not  
3 limited to, third-party claims, cross-claims, counter-  
4 claims, or contribution claims, which are based upon  
5 the provision or use of (or the failure to provide or  
6 use) health care services or medical products, re-  
7 gardless of the theory of liability on which the claim  
8 is based, or the number of plaintiffs, defendants, or  
9 other parties, or the number of causes of action.

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

20 (11) HEALTH CARE SERVICES.—The term  
21 “health care services” means the provision of any  
22 goods or services (including safety, professional, or  
23 administrative services directly related to health  
24 care) by a health care provider, or by any individual  
25 working under the supervision of a health care pro-

1 vider, that relates to the diagnosis, prevention, or  
2 treatment of any human disease or impairment, or  
3 the assessment or care of the health of human  
4 beings.

5 (12) MEDICAL PRODUCT.—The term “medical  
6 product” means a drug, device, or biological product  
7 intended for humans, and the terms “drug”, “de-  
8 vice”, and “biological product” have the meanings  
9 given such terms in sections 201(g)(1) and 201(h)  
10 of the Federal Food, Drug and Cosmetic Act (21  
11 U.S.C. 321(g)(1) and (h)) and section 351(a) of the  
12 Public Health Service Act (42 U.S.C. 262(a)), re-  
13 spectively, including any component or raw material  
14 used therein, but excluding health care services.

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

1 or medical products, unless otherwise defined under  
2 applicable State law.

3 (14) RECOVERY.—The term “recovery” means  
4 the net sum recovered after deducting any disburse-  
5 ments or costs incurred in connection with prosecu-  
6 tion or settlement of the claim, including all costs  
7 paid or advanced by any person. Costs of health care  
8 incurred by the plaintiff and the attorneys’ office  
9 overhead costs or charges for legal services are not  
10 deductible disbursements or costs for such purpose.

11 (15) REPRESENTATIVE.—The term “represent-  
12 ative” means a legal guardian, attorney, person des-  
13 ignated to make decisions on behalf of a patient  
14 under a medical power of attorney, or any person  
15 recognized in law or custom as a patient’s agent.

16 (16) STATE.—The term “State” means each of  
17 the several States, the District of Columbia, the  
18 Commonwealth of Puerto Rico, the Virgin Islands,  
19 Guam, American Samoa, the Northern Mariana Is-  
20 lands, the Trust Territory of the Pacific Islands, and  
21 any other territory or possession of the United  
22 States, or any political subdivision thereof.

23 **SEC. 382. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

24 (a) STATUTE OF LIMITATIONS.—

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

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

7                   (B) Three years after the date the medical  
8                   or health care treatment that is the subject of  
9                   the claim is completed.

10                  (C) One year after the claimant discovers,  
11                  or through the use of reasonable diligence  
12                  should have discovered, the injury.

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

20                   (A) upon proof of fraud;

21                   (B) intentional concealment; or

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

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

20      (b) STATE FLEXIBILITY.—No provision of subsection  
21 (a) shall be construed to preempt any State law (whether  
22 effective before, on, or after the date of the enactment of  
23 this Act) that—

24           (1) specifies a time period of less than 3 years  
25      after the date of injury or less than 1 year after the

1 claimant discovers, or through the use of reasonable  
2 diligence should have discovered, the injury, for the  
3 filing of a health care lawsuit;

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

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

8 (4) establishes a statute of repose for the filing  
9 of a health care lawsuit.

10 **SEC. 383. COMPENSATING PATIENT INJURY.**

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

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

22 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC  
23 DAMAGES.—For purposes of applying the limitation in  
24 subsection (b), future noneconomic damages shall not be  
25 discounted to present value. The jury shall not be in-

1 formed about the maximum award for noneconomic dam-  
2 ages. An award for noneconomic damages in excess of  
3 \$250,000 shall be reduced either before the entry of judg-  
4 ment, or by amendment of the judgment after entry of  
5 judgment, and such reduction shall be made before ac-  
6 counting for any other reduction in damages required by  
7 law. If separate awards are rendered for past and future  
8 noneconomic damages and the combined awards exceed  
9 \$250,000, the future noneconomic damages shall be re-  
10 duced first.

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

23 (e) STATE FLEXIBILITY.—No provision of this sec-  
24 tion shall be construed to preempt any State law (whether  
25 effective before, on, or after the date of the enactment of



1 this Act) that specifies a particular monetary amount of  
2 economic or noneconomic damages (or the total amount  
3 of damages) that may be awarded in a health care lawsuit,  
4 regardless of whether such monetary amount is greater  
5 or lesser than is provided for under this section.

6 **SEC. 384. MAXIMIZING PATIENT RECOVERY.**

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

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

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

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

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

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

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

20   **SEC. 385. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**  
21                   **AGES TO CLAIMANTS IN HEALTH CARE LAW-**  
22                   **SUITS.**

23      (a) IN GENERAL.—In any health care lawsuit, if an  
24      award of future damages, without reduction to present  
25      value, equaling or exceeding \$50,000 is made against a

1 party with sufficient insurance or other assets to fund a  
2 periodic payment of such a judgment, the court shall, at  
3 the request of any party, enter a judgment ordering that  
4 the future damages be paid by periodic payments, in ac-  
5 cordance with the Uniform Periodic Payment of Judg-  
6 ments Act promulgated by the National Conference of  
7 Commissioners on Uniform State Laws.

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

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

17 **SEC. 386. PRODUCT LIABILITY FOR HEALTH CARE PRO-**  
18 **VIDERS.**

19 A health care provider who prescribes, or who dis-  
20 penses pursuant to a prescription, a medical product ap-  
21 proved, licensed, or cleared by the Food and Drug Admin-  
22 istration shall not be named as a party to a product liabil-  
23 ity lawsuit involving such product and shall not be liable  
24 to a claimant in a class action lawsuit against the manu-  
25 facturer, distributor, or seller of such product.

1 **SEC. 387. EFFECT ON OTHER LAWS.**

2 (a) VACCINE INJURY.—

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

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

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

12 (2) If there is an aspect of a civil action  
13 brought for a vaccine-related injury or death to  
14 which a Federal rule of law under title XXI of the  
15 Public Health Service Act does not apply, then this  
16 subtitle or otherwise applicable law (as determined  
17 under this subtitle) will apply to such aspect of such  
18 action.

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

23 **SEC. 388. LIMITATION ON EXPERT WITNESS TESTIMONY.**

24 (a) IN GENERAL.—No person in a health care profes-  
25 sion requiring licensure under the laws of a State shall

1 be competent to testify in any court of law to establish  
2 the following facts—

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

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

13           (3) that as a proximate result of the defend-  
14 ant's negligent act or omission, the claimant suf-  
15 fered injuries which would not otherwise have oc-  
16 curred,

17 unless the person was licensed to practice, in the State  
18 or a contiguous bordering State, a profession or specialty  
19 which would make the person's expert testimony relevant  
20 to the issues in the case and had practiced this profession  
21 or specialty in one of these States during the year pre-  
22 ceding the date that the alleged injury or wrongful act  
23 occurred.

1 (b) APPLICABILITY.—The requirements set forth in  
2 subsection (a) shall also apply to expert witnesses testi-  
3 fying for the defendant as rebuttal witnesses.

4 (c) WAIVER AUTHORITY.—The court may waive the  
5 requirements in this subsection if it determines that the  
6 appropriate witnesses otherwise would not be available.

7 **SEC. 389. EXPERT WITNESS QUALIFICATIONS.**

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

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

24 (2) During the 1-year period immediately pre-  
25 ceding the occurrence of the action that gave rise to

1 the lawsuit, the expert witness shall have devoted a  
2 majority of the individual's professional time to one  
3 or more of the following:

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

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

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

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

23 (B) Instruction of students in an accred-  
24 ited health professional school or accredited

1           residency or clinical research program in the  
2           same health profession as the defendant.

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

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

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

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

22 **SEC. 390. COMMUNICATIONS FOLLOWING UNANTICIPATED**  
23 **OUTCOME.**

24          (a) PROVIDER COMMUNICATIONS.—In any health  
25 care liability action, any and all statements, affirmations,



1 gestures, or conduct expressing apology, fault, sympathy,  
2 commiseration, condolence, compassion, or a general sense  
3 of benevolence which are made by a health care provider  
4 or an employee of a health care provider to the patient,  
5 a relative of the patient, or a representative of the patient  
6 and which relate to the discomfort, pain, suffering, injury,  
7 or death of the patient as the result of the unanticipated  
8 outcome of medical care shall be inadmissible for any pur-  
9 pose as evidence of an admission of liability or as evidence  
10 of an admission against interest.

11 (b) STATE FLEXIBILITY.—No provision of this sec-  
12 tion shall be construed to preempt any State law (whether  
13 effective before, on, or after the date of the enactment of  
14 this Act) that makes additional communications inadmis-  
15 sible as evidence of an admission of liability or as evidence  
16 of an admission against interest.

17 **SEC. 391. AFFIDAVIT OF MERIT.**

18 (a) REQUIRED FILING.—Subject to subsection (b),  
19 the plaintiff in a health care lawsuit alleging negligence  
20 or, if the plaintiff is represented by an attorney, the plain-  
21 tiff's attorney shall file simultaneously with the health  
22 care lawsuit an affidavit of merit signed by a health pro-  
23 fessional who meets the requirements for an expert wit-  
24 ness under section 242 of this Act. The affidavit of merit  
25 shall certify that the health professional has reviewed the

1 notice and all medical records supplied to him or her by  
2 the plaintiff's attorney concerning the allegations con-  
3 tained in the notice and shall contain a statement of each  
4 of the following:

5 (1) The applicable standard of practice or care.

6 (2) The health professional's opinion that the  
7 applicable standard of practice or care was breached  
8 by the health professional or health facility receiving  
9 the notice.

10 (3) The actions that should have been taken or  
11 omitted by the health professional or health facility  
12 in order to have complied with the applicable stand-  
13 ard of practice or care.

14 (4) The manner in which the breach of the  
15 standard of practice or care was the proximate cause  
16 of the injury alleged in the notice.

17 (5) A listing of the medical records reviewed.

18 (b) FILING EXTENSION.—Upon motion of a party for  
19 good cause shown, the court in which the complaint is filed  
20 may grant the plaintiff or, if the plaintiff is represented  
21 by an attorney, the plaintiff's attorney an additional 28  
22 days in which to file the affidavit required under sub-  
23 section (a).

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

1 effective before, on, or after the date of the enactment of  
2 this Act) that establishes additional requirements for the  
3 filing of an affidavit of merit or similar pre-litigation docu-  
4 mentation.

5 **SEC. 392. NOTICE OF INTENT TO COMMENCE LAWSUIT.**

6 (a) **ADVANCE NOTICE.**—A person shall not com-  
7 mence a health care lawsuit against a health care provider  
8 unless the person has given the health care provider 90  
9 days written notice before the action is commenced.

10 (b) **EXCEPTIONS.**—A health care lawsuit against a  
11 health care provider filed within 6 months of the statute  
12 of limitations expiring as to any claimant, or within 1 year  
13 of the statute of repose expiring as to any claimant, shall  
14 be exempt from compliance with this section.

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 a different time period for the  
19 filing of written notice.

20 **SEC. 393. LIMITATION ON LIABILITY FOR VOLUNTEER**  
21 **HEALTH CARE PROFESSIONALS.**

22 (a) **IN GENERAL.**—Title II of the Public Health Serv-  
23 ice Act (42 U.S.C. 202 et seq.) is amended by inserting  
24 after section 224 the following:

1 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**  
2 **HEALTH CARE PROFESSIONALS.**

3 “(a) LIMITATION ON LIABILITY.—A physician shall  
4 not be liable under Federal or State law in any civil action  
5 for any harm caused by an act or omission of such physi-  
6 cian, or attending medical personnel supporting such phy-  
7 sician, if such act or omission—

8 “(1) occurs in the course of furnishing qualified  
9 charity care (as such term is defined in section  
10 199B of the Internal Revenue Code of 1986); and

11 “(2) was not grossly negligent.

12 “(b) PREEMPTION.—This section preempts the laws  
13 of a State or any political subdivision of a State to the  
14 extent that such laws are inconsistent with this section,  
15 unless such laws provide greater protection from liability  
16 for a defendant.

17 “(c) DEFINITIONS.—In this section:

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

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

25 (b) EFFECTIVE DATE.—The amendments made by  
26 this section shall apply to any claim filed to the extent

1 that it is with respect to acts or omissions occurring after  
2 the date of the enactment of this Act.

3 **SEC. 394. RULES OF CONSTRUCTION.**

4 (a) HEALTH CARE LAWSUITS.—Unless otherwise  
5 specified in this subtitle, the provisions governing health  
6 care lawsuits set forth in this subtitle preempt, subject to  
7 subsections (b) and (c), State law to the extent that State  
8 law prevents the application of any provisions of law estab-  
9 lished by or under this subtitle. The provisions governing  
10 health care lawsuits set forth in this subtitle supersede  
11 chapter 171 of title 28, United States Code, to the extent  
12 that such chapter—

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

18 (2) prohibits the introduction of evidence re-  
19 garding collateral source benefits, or mandates or  
20 permits subrogation or a lien on collateral source  
21 benefits.

22 (b) PROTECTION OF STATES' RIGHTS AND OTHER  
23 LAWS.—Any issue that is not governed by any provision  
24 of law established by or under this subtitle (including

1 State standards of negligence) shall be governed by other-  
2 wise applicable State or Federal law.

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

7 **SEC. 395. EFFECTIVE DATE.**

8 This subtitle shall apply to any health care lawsuit  
9 brought in a Federal or State court, or subject to an alter-  
10 native dispute resolution system, that is initiated on or  
11 after the date of the enactment of this subtitle, except that  
12 any health care lawsuit arising from an injury occurring  
13 prior to the date of the enactment of this subtitle shall  
14 be governed by the applicable statute of limitations provi-  
15 sions in effect at the time the cause of action accrued.

16 **TITLE IV—MEDICARE AND**  
17 **MEDICAID REFORMS**  
18 **Subtitle A—Medicaid Reforms**

19 **SEC. 401. MEDICAID PAYMENT REFORM.**

20 (a) IN GENERAL.—Title XIX of the Social Security  
21 Act (42 U.S.C. 1396 et seq.) is amended by inserting after  
22 section 1903 the following section:

23 **“SEC. 1903A. REFORMED PAYMENT TO STATES.**

24 **“(a) REFORMED PAYMENT SYSTEM.—**

1           “(1) IN GENERAL.—For quarters beginning on  
2           or after the implementation date (as defined in sub-  
3           section (k)(1)), in the case of a State that elects (in  
4           a time and manner specified by the Secretary) to  
5           apply this section, in lieu of amounts otherwise pay-  
6           able to such State under this title (including any  
7           payments attributable to section 1923), except as  
8           otherwise provided in this section, the amount pay-  
9           able to such State shall be equal to the sum of the  
10          following:

11                 “(A) ADJUSTED AGGREGATE BENE-  
12                 FICIARY-BASED AMOUNT.—The aggregate bene-  
13                 ficiary-based amount specified in subsection (b)  
14                 for the quarter and the State, adjusted under  
15                 subsection (e).

16                 “(B) CHRONIC CARE QUALITY BONUS.—  
17                 The amount (if any) of the chronic care quality  
18                 bonus payment specified in subsection (f) for  
19                 the quarter for the State.

20          “(2) REQUIREMENT OF STATE SHARE.—

21                 “(A) IN GENERAL.—A State shall make,  
22                 from non-Federal funds, expenditures in an  
23                 amount equal to its State share (as determined  
24                 under subparagraph (B)) for a quarter for  
25                 items, services, and other costs for which, but

1           for paragraph (1), Federal funds would have  
2           been payable under this title.

3           “(B) STATE SHARE.—The State share for  
4           a State for a quarter in a fiscal year is equal  
5           to the product of—

6                   “(i) the aggregate beneficiary-based  
7                   amount specified in subsection (b) for the  
8                   quarter and the State; and

9                   “(ii) the ratio of—

10                          “(I) the State percentage de-  
11                          scribed in subparagraph (D)(ii) for  
12                          such State and fiscal year; to

13                          “(II) the Federal percentage de-  
14                          scribed in subparagraph (D)(i) for  
15                          such State and fiscal year.

16           “(C) NONPAYMENT FOR FAILURE TO PAY  
17           STATE SHARE.—

18                   “(i) IN GENERAL.—If a State fails to  
19                   expend the amount required under sub-  
20                   paragraph (A) for a quarter in a fiscal  
21                   year, the amount payable to the State  
22                   under paragraph (1) shall be reduced by  
23                   the product of the amount by which the  
24                   State payment is less than the State share  
25                   and the ratio of—



1                   “(I) the Federal percentage de-  
2                   scribed in subparagraph (D)(i) for  
3                   such State and fiscal year; to

4                   “(II) the State percentage de-  
5                   scribed in subparagraph (D)(ii) for  
6                   such State and fiscal year.

7                   “(ii) GRACE PERIOD.—A State shall  
8                   not be considered to have failed to provide  
9                   payment of its required State share for a  
10                  quarter under subparagraph (A) if the ag-  
11                  gregate State payment towards the State’s  
12                  required State share for the 4-quarter pe-  
13                  riod beginning with such quarter exceeds  
14                  the required State share amount for such  
15                  4-quarter period.

16                  “(D) FEDERAL AND STATE PERCENT-  
17                  AGES.—In this paragraph, with respect to a  
18                  State and a fiscal year:

19                       “(i) FEDERAL PERCENTAGE.—The  
20                       Federal percentage described in this clause  
21                       is 75 percent or, if higher, the Federal  
22                       medical assistance percentage for such  
23                       State for such fiscal year.

24                       “(ii) STATE PERCENTAGE.—The State  
25                       percentage described in this clause is 100

1           percent minus the Federal percentage de-  
2           scribed in clause (i).

3           “(E) RULES FOR CREDITING TOWARD  
4           STATE SHARE.—

5                   “(i) GENERAL LIMITATION TO MATCH-  
6           ABLE EXPENDITURES.—A payment for ex-  
7           penditures shall not be counted toward the  
8           State share under subparagraph (A) unless  
9           Federal payments may be used for such  
10          expenditures consistent with paragraph  
11          (3)(B).

12                   “(ii) FURTHER LIMITATIONS ON AL-  
13          LOWABLE EXPENDITURES.—A payment for  
14          expenditures shall not be counted towards  
15          the State share under subparagraph (A) if  
16          the expenditure is for any of the following:

17                           “(I) ABORTION.—Expenditures  
18                           for an abortion.

19                           “(II) INTERGOVERNMENTAL  
20          TRANSFERS.—An expenditure that is  
21          attributable to an intergovernmental  
22          transfer.

23                           “(III) CERTIFIED PUBLIC EX-  
24          PENDITURES.—An expenditure that is

1                   attributable to certified public expend-  
2                   itures.

3                   “(iii) CREDITING FRAUD AND ABUSE  
4                   RECOVERIES.—Amounts recovered by a  
5                   State through the operation of its Medicaid  
6                   fraud and abuse control unit described in  
7                   section 1903(q) shall be fully counted to-  
8                   ward the State share under subparagraph  
9                   (A).

10                  “(F) CONSTRUCTION.—Nothing in the  
11                  paragraph shall be construed as preventing a  
12                  State from expending, from non-Federal funds,  
13                  an amount under this title in excess of the  
14                  amount of the State share.

15                  “(G) DETERMINATION BASED UPON SUB-  
16                  MITTED CLAIMS.—In applying this paragraph  
17                  with respect to expenditures of a State for a  
18                  quarter, the determination of the expenditures  
19                  for such State for such quarter shall be made  
20                  after the end of the period (which, as of the  
21                  date of the enactment of this section, is 2  
22                  years) for which the Secretary accepts claims  
23                  for payment under this title with respect to  
24                  such quarter.

25                  “(3) USE OF FEDERAL PAYMENTS.—

1           “(A) APPLICATION OF MEDICAID LIMITA-  
2           TIONS.—A State may only use Federal pay-  
3           ments received under subsection (a) for expend-  
4           itures for which Federal funds would have been  
5           payable under this title but for this section.

6           “(B) LIMITATION FOR CERTAIN ELIGI-  
7           BLES.—

8           “(i) APPLICATION OF 100 PERCENT  
9           FEDERAL POVERTY LINE LIMIT ON ELIGI-  
10          BILITY.—Subject to clause (iii), a State  
11          may not use such Federal payments to  
12          provide medical assistance for an indi-  
13          vidual who has an income (as determined  
14          under clause (ii)) that exceeds 100 percent  
15          of the poverty line (as defined in section  
16          2110(c)(5)) applicable to a family of the  
17          size involved.

18          “(ii) DETERMINATION OF INCOME  
19          USING MODIFIED ADJUSTED GROSS IN-  
20          COME WITHOUT ANY 5 PERCENT IN-  
21          CREASE.—In determining income for pur-  
22          poses of clause (i) under section  
23          1902(e)(14) (relating to modified adjusted  
24          gross income), the following rules shall  
25          apply:

1                   “(I) APPLICATION OF SPEND  
2 DOWN.—The State shall take into ac-  
3 count the costs incurred for medical  
4 care or for any other type of remedial  
5 care recognized under State law in the  
6 same manner and to the same extent  
7 that such State takes such costs into  
8 account for purposes of section  
9 1902(a)(17).

10                   “(II) DISREGARD OF 5 PERCENT  
11 INCREASE.—Subparagraph (I) of sec-  
12 tion 1902(e)(14) (relating to a 5 per-  
13 cent reduction) shall not apply.

14                   “(iii) EXCEPTION.—Clause (i) shall  
15 not apply to an individual who is—

16                   “(I) a woman described in clause  
17 (i) of section 1903(v)(4)(A);

18                   “(II) a child who is an individual  
19 described in clause (i) of section  
20 1905(a);

21                   “(III) enrolled in a State plan  
22 under this title as of the date of the  
23 enactment of this section for the pe-  
24 riod of continuous enrollment; or

1 “(IV) described in section  
2 1902(e)(14)(D) (relating to modified  
3 adjusted gross income).

4 “(iv) CLARIFICATION RELATED TO  
5 COMMUNITY SPOUSE.—Nothing in this  
6 subparagraph shall supersede the applica-  
7 tion of section 1924 (related to community  
8 spouse income and assets).

9 “(4) EXCEPTIONS FOR PASS-THROUGH PAY-  
10 MENTS.—

11 “(A) IN GENERAL.—Paragraph (1) shall  
12 not apply, and amounts shall continue to be  
13 payable under this title (and not under sub-  
14 section (a)), in the case of the following pay-  
15 ments (and related administrative costs and ex-  
16 penditures):

17 “(i) PAYMENTS TO TERRITORIES.—  
18 Payments to a State other than the 50  
19 States and the District of Columbia.

20 “(ii) MEDICARE COST-SHARING.—  
21 Payments attributable to Medicare cost-  
22 sharing under section 1905(p).

23 “(iii) PEDIATRIC VACCINES.—Pay-  
24 ments attributable to section 1928.

1 “(iv) EMERGENCY SERVICES FOR CER-  
2 TAIN INDIVIDUALS.—Payments for treat-  
3 ment of emergency medical conditions at-  
4 tributable to the application of section  
5 1903(v)(2).

6 “(v) INDIAN HEALTH CARE FACILI-  
7 TIES.—Payments for medical assistance  
8 described in the third sentence of section  
9 1905(b).

10 “(vi) EMPLOYER-SPONSORED INSUR-  
11 ANCE (ESI).—Payments for medical assist-  
12 ance attributable to payments to employers  
13 for employer-sponsored health benefits cov-  
14 erage.

15 “(vii) OTHER POPULATIONS WITH  
16 LIMITED BENEFIT COVERAGE.—Other pay-  
17 ments that are determined by the Sec-  
18 retary to be related to a specified popu-  
19 lation for which the medical assistance  
20 under this title is limited and does not in-  
21 clude any inpatient, nursing facility, or  
22 long-term care services.

23 “(B) CERTAIN EXPENSES.—Paragraph (1)  
24 shall not apply, and amounts shall continue to

1 be payable under this title (and not under sub-  
2 section (a)), in the case of the following:

3 “(i) ADMINISTRATION OF MEDICARE  
4 PRESCRIPTION DRUG BENEFIT.—Expendi-  
5 tures described in section 1935(b) (relating  
6 to administration of the Medicare prescrip-  
7 tion drug benefit).

8 “(ii) PAYMENTS FOR HIT BONUSES.—  
9 Payments under section 1903(a)(3)(F) (re-  
10 lating to payments to encourage the adop-  
11 tion and use of certified EHR technology).

12 “(iii) PAYMENTS FOR DESIGN, DEVEL-  
13 OPMENT, AND INSTALLATION OF MMIS AND  
14 ELIGIBILITY SYSTEMS.—Payments under  
15 subparagraphs (A)(i) and (H)(i) of section  
16 1903(a)(3) for expenditures for design, de-  
17 velopment, and installation of the Medicaid  
18 management information systems and  
19 mechanized verification and information  
20 retrieval systems (related to eligibility).

21 “(5) PAYMENT OF AMOUNTS.—

22 “(A) IN GENERAL.—Except as the Sec-  
23 retary may otherwise provide, amounts shall be  
24 payable to a State under subsection (a) in the  
25 same manner as amounts are payable under



1 subsection (d) of section 1903 to a State under  
2 subsection (a) of such section.

3 “(B) INFORMATION AND FORMS.—

4 “(i) SUBMISSION.—As a condition of  
5 receiving payment under subsection (a), a  
6 State shall submit such information, in  
7 such form, and manner, as the Secretary  
8 shall specify, including information nec-  
9 essary to make the computations under  
10 subsections (c)(2)(C) and (e).

11 “(ii) UNIFORM REPORTING.—The  
12 Secretary shall develop such forms as may  
13 be needed to assure a system of uniform  
14 reporting of such information across  
15 States.

16 “(C) REQUIRED REPORTING OF INFORMA-  
17 TION ON MEDICAL LOSS RATIOS FOR MANAGED  
18 CARE.—The information required to be reported  
19 under subparagraph (B)(i) shall include infor-  
20 mation on the medical loss ratio with respect to  
21 coverage provided under each Medicaid man-  
22 aged care plan with a contract with the State  
23 under section 1903(m) or 1932.

24 “(b) AGGREGATE BENEFICIARY-BASED AMOUNT.—

1           “(1) IN GENERAL.—The aggregate beneficiary-  
 2           based amount specified in this subsection for a State  
 3           for a quarter is equal to the sum of the products,  
 4           for each of the categories of Medicaid beneficiaries  
 5           specified in paragraph (2), of the following:

6                   “(A) BENEFICIARY-BASED QUARTERLY  
 7           AMOUNT.—The beneficiary-based quarterly  
 8           amount for such category computed under sub-  
 9           section (c) for such State for such quarter.

10                   “(B) NUMBER OF INDIVIDUALS IN CAT-  
 11           EGORY.—Subject to subsection (d), the average  
 12           number of Medicaid beneficiaries enrolled in  
 13           such category in the State in such quarter.

14           “(2) CATEGORIES.—The categories specified in  
 15           this paragraph are the following:

16                   “(A) ELDERLY.—A category of Medicaid  
 17           beneficiaries who are 65 years of age or older.

18                   “(B) BLIND OR DISABLED.—A category of  
 19           Medicaid beneficiaries not described in subpara-  
 20           graph (A) who are described in section  
 21           1937(a)(2)(B)(ii).

22                   “(C) CHILDREN.—A category of Medicaid  
 23           beneficiaries not described in subparagraph (B)  
 24           who are under 21 years of age.

1                   “(D) OTHER ADULTS.—A category of any  
2                   Medicaid beneficiaries who are not described in  
3                   a previous subparagraph of this paragraph.

4                   “(c) COMPUTATION OF PER BENEFICIARY, PER CAT-  
5                   EGORY QUARTERLY AMOUNT.—

6                   “(1) IN GENERAL.—For a State, for each cat-  
7                   egory of beneficiary for a quarter—

8                   “(A) FIRST REFORM YEAR.—For quarters  
9                   in the first reform year (as defined in sub-  
10                  section (k)(2)), the beneficiary-based quarterly  
11                  amount is equal to  $\frac{1}{4}$  of the base average per  
12                  beneficiary Federal payments for such State for  
13                  such category determined under paragraph (2),  
14                  increased by a factor that reflects the sum of  
15                  the following:

16                  “(i) HISTORICAL MEDICAL CARE COM-  
17                  PONENT OF CPI THROUGH PREVIOUS RE-  
18                  FORM YEAR.—The percentage increase in  
19                  the historical medical care component of  
20                  the Consumer Price Index for all urban  
21                  consumers (U.S. city average) from the  
22                  midpoint of the base fiscal year (as defined  
23                  in paragraph (6)) to the midpoint of the  
24                  fiscal year preceding the first reform year.

1                   “(ii) PROJECTED MEDICAL CARE COM-  
2                   PONENT OF CPI FOR THE FIRST REFORM  
3                   YEAR.—The percentage increase in the  
4                   projected medical care component of the  
5                   Consumer Price Index for all urban con-  
6                   sumers (U.S. city average) from the mid-  
7                   point of the previous fiscal year referred to  
8                   in clause (i) to the midpoint of the first re-  
9                   form year.

10                  “(B) SECOND AND THIRD REFORM  
11                  YEARS.—The beneficiary-based quarterly  
12                  amount for a State for a category for quarters  
13                  in the second reform year or the third reform  
14                  year is equal to the beneficiary-based quarterly  
15                  amount under this paragraph for such State  
16                  and category for the previous reform year in-  
17                  creased by the per beneficiary percentage in-  
18                  crease (as defined in subparagraph (E)) for  
19                  such category and reform year.

20                  “(C) FOURTH THROUGH TENTH REFORM  
21                  YEARS.—The beneficiary-based quarterly  
22                  amount for a State for a category for quarters  
23                  in a reform year beginning with the fourth re-  
24                  form year and ending with the tenth reform  
25                  year is—

1           “(i) in the case of a State that is a  
2           high per beneficiary State or a low per  
3           beneficiary State (as defined in paragraph  
4           (4)(B)(iii)) for the category, the amount  
5           determined under clause (i) or (ii) of para-  
6           graph (4)(B) for such State, category, and  
7           reform year; or

8           “(ii) in the case of any other State,  
9           the beneficiary-based quarterly amount  
10          under this paragraph for such State and  
11          category for the previous reform year in-  
12          creased by the per beneficiary percentage  
13          increase for such category and reform  
14          year.

15          “(D) ELEVENTH REFORM YEAR AND SUB-  
16          SEQUENT REFORM YEARS.—The beneficiary-  
17          based quarterly amount for a State for a cat-  
18          egory for quarters in a reform year beginning  
19          with the eleventh reform year is equal to the  
20          beneficiary-based quarterly amount under this  
21          paragraph for such State and category for the  
22          previous reform year increased by the per bene-  
23          ficiary percentage increase for such category  
24          and reform year.

1           “(E) ANNUAL PERCENTAGE INCREASE BE-  
 2           GINNING WITH SECOND REFORM YEAR.—For  
 3           purposes of this subsection, the term ‘per bene-  
 4           ficiary percentage increase’ means, for a reform  
 5           year, the sum of—

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

12                  “(ii) one percentage point.

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

15                   “(A) AVERAGE PER CATEGORY.—

16                   “(i) IN GENERAL.—The Secretary  
 17                   shall determine, consistent with this para-  
 18                   graph and paragraph (3), a base per bene-  
 19                   ficiary, per category amount for each of  
 20                   the 50 States and the District of Columbia  
 21                   equal to the average amount, per Medicaid  
 22                   beneficiary, of Federal payments under  
 23                   this title, including payments attributable  
 24                   to disproportionate share hospital pay-  
 25                   ments under section 1923, for each of the

1 categories of beneficiaries under subsection  
2 (b)(2) for the base fiscal year for each of  
3 the 50 States and the District of Colum-  
4 bia.

5 “(ii) BEST AVAILABLE DATA.—The  
6 determination under clause (i) shall ini-  
7 tially be estimated by the Secretary, based  
8 upon the best available data at the time  
9 the determination is made.

10 “(iii) UPDATES.—The determination  
11 under clause (i) shall be updated by the  
12 Secretary on an annual basis based upon  
13 improved data. The Secretary shall adjust  
14 the amounts under subsection (a)(1)(A) to  
15 reflect changes in the amounts so deter-  
16 mined based on such updates.

17 “(B) EXCLUSION OF PASS-THROUGH PAY-  
18 MENTS.—In computing base per beneficiary,  
19 per category amounts under subparagraph  
20 (A)(i) the Secretary shall exclude payments de-  
21 scribed in subsection (a)(4).

22 “(C) STANDARDIZATION.—

23 “(i) IN GENERAL.—In computing each  
24 such amount, the Secretary shall stand-

ardize the amount in order to remove the  
variation attributable to the following:

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

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

“(ii) METHOD OF STANDARDIZA-  
TION.—

“(I) CONSULTATION IN DEVEL-  
OPMENT OF RISK STANDARDIZA-  
TION.—In developing the methodology  
for risk standardization for purposes  
of clause (i)(I), the Secretary shall  
consult with the Medicaid and CHIP  
Payment and Access Commission, the  
Medicare Payment Advisory Commis-  
sion, and the National Association of  
Medicaid Directors.



1 “(II) METHOD FOR RISK STAND-  
2 ARDIZATION.—In carrying out clause  
3 (i)(I), the Secretary may apply the  
4 hierarchal condition category method-  
5 ology under section 1853(a)(1)(C). If  
6 the Secretary uses such methodology,  
7 the Secretary shall adjust the applica-  
8 tion of such methodology to take into  
9 account the differences in services  
10 provided under this title compared to  
11 title XVIII, such as the coverage of  
12 long term care, pregnancy, and pedi-  
13 atric services.

14 “(III) METHOD FOR GEOGRAPHIC  
15 STANDARDIZATION.—The Secretary  
16 shall apply the standardization under  
17 clause (i)(II) in a manner similar to  
18 that applied under section  
19 1853(e)(4)(A)(iii).

20 “(iii) APPLICATION ON A NATIONAL,  
21 BUDGET NEUTRAL BASIS.—The standard-  
22 ization under clause (i) shall be designed  
23 and implemented on a uniform national  
24 basis and shall be budget neutral so as to

1 not result in any aggregate change in pay-  
2 ments under subsection (a).

3 “(iv) RESPONSE TO NEW RISK.—Sub-  
4 ject to clause (iii), the Secretary may ad-  
5 just the standardization under clause (i) to  
6 respond promptly to new instances of com-  
7 municable diseases and other public health  
8 hazards.

9 “(v) REFERENCE TO APPLICATION OF  
10 RISK ADJUSTMENT.—For rules related to  
11 the application of risk adjustment to  
12 amounts under subsection (a)(1)(A), see  
13 subsection (e).

14 “(D) ADJUSTMENT FOR TEMPORARY FMAP  
15 INCREASES.—In computing each base per bene-  
16 ficiary, per category amounts under subpara-  
17 graph (A)(i) the Secretary shall disregard por-  
18 tions of payments that are attributable to a  
19 temporary increase in the Federal matching  
20 rates, including those attributable to the fol-  
21 lowing:

22 “(i) PPACA DISASTER FMAP.—Sec-  
23 tion 1905(aa).

1 “(ii) ARRA.—Section 5001 of the  
2 American Recovery and Reinvestment Act  
3 of 2009 (42 U.S.C. 1396d note).

4 “(iii) EXTRAORDINARY EMPLOYER  
5 PENSION CONTRIBUTION.—Section 614 of  
6 the Children’s Health Insurance Program  
7 Reauthorization Act of 2009 (42 U.S.C.  
8 1396d note).

9 “(3) ALLOCATION OF NONMEDICAL ASSISTANCE  
10 PAYMENTS.—The Secretary shall establish rules for  
11 the allocation of payments under this title (other  
12 than those payments described in paragraph (1) or  
13 (5) of section 1903(a) and including such payments  
14 attributable to section 1923)—

15 “(A) among different categories of bene-  
16 ficiaries; and

17 “(B) between payments included under  
18 subsection (a)(1) and payments described in  
19 subsection (a)(4).

20 “(4) TRANSITION TO A CORRIDOR AROUND THE  
21 NATIONAL AVERAGE.—

22 “(A) DETERMINATION OF NATIONAL AVER-  
23 AGE BASE PER BENEFICIARY, PER CATEGORY  
24 AMOUNT.—Subject to subparagraph (C), the  
25 Secretary shall determine a national average

base per beneficiary, per category amount equal to the average of the base per beneficiary, per category amounts for each of the 50 States and the District of Columbia determined under paragraph (2), weighted by the average number of beneficiaries in each such category and State as determined by the Secretary consistent with subsection (d) for the base fiscal year.

“(B) TRANSITION ADJUSTMENT.—

“(i) HIGH PER BENEFICIARY STATES.—In the case of a high per beneficiary State (as defined in clause (iii)(I)) for a category, the beneficiary-based quarterly amount for such State and category for a quarter in a reform year (beginning with the fourth reform year and ending with the tenth reform year) is equal to the sum of—

“(I) the product of the State-specific factor for such reform year (as defined in clause (iv)) and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for such State and category if the State were a State de-

scribed in clause (ii) of paragraph (1)(C), instead of a State described in clause (i) of such paragraph; and

“(II) the product of 1 minus the State-specific factor for such reform year and the beneficiary-based quarterly amount that would otherwise be determined under paragraph (1) for a State and category if the base per beneficiary, per category amount determined under paragraph (2) for the State and category were equal to 110 percent of the national average base per beneficiary, per category amount determined under subparagraph (A) for such category.

“(ii) LOW PER BENEFICIARY STATES.—In the case of a low per beneficiary State (as defined in clause (iii)(II)) for a category, the beneficiary-based quarterly amount for such State and category for a quarter in a reform year (beginning with the fourth reform year and ending with the tenth reform year) is equal to the sum of—

1           “(I) the product of the State-spe-  
2           cific factor for such reform year and  
3           the beneficiary-based quarterly  
4           amount that would otherwise be deter-  
5           mined under paragraph (1) for such  
6           State and category if the State were  
7           a State described in clause (ii) of  
8           paragraph (1)(C), instead of a State  
9           described in clause (i) of such para-  
10          graph; and

11          “(II) the product of 1 minus the  
12          State-specific factor for such reform  
13          year and the beneficiary-based quar-  
14          terly amount that would otherwise be  
15          determined under paragraph (1) for a  
16          State and category if the base per  
17          beneficiary, per category amount de-  
18          termined under paragraph (2) for the  
19          State and category were equal to 90  
20          percent of the national average base  
21          per beneficiary, per category amount  
22          determined under subparagraph (A)  
23          for such category.

1           “(iii) HIGH AND LOW PER BENE-  
2           FICIARY STATES DEFINED.—In this sub-  
3           paragraph:

4                   “(I) HIGH PER BENEFICIARY  
5           STATE.—The term ‘high per bene-  
6           ficiary State’ means, with respect to a  
7           category, a State for which the base  
8           per beneficiary, per category amount  
9           determined under paragraph (2) for  
10          such category is greater than 110 per-  
11          cent of the national average base per  
12          beneficiary, per category amount de-  
13          termined under subparagraph (A) for  
14          such category.

15                   “(II) LOW PER BENEFICIARY  
16          STATE.—The term ‘low per bene-  
17          ficiary State’ means, with respect to a  
18          category, a State for which the base  
19          per beneficiary, per category amount  
20          determined under paragraph (2) for  
21          such category is less than 90 percent  
22          of the national average base per bene-  
23          ficiary, per category amount deter-  
24          mined under subparagraph (A) for  
25          such category.

1                   “(iv) STATE-SPECIFIC FACTOR.—In  
2                   this subparagraph, the term ‘State-specific  
3                   factor’ means—

4                   “(I) for the fourth reform year,  
5                    $\frac{7}{8}$ ; and

6                   “(II) for a subsequent reform  
7                   year, the State-specific factor under  
8                   this clause for the previous reform  
9                   year minus  $\frac{1}{8}$ .

10                  “(C) NO ADDITIONAL EXPENDITURES.—

11                  “(i) DETERMINATION OF INCREASE IN  
12                  FEDERAL EXPENDITURES.—For each cat-  
13                  egory for each reform year (beginning with  
14                  the fourth reform year and ending with the  
15                  tenth reform year), the Secretary shall de-  
16                  termine whether the application of this  
17                  paragraph—

18                  “(I) to the category for the re-  
19                  form year will result in an aggregate  
20                  increase in the aggregate Federal ex-  
21                  penditures under subsection (a); and

22                  “(II) to all the categories for the  
23                  reform year will result in a net aggre-  
24                  gate increase in the aggregate Federal  
25                  expenditures under subsection (a).



1                   “(ii) ADJUSTMENT.—If the Secretary  
2                   determines under clause (i)(II) that the  
3                   application of this paragraph to all the cat-  
4                   egories for a reform year will result in a  
5                   net aggregate increase in the aggregate  
6                   Federal expenditures under subsection (a),  
7                   the Secretary shall reduce the national av-  
8                   erage base per beneficiary, per category  
9                   amount computed under subparagraph (A)  
10                  for each of the categories determined  
11                  under clause (i)(I) for which there will be  
12                  an aggregate increase in the aggregate  
13                  Federal expenditures under subsection (a)  
14                  by such uniform percentage as will ensure  
15                  that there is no net aggregate Federal ex-  
16                  penditure increase described in clause  
17                  (i)(II) for the reform year.

18                  “(5) REPORTS ON PER BENEFICIARY RATES;  
19                  APPEALS.—

20                  “(A) REPORT TO STATES.—Not later than  
21                  8 months after the date of the enactment of  
22                  this section, the Secretary shall submit to each  
23                  State the Secretary’s initial determination of—

1 “(i) the base per beneficiary, per cat-  
2 egory amounts under paragraph (2) for  
3 such State; and

4 “(ii) the national average base per  
5 beneficiary, per category amounts under  
6 paragraph (4)(A).

7 “(B) OPPORTUNITY TO APPEAL.—Not  
8 later than 3 months after the date a State re-  
9 ceives notice of the Secretary’s initial deter-  
10 mination of such base per beneficiary, per cat-  
11 egory amounts for such State under subpara-  
12 graph (A)(i), the State may file with the Sec-  
13 retary, in a form and manner specified by the  
14 Secretary, an appeal of such determination.

15 “(C) DETERMINATION ON APPEAL.—Not  
16 later than 3 months after receiving such an ap-  
17 peal, the Secretary shall make a final deter-  
18 mination on such amounts for such State. If no  
19 such appeal is received for a State, the Sec-  
20 retary’s initial determination under subpara-  
21 graph (A)(i) shall become final.

22 “(6) BASE FISCAL YEAR DEFINED.—In this  
23 section, the term ‘base fiscal year’ means the latest  
24 fiscal year, ending before the date of the enactment  
25 of this section, for which the Secretary determines

1       that adequate data are available to make the com-  
2       putations required under this subsection.

3       “(d) NOT COUNTING INDIVIDUALS TO ACCOUNT FOR  
4 EXCLUDED PAYMENTS.—Under rules specified by the  
5 Secretary, individuals shall not be counted as Medicaid  
6 beneficiaries for purposes of subsection (b)(1)(B) and sub-  
7 section (c)(2)(A) to the extent that such individuals—

8               “(1) are receiving medical assistance for which  
9       payments described under subsection (a)(4)(A) are  
10      made; or

11              “(2) would not have been eligible to enroll  
12      under the State plan (or waiver of such plan) in the  
13      State in which such individual is so enrolled if the  
14      rules for eligibility for enrollment under such plan  
15      (or waiver) were the same as such rules for eligi-  
16      bility in effect as of January 1, 2009.

17      “(e) RISK ADJUSTMENT.—

18              “(1) IN GENERAL.—The amount under sub-  
19      section (a)(1)(A) shall be adjusted under this sub-  
20      section in an appropriate manner, specified by the  
21      Secretary and consistent with paragraph (2), to take  
22      into account—

23                      “(A) the factors described in subsection  
24                      (c)(2)(C)(i)(I) within a category of bene-  
25                      ficiaries; and

1 “(B) variations in costs on a county-by-  
2 county basis for medical assistance and admin-  
3 istrative expenses.

4 “(2) METHOD OF ADJUSTMENT.—

5 “(A) IN GENERAL.—The adjustments  
6 under paragraph (1) shall be made in a manner  
7 similar to the manner in which similar adjust-  
8 ments are made under subsection (c)(2)(C) and  
9 consistent with the requirements of clause (iii)  
10 of such subsection and subparagraph (B).

11 “(B) BIENNIAL UPDATE OF RISK ADJUST-  
12 MENT METHODOLOGY.—In applying clause  
13 (i)(I) of subsection (c)(2)(C) for purposes of  
14 subparagraph (A), the Secretary shall, in con-  
15 sultation with the entities described in clause  
16 (ii)(I) of such subsection, update the risk ad-  
17 justment methodology applied as appropriate  
18 not less often than every 2 years.

19 “(f) CHRONIC CARE QUALITY BONUS PAYMENTS.—

20 “(1) DETERMINATION OF BONUS PAYMENTS.—

21 If the Secretary determines that, based on the re-  
22 ports under paragraph (5), with respect to cat-  
23 egories of chronic disease for which chronic care per-  
24 formance targets had been established under para-  
25 graph (3) for each category of Medicaid beneficiaries

1 specified under subsection (b)(2) such targets have  
2 been met by a State for a reform year, the Secretary  
3 shall make an additional payment to such State in  
4 the amount specified in paragraph (6) for each quar-  
5 ter in the succeeding reform year. Such payments  
6 shall be made in a manner specified by the Secretary  
7 and may only be used consistent with subsection  
8 (a)(3).

9 “(2) IDENTIFICATION OF CATEGORIES OF  
10 CHRONIC DISEASE.—The Secretary shall determine  
11 the categories of chronic disease for which bonus  
12 payments may be available under this subsection for  
13 each category of Medicaid beneficiaries.

14 “(3) ADOPTION OF QUALITY MEASUREMENT  
15 SYSTEM AND IDENTIFICATION OF PERFORMANCE  
16 TARGETS.—

17 “(A) SYSTEM AND DATA.—With respect to  
18 the categories of chronic disease under para-  
19 graph (2), the Secretary shall adopt a quality  
20 measurement system that uses data described  
21 in paragraph (4) and is similar to the Five-Star  
22 Quality Rating System used to indicate the per-  
23 formance of Medicare Advantage plans under  
24 part C of title XVIII.

1           “(B) TARGETS.—Using such system and  
2           data, the Secretary shall establish for each re-  
3           form year the chronic care performance targets  
4           for purposes of the payments under paragraph  
5           (1). Such performance targets shall be estab-  
6           lished in consultation with States, associations  
7           representing individuals with chronic illnesses,  
8           entities providing treatment to such individuals  
9           for such chronic illnesses, and other stake-  
10          holders, including the National Association of  
11          Medicaid Directors and the National Governors  
12          Association.

13          “(4) DATA TO BE USED.—The data to be used  
14          under paragraph (3) shall include—

15               “(A) data collected through methods such  
16               as—

17                   “(i) the ‘Healthcare Effectiveness  
18                   Data and Information Set’ (also known as  
19                   ‘HEDIS’) (or an appropriate successor  
20                   performance measurement tool);

21                   “(ii) the ‘Consumer Assessment of  
22                   Healthcare Providers and Systems’ (also  
23                   known as ‘CAHPS’) (or an appropriate  
24                   successor performance measurement tool);  
25                   and

1 “(iii) the ‘Health Outcomes Survey’  
2 (also known as ‘HOS’) (or an appropriate  
3 successor performance measurement tool);  
4 and  
5 “(B) other data collected by the State.

6 “(5) REPORTS.—

7 “(A) IN GENERAL.—Each State shall col-  
8 lect, analyze, and report to the Secretary, at a  
9 frequency and in a manner to be established by  
10 the Secretary, data described in paragraph (4)  
11 that permit the Secretary to monitor the State’s  
12 performance relative to the chronic care per-  
13 formance targets established under paragraph  
14 (3).

15 “(B) REVIEW AND VERIFICATION.—The  
16 Secretary may review the data collected by the  
17 State under subparagraph (A) to verify the  
18 State’s analysis of such data with respect to the  
19 performance targets under paragraph (3).

20 “(6) AMOUNT OF BONUS PAYMENTS.—

21 “(A) IN GENERAL.—Subject to subpara-  
22 graphs (B) and (C), with respect to each cat-  
23 egory of Medicaid beneficiaries, in the case of  
24 a State that the Secretary determines, based on  
25 the chronic care performance targets set under

1 paragraph (3) for a reform year for such cat-  
2 egory, performs—

3 “(i) in the top five States in such cat-  
4 egory, subject to subparagraph (C)(ii), the  
5 amount of the bonus for each quarter in  
6 the succeeding reform year shall be 10 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 “(ii) in the next five States in such  
12 category, subject to subparagraph (C)(ii),  
13 the amount of the bonus for each such  
14 quarter shall be 5 percent of the payment  
15 amount otherwise paid to the State under  
16 subsection (a) for individuals enrolled  
17 under the plan within such category;

18 “(iii) in the next five States in such  
19 category, subject to clauses (i) and (iii) of  
20 subparagraph (C), the amount of the  
21 bonus for each such quarter shall be 3 per-  
22 cent of the payment amount otherwise paid  
23 to the State under subsection (a) for indi-  
24 viduals enrolled under the plan within such  
25 category;



1           “(iv) in the next five States in such  
2           category, subject to clauses (i) and (iii) of  
3           subparagraph (C), the amount of the  
4           bonus for each such quarter shall be 2 per-  
5           cent of the payment amount otherwise paid  
6           to the State under subsection (a) for indi-  
7           viduals enrolled under the plan within such  
8           category; and

9           “(v) in the next five States in such  
10          category, subject to clauses (i) and (iii) of  
11          subparagraph (C), the amount of the  
12          bonus for each such quarter shall be 1 per-  
13          cent of the payment amount otherwise paid  
14          to the State under subsection (a) for indi-  
15          viduals enrolled under the plan within such  
16          category.

17          “(B) AGGREGATE ANNUAL LIMIT FOR  
18          EACH CATEGORY OF MEDICAID BENE-  
19          FICIARIES.—

20               “(i) IN GENERAL.—In no case may  
21               the aggregate amount of bonuses under  
22               this subsection for quarters in a reform  
23               year for a category of Medicaid bene-  
24               ficiaries exceed the limit specified in clause  
25               (ii) for the reform year.

1                   “(ii) LIMIT.—The limit specified in  
2 this clause—

3                   “(I) for the second reform year is  
4 equal to \$250,000,000; or

5                   “(II) for a subsequent reform  
6 year is equal to the limit specified in  
7 this clause for the previous reform  
8 year increased by the per beneficiary  
9 percentage increase determined under  
10 paragraph (1)(E) of subsection (c).

11                   “(C) LIMITATION AND PRORATION OF BO-  
12 NUSES BASED ON APPLICATION OF AGGREGATE  
13 LIMIT.—

14                   “(i) NO BONUS FOR THIRD OR SUBSE-  
15 QUENT TIERS UNLESS AGGREGATE LIMIT  
16 NOT REACHED ON FIRST TWO TIERS.—No  
17 bonus shall be payable under clause (iii),  
18 (iv), or (v) of subparagraph (A) for a cat-  
19 egory of Medicaid beneficiaries for a quar-  
20 ter in a reform year unless the aggregate  
21 amount of bonuses under clauses (i) and  
22 (ii) of such subparagraph for such category  
23 and reform year is less than the limit spec-  
24 ified in subparagraph (B)(ii) for the re-  
25 form year.

1                   “(ii) PRORATION FOR FIRST TWO  
2                   TIERS.—If the aggregate amount of bo-  
3                   nuses under clauses (i) and (ii) of subpara-  
4                   graph (A) for a category of Medicaid bene-  
5                   ficiaries for quarters in a reform year ex-  
6                   ceeds the limit specified in subparagraph  
7                   (B)(ii) for the reform year, the amount of  
8                   each such bonus shall be prorated in a  
9                   manner so the aggregate amount of such  
10                  bonuses is equal to such limit.

11                  “(iii) PRORATION FOR NEXT THREE  
12                  TIERS.—If the aggregate amount of bo-  
13                  nuses under clauses (i) and (ii) of subpara-  
14                  graph (A) for a category of Medicaid bene-  
15                  ficiaries for quarters in a reform year is  
16                  less than the limit specified in subpara-  
17                  graph (B)(ii) for the reform year, but the  
18                  aggregate amount of bonuses under clauses  
19                  (i) through (v) of subparagraph (A) for the  
20                  category and such quarters in the reform  
21                  year exceeds the limit specified in subpara-  
22                  graph (B)(ii) for the reform year, the  
23                  amount of each bonus in clauses (iii), (iv),  
24                  and (v) of subparagraph (A) shall be pro-  
25                  rated in a manner so the aggregate

1 amount of all the bonuses under subpara-  
2 graph (A) is equal to such limit.

3 “(g) STATE OPTION FOR RECEIVING MEDICARE PAY-  
4 MENTS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVID-  
5 UALS.—

6 “(1) IN GENERAL.—Under this subsection a  
7 State may elect for quarters beginning on or after  
8 the implementation date in a reform year to receive  
9 payment from the Secretary under paragraph (3).  
10 As a condition of receiving such payment, the State  
11 shall agree to provide to full-benefit dual eligible in-  
12 dividuals eligible for medical assistance under the  
13 State plan—

14 “(A) the medical assistance to which such  
15 eligible individuals would otherwise be entitled  
16 under this title; and

17 “(B) any items and services which such eli-  
18 gible individuals would otherwise receive under  
19 title XVIII.

20 “(2) PROVIDER PAYMENT REQUIREMENT.—

21 “(A) IN GENERAL.—A State electing the  
22 option under this subsection shall provide pay-  
23 ment to health care providers for the items and  
24 services described under paragraph (1)(B) at a  
25 rate that is not less than the rate at which pay-

1           ments would be made to such providers for such  
2           items and services under title XVIII.

3           “(B) FLEXIBILITY IN PAYMENT METH-  
4           ODS.—Nothing in subparagraph (A) shall be  
5           construed as preventing a State from using al-  
6           ternative payment methodologies (such as bun-  
7           dled payments or the use of accountable care  
8           organizations (as such term is used in section  
9           1899)) for purposes of making payments to  
10          health care providers for items and services pro-  
11          vided to dual eligible individuals in the State  
12          under the option under this subsection.

13          “(3) PAYMENTS TO STATES IN LIEU OF MEDI-  
14          CARE PAYMENTS.—With respect to a full-benefit  
15          dual eligible individual, in the case of a State that  
16          elects the option under paragraph (1) for quarters in  
17          a reform year—

18                 “(A) the Secretary shall not make any pay-  
19                 ment under title XVIII for items and services  
20                 furnished to such individual for such quarters;  
21                 and

22                 “(B) the Secretary shall pay to the State,  
23                 in addition to the amounts paid to such State  
24                 under subsection (a), the amount that the Sec-  
25                 retary would, but for this subsection, otherwise

1           pay under title XVIII for items and services  
2           furnished to such an individual in such State  
3           for such quarters.

4           “(4) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL  
5           DEFINED.—In this subsection, the term  
6           ‘full-benefit dual eligible individual’ means an indi-  
7           vidual who meets the requirements of section  
8           1935(c)(6)(A)(ii).

9           “(h) AUDITS.—The Secretary shall conduct such au-  
10          dits on the number and classification of Medicaid bene-  
11          ficiaries under such subsections and expenditures under  
12          this section as may be necessary to ensure appropriate  
13          payments under this section.

14          “(i) TREATMENT OF WAIVERS.—

15                 “(1) NO IMPACT ON CURRENT WAIVERS.—In  
16                 the case of a waiver of requirements of this title pur-  
17                 suant to section 1115 or other law that is in effect  
18                 as of the date of the enactment of this section, noth-  
19                 ing in this section shall be construed to affect such  
20                 waiver for the period of the waiver as approved as  
21                 of such date.

22                 “(2) APPLICATION OF BUDGET NEUTRALITY TO  
23                 SUBSEQUENT WAIVERS AND RENEWALS TAKING SEC-  
24                 TION INTO ACCOUNT.—In the case of a waiver of re-  
25                 quirements of this title pursuant to section 1115 or

1 other law that is approved or renewed after the date  
2 of the enactment of this section, to the extent that  
3 such approval or renewal is conditioned upon a dem-  
4 onstration of budget neutrality, budget neutrality  
5 shall be determined taking into account the applica-  
6 tion of this section.

7 “(j) REPORT TO CONGRESS.—Not later than Janu-  
8 ary 1 of the second reform year, the Secretary shall submit  
9 to Congress a report on the implementation of this section.

10 “(k) DEFINITIONS.—In this section:

11 “(1) IMPLEMENTATION DATE.—The term ‘im-  
12 plementation date’ means—

13 “(A) July 1, 2025, if this section is en-  
14 acted on or before July 1, 2024; or

15 “(B) July 1, 2026, if this section is en-  
16 acted after July 1, 2024.

17 “(2) REFORM YEARS.—

18 “(A) The term ‘reform year’ means a fiscal  
19 year beginning with the first reform year.

20 “(B) The term ‘first reform year’ means  
21 the fiscal year in which the implementation date  
22 occurs.

23 “(C) The terms ‘second’, ‘third’, and suc-  
24 cessive similar terms mean, with respect to a  
25 reform year, the second, third, or successive re-

1 form year, respectively, succeeding the first re-  
2 form year.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) CONTINUED APPLICATION OF CLAWBACK  
5 PROVISIONS.—

6 (A) CONTINUED APPLICATION.—Sub-  
7 sections (a) and (c)(1)(C) of section 1935 of  
8 such Act (42 U.S.C. 1396u–5) are each amend-  
9 ed by inserting “or 1903A(a)” after “1903(a)”.

10 (B) TECHNICAL AMENDMENT.—Section  
11 1935(d)(1) of the Social Security Act (42  
12 U.S.C. 1396u–5(d)(1)) is amended by inserting  
13 “except as provided in section 1903A(g)” after  
14 “any other provision of this title”.

15 (2) PAYMENT RULES UNDER SECTION 1903.—

16 (A) Section 1903(a) of the Social Security  
17 Act (42 U.S.C. 1396b(a)) is amended, in the  
18 matter before paragraph (1), by inserting “and  
19 section 1903A” after “except as otherwise pro-  
20 vided in this section”.

21 (B) Section 1903(d) of such Act (42  
22 U.S.C. 1396b(d)) is amended—

23 (i) in paragraph (1), by inserting  
24 “and under section 1903A” after “sub-  
25 sections (a) and (b)”;



1 (ii) in paragraph (2)—

2 (I) in subparagraph (A), by in-  
3 serting “or section 1903A” after “was  
4 made under this section”; and

5 (II) in subparagraph (B), by in-  
6 serting “or section 1903A” after  
7 “under subsection (a)”; and

8 (iii) in paragraph (4)—

9 (I) by striking “under this sub-  
10 section” and inserting “, with respect  
11 to this section or section 1903A,  
12 under this subsection”; and

13 (II) by striking “under this sec-  
14 tion” and inserting “under the respec-  
15 tive section”; and

16 (iv) in paragraph (5), by inserting “or  
17 section 1903A” after “overpayment under  
18 this section”.

19 (3) CONFORMING WAIVER AUTHORITY.—Section  
20 1115(a)(2)(A) of the Social Security Act (42 U.S.C.  
21 1315(a)(2)(A)) is amended by striking “or 1903”  
22 and inserting “1903, or 1903A”.

23 (4) REPORT ON ADDITIONAL CONFORMING  
24 AMENDMENTS NEEDED.—Not later than 6 months  
25 after the date of the enactment of this Act, the Sec-

1       retary of Health and Human Services shall submit  
2       to Congress a report that includes a description of  
3       any additional technical and conforming amend-  
4       ments to law that are required to properly carry out  
5       this Act.

6   **SEC. 402. INCOME LIMITATIONS FOR REFUNDABLE CRED-**  
7                   **ITS FOR COVERAGE UNDER A QUALIFIED**  
8                   **HEALTH PLAN.**

9       (a) IN GENERAL.—Subparagraphs (A) and (B) of  
10      section 36B(c)(1) of the Internal Revenue Code of 1986  
11      are amended by inserting after “100 percent” each place  
12      such term appears the following: “(or, in the case of a  
13      taxpayer enrolled through an Exchange utilized by such  
14      State that makes the election described in section 1903A  
15      of the Social Security Act, the percentage established by  
16      such State under part A of title IV of such Act for pur-  
17      poses of eligibility under title XIX of such Act as of Janu-  
18      ary 1, 2009)”.

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

22   **SEC. 403. MEDICAID ELIGIBILITY DETERMINATIONS.**

23      (a) STATE FLEXIBILITY TO USE CONTRACTORS TO  
24      MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF  
25      STATE.—Section 1902(a)(5) of the Social Security Act

1 (42 U.S.C. 1396a(a)(5)) is amended by inserting before  
 2 the semicolon at the end the following: “, but such deter-  
 3 minations of eligibility may be made, at the option of a  
 4 State, under a contract with another State or local agency  
 5 or a contractor so long as the contract does not provide  
 6 incentives for the agency or contractor to delay eligibility  
 7 determinations or to deny eligibility for individuals other-  
 8 wise eligible for medical assistance”.

9 (b) FREQUENCY OF ELIGIBILITY REDETERMINA-  
 10 TIONS.—Section 1902(e)(14) of the Social Security Act  
 11 (42 U.S.C. 1396a(e)(14)) is amended by adding at the  
 12 end the following:

13 “(L) FREQUENCY OF ELIGIBILITY REDE-  
 14 TERMINATIONS.—Beginning on October 1,  
 15 2024, and notwithstanding subparagraph (H),  
 16 in the case of an individual whose eligibility for  
 17 medical assistance under the State plan under  
 18 this title (or a waiver of such plan) is deter-  
 19 mined based on the application of modified ad-  
 20 justed gross income under subparagraph (A)  
 21 and who is so eligible on the basis of clause  
 22 (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection  
 23 (a)(10)(A), at the option of the State, the State  
 24 plan may provide that the individual’s eligibility  
 25 shall be redetermined every 6 months (or such

1 shorter number of months as the State may  
2 elect).”.

3 **SEC. 404. LOWERING SAFE HARBOR THRESHOLD WITH RE-**  
4 **SPECT TO STATE TAXES ON HEALTH CARE**  
5 **PROVIDERS.**

6 Section 1903(w)(4)(C)(ii) of the Social Security Act  
7 (42 U.S.C. 1396b(w)(4)(C)(ii)) is amended—

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

10 “(I) beginning”; and

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

13 “(II) beginning on or after January 1,  
14 2025, and before January 1, 2034, ‘4 percent’  
15 shall be substituted for ‘6 percent’ each place it  
16 appears;

17 “(III) beginning on or after January 1,  
18 2034, and before January 1, 2039, ‘3 percent’  
19 shall be substituted for ‘6 percent’ each place it  
20 appears;

21 “(IV) beginning on or after January 1,  
22 2039, and before January 1, 2044, ‘2 percent’  
23 shall be substituted for ‘6 percent’ each place it  
24 appears;

1 “(V) beginning on or after January 1,  
 2 2044, and before January 1, 2049, ‘1 percent’  
 3 shall be substituted for ‘6 percent’ each place it  
 4 appears; and

5 “(VI) beginning on or after January 1,  
 6 2049, ‘0 percent’ shall be substituted for ‘6 per-  
 7 cent’ each place it appears.”.

8 **SEC. 405. PROVIDING FOR STATE APPROVAL AND IMPLE-**  
 9 **MENTATION OF SPECIFIED WAIVERS UNDER**  
 10 **THE MEDICAID PROGRAM.**

11 Section 1115 of the Social Security Act (42 U.S.C.  
 12 1315) is amended—

13 (1) in subsection (d)—

14 (A) in paragraph (1), by striking “An ap-  
 15 plication” and inserting “Subject to paragraph  
 16 (4), an application”; and

17 (B) by adding at the end the following new  
 18 paragraph:

19 “(4)(A) An experimental, pilot, or demonstra-  
 20 tion project undertaken under subsection (a) may be  
 21 approved or renewed by a State if such project is de-  
 22 scribed in subparagraph (B).

23 “(B) An experimental, pilot, or demonstration  
 24 project is described in this subparagraph if such  
 25 project provides for a waiver of requirements with

1       respect to a State plan (or a waiver of such plan)  
2       under title XIX such that—

3               “(i) individuals enrolled under such plan  
4               (or such waiver) may elect to participate in  
5               such project with respect to a year; and

6               “(ii) such individuals who elect to so par-  
7               ticipate are furnished with primary care serv-  
8               ices (as described in section 223(c)(1)(D)(ii)(I)  
9               of the Internal Revenue Code of 1986) through  
10              a direct primary care service arrangement (as  
11              defined in such section).

12             “(C) For purposes of a State’s approval or re-  
13             newal of an experimental, pilot, or demonstration  
14             project under subparagraph (A), each reference to  
15             ‘the Secretary’ in subsection (a) shall be deemed to  
16             be a reference to ‘the State.’”; and

17             (2) in subsection (e), by inserting “(other than  
18             such a project that is described in paragraph  
19             (4)(B))” before the period at the end.

20   **SEC. 406. DEDUCTION FOR QUALIFIED CHARITY CARE.**

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

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

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

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

6 “(A) the fee (as published on a publicly  
7 available website of such physician) for physi-  
8 cians’ services that are qualified charity care  
9 furnished by such taxpayer during such year,  
10 and

11 “(B) for each visit by a patient to such  
12 physician during which qualified charity care is  
13 furnished, half of so much of the lowest sub-  
14 scription fee of such physician that is attrib-  
15 utable to a month, and

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

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

20 “(1) UNREIMBURSED MEDICARE-BASED  
21 VALUE.—The term ‘unreimbursed Medicare-based  
22 value’ means, with respect to physicians’ services,  
23 the amount payable for such services under the phy-  
24 sician fee schedule established under section 1848 of  
25 the Social Security Act.

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

4                   “(A) without expectation of reimburse-  
5                   ment, and

6                   “(B) to an individual enrolled—

7                           “(i) under a State plan under title  
8                           XIX of the Social Security Act (or a waiv-  
9                           er of such plan), or

10                           “(ii) under a State child health plan  
11                           under title XXI of the Social Security Act  
12                           (or a waiver of such plan).

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

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

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

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



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

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

“Sec. 199B. Qualified charity care.”.

## 9       **Subtitle B—Medicare Reforms**

### 10   **SEC. 411. OFF-CAMPUS PROVIDER-BASED DEPARTMENT** 11       **MEDICARE SITE NEUTRAL PAYMENT.**

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

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

17               “(1) IN GENERAL.—With respect to items and  
 18       services furnished in an off-campus provider-based  
 19       department, payment under this section for such  
 20       items and services shall be the amount determined  
 21       under the fee schedule under section 1848 for such  
 22       items and services furnished if furnished in a physi-  
 23       cian office setting.

24               “(2) OFF-CAMPUS PROVIDER-BASED DEPART-  
 25       MENT.—For purposes of this subsection, the term

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply with respect to items and services furnished on or after January 1, 2025.

6 SEC. 412. ELIMINATING FEHBP ELIGIBILITY FOR ANNU-  
7 ITANTS.

8       Section 8905(b) of title 5, United States Code, is  
9 amended—

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

(2) by adding at the end the following: “. An individual who is entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) by reason of section 226 or 226A of such Act (42 U.S.C. 426, 426–1), or otherwise eligible to enroll under such part pursuant to section 1818 or 1818A of such Act (42 U.S.C. 1395i–2, 1395i–2a), and who first becomes an annuitant after the date of enactment of this sentence may not continue enrollment in any health benefits plan under this chapter.”.

1 **SEC. 413. ELIMINATION OF MEDICARE ELIGIBILITY FOR**  
2 **CERTAIN INDIVIDUALS.**

3 (a) **ENROLLMENT PROHIBITION.**—

4 (1) **PART B.**—Section 1836 of the Social Secu-  
5 rity Act (42 U.S.C. 1395o) is amended by striking  
6 the period at the end and inserting “, except that an  
7 individual who attains age 65 on or after January  
8 1, 2032, and is an individual who, upon attaining  
9 such age, has earned \$10,000,000 or more in life-  
10 time wages, shall not be eligible to so enroll.”.

11 (2) **PART D.**—Section 1860D–1(a)(3)(A) of  
12 such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amend-  
13 ed by striking the period at the end and inserting  
14 “, excluding an individual who, upon attaining age  
15 65, has earned \$10,000,000 or more in lifetime  
16 wages.”.

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

20 “(aa) **ADDITIONAL LIMITATION ON NEWLY ELIGI-**  
21 **BLE BENEFICIARIES.**—

22 “(1) **IN GENERAL.**—Notwithstanding any other  
23 provision of this section, on or after January 1,  
24 2032, a medicare supplemental policy may not be  
25 sold or issued to a targeted newly eligible Medicare  
26 beneficiary.

1           “(2) TARGETED NEWLY ELIGIBLE MEDICARE  
2       BENEFICIARY.—For purposes of this subsection, the  
3       term ‘targeted newly eligible Medicare beneficiary’  
4       means an individual who, upon attaining the age of  
5       65, has earned \$10,000,000 or more in lifetime  
6       wages.”.

7   **SEC. 414. MEDICARE PART D TAX DEDUCTION.**

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

14      (b) EFFECTIVE DATE.—The amendment made by  
15      this section shall apply to taxable years beginning after  
16      December 31, 2022.

17   **SEC. 415. REPEAL OF NET INVESTMENT INCOME TAX.**

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

20      (b) EFFECTIVE DATE.—The amendment made by  
21      this section shall apply to taxable years beginning after  
22      December 31, 2024.

23   **SEC. 416. MEDICARE COVERAGE OF BAD DEBT.**

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

1 (1) in subparagraph (T)—

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

4 (B) in clause (v)—

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

7 (ii) by striking “or a subsequent fiscal  
8 year” and inserting “through 2024”; and

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

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

13 “(vi) for cost reporting periods beginning dur-  
14 ing fiscal year 2025 or a subsequent fiscal year, by  
15 the percent applicable for cost reporting periods be-  
16 ginning during the previous fiscal year, increased  
17 (through fiscal year 2027) by 10 percentage  
18 points.”;

19 (2) in subparagraph (V)—

20 (A) in clause (i)—

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

23 (ii) in subclause (IV)—

1 (I) by striking “during fiscal  
2 year” and inserting “during fiscal  
3 years 2017 through 2024”; and

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

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

8 “(V) for cost reporting periods beginning  
9 during fiscal year 2025 or a subsequent fiscal  
10 year, the percent applicable for cost reporting  
11 periods beginning during the previous fiscal  
12 year, increased (through fiscal year 2027) by  
13 10 percentage points.”; and

14 (B) in clause (ii)—

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

17 (ii) in subclause (IV)—

18 (I) by striking “a subsequent fis-  
19 cal year” and inserting “fiscal years  
20 2015 through 2024”;

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

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

1           “(V) for cost reporting periods beginning  
2           during fiscal year 2025 or a subsequent fiscal  
3           year, shall be reduced by the percent applicable  
4           for cost reporting periods beginning during the  
5           previous fiscal year, increased (through fiscal  
6           year 2027) by 10 percentage points.”; and

7           (3) in subparagraph (W)(i)—

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

10                (B) in subclause (III)—

11                       (i) by striking “during a subsequent  
12                       fiscal year” and inserting “during fiscal  
13                       years 2015 through 2024”; and

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

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

18                 “(IV) for cost reporting periods beginning dur-  
19           ing fiscal year 2025 or a subsequent fiscal year, by  
20           the percent applicable for cost reporting periods be-  
21           ginning during the previous fiscal year, increased  
22           (through fiscal year 2027) by 10 percentage  
23           points.”.

1     **Subtitle C—Medicare Choice and**  
2                     **Competition**

3     **SEC. 421. COMPETITIVE BIDDING AND PREMIUMS UNDER**  
4                     **UNIFIED MEDICARE.**

5             (a) IN GENERAL.—Part E of title XVIII of the Social  
6     Security Act, as added by section 101 and amended by  
7     section 103, is further amended by adding at the end the  
8     following:

9             **“Subpart 3—Competitive Bidding and Premiums**  
10            **“SEC. 1860E-31. APPLICATION OF COMPETITIVE BIDDING IN**  
11                     **ENROLLMENT.**

12            “(a) IN GENERAL.—Notwithstanding any other pro-  
13     vision of this title, the Secretary shall, beginning with plan  
14     year 2025, establish a method whereby individuals enroll-  
15     ing under this title so enroll through an online process  
16     designed to highlight enrollment options for such individ-  
17     uals and allow such individuals to compare costs of enroll-  
18     ment in such options.

19            “(b) ENROLLMENT OPTIONS.—For purposes of sub-  
20     section (a), the Secretary shall make the following options  
21     available to individuals for enrollment under this title:

22                     “(1) Traditional fee-for-service coverage.

23                     “(2) provider-led risk-bearing plans (also known  
24     as ACOs).

25                     “(3) Medicare Advantage plans.



1       “(c) MEDICARE ADVANTAGE PLAN ACTUARIAL  
2 VALUE REQUIREMENT.—Each Medicare Advantage plan  
3 offered through the process described in subsection (a)  
4 shall have an actuarial value equal to traditional fee-for-  
5 service coverage under parts A and B.

6       “(d) MA DIRECT DEPOSIT OF CERTAIN REBATES.—  
7 In the case of an Medicare Advantage plan with a bid for  
8 a year that involves a premium differential between such  
9 bid and the benchmark for such year and plan, such plan  
10 shall provide for a direct deposit of such differential if the  
11 applicable enrollee in such plan does not elect any supple-  
12 mental coverage under such plan.

13       “(e) ENROLLMENT IN PRESCRIPTION DRUG COV-  
14 ERAGE.—As part of the method described in subsection  
15 (a), the Secretary shall establish a process to allow an in-  
16 dividual to enroll in prescription drug coverage. In the  
17 case of an individual who enrolls in a Medicare Advantage  
18 plan, such coverage shall be provided under such plan. In  
19 a case of an individual who enrolls in an ACO, such cov-  
20 erage shall be provided under such network. In the case  
21 of an individual who enrolls under traditional fee-for-serv-  
22 ice coverage, such drug coverage shall be provided through  
23 a prescription drug plan.

24       “(f) SUPPLEMENTAL BENEFITS.—

1           “(1) MA PLANS.—An MA plan is allowed to  
2           offer two different packages of supplemental benefits  
3           (these packages are available only to individuals who  
4           select such plans).

5           “(2) ACOs.—ACOs may limit supplemental op-  
6           tions for their enrollees to Medigap plans with con-  
7           tractual ties.

8           “(3) FEE-FOR-SERVICE.—Fee-for-service indi-  
9           viduals may select supplemental coverage from  
10          Medigap policies.

11   **“SEC. 1860E-32. COMPETITION.**

12          “(a) BID AREAS.—Market areas used for bid submis-  
13          sions for Medicare Advantage plans, ACOs, and for cal-  
14          culation per person fee-for-services costs shall be metro-  
15          politan statistical regions plus associated regions.

16          “(b) PREMIUMS.—Medicare payment benchmark by  
17          market area shall be calculated based on weighted average  
18          (by enrollment in previous year) of the premium bids from  
19          MA plans, ACOs, and the per person costs of fee-for-serv-  
20          ice, less the statutory part B premium.

21          “(c) BENEFICIARY RESPONSIBILITY.—Beneficiaries  
22          shall pay the difference between Medicare payment and  
23          required premium of the plan they choose, and get 100  
24          percent of the savings by choosing a plan with a premium  
25          below the benchmark.

1       “(d) TRANSITION.—For beneficiaries who are in fee-  
2 for-service at the time of the enactment of this section,  
3 there shall be a limit on the amount of a premium increase  
4 allowable by year of no more than \$20 per month com-  
5 pared to what such premium would have otherwise been  
6 if this subpart had not been enacted for each year through  
7 the fifth year.

8       “(e) MULTIYEAR CONTRACTS.—A Medicare Advan-  
9 tage plan may offer to beneficiaries multiyear contracts  
10 with guaranteed premiums over such years, bearing the  
11 risk of any change in payments from the Secretary in sub-  
12 sequent years. A beneficiary enrolling under such a con-  
13 tract shall be exempt from the method described in sub-  
14 section (a).”.

15       (b) CONFORMING AMENDMENTS.—

16               (1) Section 1853(a)(1)(A) of the Social Security  
17 Act is amended by striking “and section 1859(e)(4)”  
18 and inserting “, section 1859(e)(4), and subpart 3  
19 of part E”.

20               (2) Section 1853(j) of such Act is amended by  
21 inserting “and subpart 3 of part E” after “sub-  
22 section (o)”.

23               (3) Section 1854 of such Act is amended—

24                       (A) in subsection (a), after the heading, by  
25 inserting “Subject to subpart 3 of part E.”;

1 (B) in subsection (b), after the heading, by  
 2 inserting “Subject to subpart 3 of part E.”;

3 (C) in subsection (d), after the heading, by  
 4 inserting “Subject to subpart 3 of part E.”;  
 5 and

6 (D) in subsection (e), after the heading, by  
 7 inserting “Subject to subpart 3 of part E.”.

8 **SEC. 422. NEW UNIFIED ELIGIBILITY AND ENROLLMENT**  
 9 **RULES.**

10 (a) IN GENERAL.—Title XVIII of the Social Security  
 11 Act is amended—

12 (1) by redesignating part E as part F; and

13 (2) by inserting after part D the following new  
 14 part:

15 **“PART E—MEDICARE WITH CHOICE AND**  
 16 **COMPETITION**

17 **“Subpart 1—Opt-Out and Auto-Enrollment**

18 **“SEC. 1860E-11. PART A OPT-OUT AND MA AUTO-ENROLL-**  
 19 **MENT.**

20 **“(a) PERMITTING INDIVIDUALS TO OPT OUT OF**  
 21 **PART A COVERAGE WITHOUT LOSING SOCIAL SECURITY**  
 22 **BENEFITS.—**

23 **“(1) IN GENERAL.—The Secretary shall estab-**  
 24 **lish—**

1           “(A) a process by which an individual oth-  
2           erwise entitled to benefits under part A may  
3           elect (at a time and in a manner specified  
4           under the process) to waive such entitlement;  
5           and

6           “(B) a process by which an individual who  
7           elects to waive such entitlement may revoke (at  
8           a time and in a manner specified under the  
9           process) such waiver.

10          The process under subparagraph (B) shall be coordi-  
11          nated with the enrollment process under section  
12          1837 for part B.

13           “(2) APPLICATION OF LATE ENROLLMENT PEN-  
14          ALTY.—An individual who revokes a waiver under  
15          paragraph (1)(B) shall be subject to a late enroll-  
16          ment penalty as applied under section 1860E-  
17          32(c)(2)(C).

18           “(3) NO IMPACT ON TITLE II BENEFITS.—Not-  
19          withstanding any other provision of law, an election  
20          of an individual to waive entitlement to benefits  
21          under part A under paragraph (1)(A) shall not re-  
22          sult in any loss of benefits under title II.

23           “(4) DEEMED OPT-OUT.—

24           “(A) An election of an individual to waive  
25          entitlement to benefits under part A under

1 paragraph (1)(A) is also deemed the filing of a  
2 notice of termination of benefits under part B  
3 pursuant to section 1838(b)(1).

4 “(B) The termination of benefits under  
5 part B pursuant to section 1838(b) is also  
6 deemed to be a waiver of any entitlement to  
7 benefits under part A.

8 “(b) SPECIAL OPEN ENROLLMENT PERIOD WITH-  
9 OUT LATE ENROLLMENT PENALTY FOR CURRENT PART  
10 A ONLY OR PART B ONLY ENROLLEES.—Notwith-  
11 standing any other provision of law, in the case of an indi-  
12 vidual who as of the general effective date, is entitled to  
13 benefits under part A but not enrolled under part B, or  
14 who is enrolled under part B but not entitled to benefits  
15 (or enrolled) under part A, beginning as of such date, such  
16 individual shall be deemed to be enrolled under part B  
17 or part A, respectively, unless such individual elects to be  
18 enrolled (or entitled to benefits) under neither of such  
19 parts during a special open enrollment period specified by  
20 the Secretary. No increase in the monthly premium of an  
21 individual pursuant to section 1839(b) or section 1818(c)  
22 shall be effected in the case of any such individual who  
23 is deemed enrolled under part B or part A pursuant to  
24 the previous sentence with respect to any period prior to  
25 the date of such enrollment.

1       “(c) AUTO ENROLLMENT OF DUAL ELIGIBLE INDIVIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

2  
3               “(1) IN GENERAL.—Except in the case of a  
4       State that has elected the maintenance of effort option described in section 1944(b)(2), in the case of  
5       an individual described in subparagraph (A)(ii) of section 1935(c)(6) (taking into account the application of subparagraph (B) of such section), the Secretary shall establish a process for the enrollment in  
6       an MA–PD plan that is a managed care plan under part C that has a monthly beneficiary premium that  
7       does not exceed the premium assistance available under section 1860E–41(b)(1)(A). If there is more  
8       than one such plan available, the Secretary shall enroll such an individual on a random basis among all  
9       such plans in the PDP region.  
10  
11  
12  
13  
14  
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16

17               “(2) RIGHT TO DISENROLL.—Nothing in paragraph (1) shall prevent such an individual from declining enrollment in any such plan (and thereby obtaining coverage under Medicare fee-for-service) or  
18       from changing enrollment in such a plan to another MA–PD plan.  
19  
20  
21  
22

23       **“SEC. 1860E–12. COORDINATION WITH PART D.**

24       “(a) DEEMED ENROLLMENT UNDER PART D.—

1           “(1) IN GENERAL.—The Secretary shall estab-  
2       lish a process that, beginning as of the general effec-  
3       tive date, provides for the enrollment in a prescrip-  
4       tion drug plan that has a monthly base beneficiary  
5       premium that does not exceed the weighted average  
6       of premiums for such plans that provide standard  
7       prescription drug coverage (as defined in section  
8       1860D–2(b)) with respect to the area involved (on  
9       a random basis among all such plans in the applica-  
10      ble PDP region) of each Medicare enrollee (as de-  
11      fined in section 1860E–51) who—

12           “(A) failed to enroll in such a prescription  
13      drug plan during the applicable enrollment or  
14      coverage election period under section 1860D–  
15      1(b); and

16           “(B) failed to elect not to enroll in such a  
17      prescription drug plan during an applicable opt-  
18      out period described in paragraph (2).

19      Nothing in the previous sentence shall prevent such  
20      an individual from declining or changing such enroll-  
21      ment. Such process shall be carried out in the same  
22      manner as the process described in section 1860D–  
23      1(b)(1)(C).

24           “(2) OPT-OUT PERIODS.—The process under  
25      paragraph (1) shall provide for the opportunity to



1 make an election described in subparagraph (B) of  
2 such paragraph during an opt-out period that is co-  
3 ordinated with the relevant enrollment or coverage  
4 election period under section 1860D–1.

5 “(3) LATE ENROLLMENT PENALTIES.—In the  
6 case of an individual who makes an election de-  
7 scribed in paragraph (1)(B) and then enrolls in a  
8 prescription drug plan, the late enrollment penalty  
9 under section 1860D–13(b) shall apply to the  
10 monthly beneficiary premium of such individual, ex-  
11 cept that in applying such section, any reference to  
12 the initial enrollment period of such individual shall  
13 be deemed to be a reference to the opt-out period  
14 under paragraph (2) during which the individual  
15 elected not to enroll in a prescription drug plan.

16 “(4) NO LATE ENROLLMENT PENALTY FOR  
17 CURRENT FEE-FOR-SERVICE BENEFICIARIES WITH-  
18 OUT DRUG COVERAGE.—In the case of an individual  
19 who is a Medicare enrollee before the date of enact-  
20 ment of this section and who was not enrolled under  
21 a prescription drug plan before being enrolled under  
22 such a plan pursuant to paragraph (1), there shall  
23 be no increase in the base beneficiary premium of an  
24 individual under section 1860D–13 by a late enroll-  
25 ment penalty under subsection (b) of such section

1 with respect to any period prior to the date of such  
2 enrollment.

3 “(b) REFERENCE TO REQUIRED PRESCRIPTION  
4 DRUG COVERAGE UNDER PART C.—For provision requir-  
5 ing coverage under MA plans to include prescription drug  
6 coverage, see section 1860E–26.”.

7 (b) LIMITATION ON MEDICAID BENEFITS FOR FULL-  
8 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Section 1902  
9 of the Social Security Act (42 U.S.C. 1396a) is amended  
10 by adding at the end the following new subsection:

11 “(II) LIMITATION ON BENEFITS FOR FULL-BENEFIT  
12 DUAL ELIGIBLE INDIVIDUALS.—Effective as of the gen-  
13 eral effective date (as specified in section 1860E–62), ex-  
14 cept in the case of a State which has elected the option  
15 described in section 1944(b)(2), in the case of an indi-  
16 vidual described in subparagraph (A)(ii) of section  
17 1935(c)(6) (taking into account the application of sub-  
18 paragraph (B) of such section), notwithstanding any other  
19 provision of law, medical assistance shall not be available  
20 under this title for any items and services for which pay-  
21 ment may be made under title XVIII.”.

22 (c) MEDICAID MAINTENANCE OF EFFORT AND AL-  
23 TERNATIVES.—Title XIX of the Social Security Act is  
24 amended by inserting after section 1943 the following new  
25 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-

tion 1860E–51 shall pay to the State the same amount that the individual would be entitled to have paid as an income-related premium subsidy under section 1860E–41(b)(1)(A) plus the amount that the Secretary estimates would have been paid with respect to the individual under part D (including the actuarial value of subsidy payments under sections 1860D–13 and 1860D–14). Such payment shall be made in appropriate part from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841.

“(C) RELATION TO PART D RULES.—In the case of a State that has elected the option under this paragraph, notwithstanding any other provision of law—

“(i) the coverage provided under this option shall be in lieu of any coverage that may otherwise be provided under part D; and

“(ii) the payment to the State under subparagraph (B) shall be in lieu of any payments otherwise made with respect to such individual under such part.

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 ceding 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****“SEC. 1860E-21. OUT-OF-POCKET LIMIT.**

“(a) IN GENERAL.—Beginning with 2025, in the case of a Medicare enrollee, if the amount of the out-of-pocket cost-sharing of such enrollee for a calendar year equals or exceeds the catastrophic limit under subsection (b) for that year—

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

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

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

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

1       “(b) CATASTROPHIC LIMIT.—The amount of the cat-  
 2   astrophic limit under this subsection for a year shall be  
 3   the dollar amount in effect under section 223(c)(2)(A)(ii)  
 4   of the Internal Revenue Code of 1986 for self-only cov-  
 5   erage for taxable years beginning in such year.

6       “(c) OUT-OF-POCKET COST-SHARING DEFINED.—In  
 7   this section, the term ‘out-of-pocket cost-sharing’ means,  
 8   with respect to an individual, the amount of costs incurred  
 9   by the individual that are attributable to—

10           “(1) deductibles and coinsurance imposed under  
 11   part A or part B; and

12           “(2) deductibles and coinsurance imposed under  
 13   standard prescription drug coverage pursuant to sec-  
 14   tion 1860D–2(b) or alternative prescription drug  
 15   coverage pursuant to section 1860D–2(c) offered by  
 16   a prescription drug plan.”.

17       (b) APPLICATION OF OUT-OF-POCKET LIMIT TO MA-  
 18   PD PLANS.—

19           (1) IN GENERAL.—Section 1852(a)(1)(B) of the  
 20   Social Security Act (42 U.S.C. 1395w–22(a)(1)(B))  
 21   is amended—

22                   (A) in clause (i), by striking “clause (iii)”  
 23                   and inserting “clauses (iii) and (vi)”; and

24                   (B) by adding at the end the following new  
 25   clause:



1                   “(vi) OUT-OF-POCKET LIMIT.—The  
2                   provisions of section 1860E–21—

3                   “(I) shall apply to individuals en-  
4                   rolled under an MA–PD plan in the  
5                   same manner as such provisions apply  
6                   to Medicare enrollees under such sec-  
7                   tion, except that in lieu of the applica-  
8                   tion of subsection (a)(2) of such sec-  
9                   tion the MA–PD plan shall establish  
10                  procedures to provide for payment of  
11                  any additional out-of-pocket cost-shar-  
12                  ing described in subsection (a)(1) of  
13                  such section incurred by individuals  
14                  enrolled under the MA–PD plan; and

15                  “(II) as applied under subclause  
16                  (I), may not be waived by application  
17                  of this subparagraph.

18                  In applying subsection (b) of section  
19                  1860E–21 pursuant to the previous sen-  
20                  tence, an MA–PD plan may substitute a  
21                  dollar amount that is less than the dollar  
22                  amount specified under such subsection.”.

23                  (2) EXEMPTING MA–PD PLANS OFFERING AL-  
24                  TERNATIVE PRESCRIPTION DRUG COVERAGE FROM  
25                  PART D DEDUCTIBLE AND OUT-OF-POCKET LIMIT

1       REQUIREMENTS.—Section 1860D–2(c) of the Social  
2       Security Act (42 U.S.C. 1395w–102(c)) is amend-  
3       ed—

4               (A) in paragraph (2), by striking “The de-  
5       ductible” and inserting “In the case of a pre-  
6       scription drug plan, the deductible”; and

7               (B) in paragraph (3), by striking “The  
8       coverage provides” and inserting “In the case  
9       of a prescription drug plan, the coverage pro-  
10      vides”.

11      (c) PRESCRIPTION DRUG PLANS REQUIRED TO RE-  
12      PORT ENROLLEES’ OUT-OF-POCKET COST-SHARING.—  
13      Section 1860D–12(b) of the Social Security Act (42  
14      U.S.C. 1395w–112(b)) is amended by adding at the end  
15      the following new paragraph:

16              “(7) OUT-OF-POCKET COST-SHARING RE-  
17      PORTS.—Each contract entered into with a PDP  
18      sponsor under this part with respect to a prescrip-  
19      tion drug plan offered by such sponsor shall require  
20      that, with respect to each claim submitted for items  
21      or services furnished to an individual enrolled under  
22      the plan pursuant to the contract, the sponsor sub-  
23      mits to the Secretary information on the amount of  
24      out-of-pocket cost-sharing (as defined in section

1       1860E–23(c)) applicable to such enrollee for such  
2       items or services.”.

3       (d) CONFORMING AMENDMENTS.—

4           (1) Section 1813 of the Social Security Act (42  
5       U.S.C. 1395e) is amended—

6           (A) in subsection (a), by inserting “Subject  
7       to subpart 2 of part E:” before paragraph (1);  
8       and

9           (B) in subsection (b), by inserting “Sub-  
10      ject to subpart 2 of part E:” before paragraph  
11      (1).

12          (2) Section 1833 of such Act (42 U.S.C. 1395l)  
13      is amended—

14          (A) in subsection (a), in the matter pre-  
15      ceding paragraph (1), by inserting “and sub-  
16      part 2 of part E” after “succeeding provisions  
17      of this section”;

18          (B) in subsection (b), in the first sentence,  
19      by striking “Before applying” and inserting  
20      “Subject to subpart 2 of part E, before apply-  
21      ing”;

22          (C) in subsection (c)(1), in the matter pre-  
23      ceding subparagraph (A), by inserting “subject  
24      to subpart 2 of part E,” after “this part,”;

1 (D) in subsection (f), by striking “In es-  
 2 tablishing” and inserting “Subject to subpart 2  
 3 of part E, in establishing”; and

4 (E) in subsection (g)(1), by inserting “and  
 5 subpart 2 of part E” and “paragraphs (4) and  
 6 (5)”.

7 (3) Section 1882(a)(2) of such Act is amended  
 8 by striking “No medicare” and inserting “Subject to  
 9 section 1860E–24(c), no medicare”.

10 **SEC. 424. LATE ENROLLMENT PENALTY NOT TO APPLY FOR**  
 11 **MONTHS OF ANY HEALTH COVERAGE.**

12 (a) IN GENERAL.—Section 1839(b) of the Social Se-  
 13 curity Act (42 U.S.C. 1395r) is amended in the second  
 14 sentence, by inserting before the period at the end the fol-  
 15 lowing: “or months during which the individual has any  
 16 other health coverage”.

17 (b) EFFECTIVE DATE.—The amendment made by  
 18 paragraph (1) shall apply for months of coverage begin-  
 19 ning after the date of the enactment of this Act.

20 **SEC. 425. MEDIGAP REFORM.**

21 Notwithstanding any provision of section 1882 of the  
 22 Social Security Act (42 U.S.C. 1395ss), as of the date  
 23 of the enactment of this Act, no policy may be offered  
 24 under such section that does not provide guaranteed cov-  
 25 erage (without regard to an individual’s preexisting condi-

1 tions, if any) to all individuals eligible to enroll under such  
2 policy.

3 **SEC. 426. ACO REVISION.**

4 (a) ENROLLMENT.—Enrollment in such an ACO  
5 under such title shall be based on the method established  
6 under part E of such title. Such a network shall bear full  
7 risk in the event payments under such title do not equal  
8 or exceed liabilities under such network.

9 (b) DIRECTION OF PAYMENT.—An ACO may direct  
10 that any payments under such title be made to a central-  
11 ized entity rather than to an individual provider or sup-  
12 plier.

13 (c) BIDS.—The Secretary of Health and Human  
14 Services shall establish a process whereby such networks  
15 compete using a bidding process similar to that described  
16 in part E of such title for Medicare Advantage plans.

17 **SEC. 427. PRIMARY CARE OPTIONS.**

18 (a) SELECTION OF PRIMARY CARE PHYSICIAN.—The  
19 Secretary shall establish a mechanism under which an in-  
20 dividual enrolled under part B of title XVIII of the Social  
21 Security Act may select such individual's primary care  
22 physician. Such an individual shall not be liable for more  
23 than \$5 for each visit to such selected physician.

24 (b) PAYMENT TO PHYSICIAN.—A physician selected  
25 under subsection (a) shall receive a monthly fee in lieu

1 of any other payment under such part B for evaluation  
 2 and monitoring of such individual. The Secretary shall  
 3 provide a list of standardized benefits that are included  
 4 in such payment, including telephone and email commu-  
 5 nications, office visits, preventive care, and vaccinations.

6 **SEC. 428. GENERAL PROVISIONS; EFFECTIVE DATE.**

7 Part E of title XVIII of the Social Security Act, as  
 8 inserted by section 101(a)(2) and as previously amended,  
 9 is further amended by adding at the end the following new  
 10 subpart:

11 **“Subpart 5.—General Provisions**

12 **“SEC. 1860E–51. APPLICABILITY; DEFINITIONS.**

13 “(a) IN GENERAL.—The provisions of this Act are  
 14 superseded to the extent inconsistent with the provisions  
 15 of this part.

16 “(b) TERMINOLOGY.—For purposes of this part:

17 “(1) MEDICARE ENROLLEE.—

18 “(A) IN GENERAL.—The term ‘Medicare  
 19 enrollee’ means—

20 “(i) an individual entitled to (or en-  
 21 rolled for benefits) under part A and en-  
 22 rolled under part B; and

23 “(ii) except as otherwise specified, an  
 24 individual described in section 1860E–  
 25 11(a)(3).

1           “(B) TREATMENT.—Any reference in this  
2           Act (or any other Act) in effect before the date  
3           of the enactment of this part, to an individual  
4           entitled to benefits under part A or enrolled  
5           under part B shall be deemed a reference to a  
6           Medicare enrollee.

7           “(2) MEDICARE FEE-FOR-SERVICE.—The term  
8           ‘Medicare fee-for-service’ means the original Medi-  
9           care fee-for-service program under parts A and B,  
10          as modified by this part, and does not include part  
11          C or part D.

12          “(3) MEDICARE FEE-FOR-SERVICE EN-  
13          ROLLEE.—The term ‘Medicare fee-for-service en-  
14          rollee’ means a Medicare enrollee who is not enrolled  
15          under a Medicare Advantage plan under part C.

16   **“SEC. 1860E-61. GENERAL EFFECTIVE DATE.**

17          “Except as otherwise specified, the provisions of this  
18          part shall apply to items and services furnished on or after  
19          January 1, 2025, and to plan years beginning on or after  
20          such date (referred to in this title as the ‘general effective  
21          date’).”.

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

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

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

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

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

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

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

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

(3) in paragraph (3)(A)—



1 (A) in the heading, by striking “PHYSI-  
2 CIAN AND PRACTITIONER” and inserting “PHY-  
3 SICIAN, PRACTITIONER, AND APPLICABLE PRO-  
4 FESSIONAL”; and

5 (B) by striking “physicians or practi-  
6 tioners” and inserting “physicians, practi-  
7 tioners, or applicable professionals”; and

8 (4) in paragraph (4), by adding at the end the  
9 following new subparagraph:

10 “(G) APPLICABLE PROFESSIONAL.—The  
11 term ‘applicable professional’ means, with re-  
12 spect to services furnished on or after the date  
13 that is 6 months after the date of the enact-  
14 ment of this subparagraph, a certified diabetes  
15 educator or licensed—

16 “(i) respiratory therapist;

17 “(ii) audiologist;

18 “(iii) occupational therapist;

19 “(iv) physical therapist; or

20 “(v) speech language pathologist.”.

21 (c) HOME-BASED MONITORING SERVICES FOR CON-  
22 GESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE  
23 PULMONARY DISEASE.—

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, 2025, 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, 2025, 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       2025, 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),”; and

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)”;

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, 2025.

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

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

“(K) the provision of technologies (as defined by the Secretary) on or after the date of the enactment of this subparagraph, by a provider of services or supplier (as such terms are defined for purposes of title XVIII) directly to an individual who is entitled to benefits under part A of title XVIII, enrolled under part B of such title, or both, for the purpose of furnishing telehealth services, remote patient monitoring services, or other services furnished through the use of technology (as defined by the Secretary), if—

“(i) the technologies are not offered as part of any advertisement or solicitation; and

“(ii) the provision of the technologies meets any other requirements set forth in regulations promulgated by the Secretary.”.

**SEC. 441. STUDY AND REPORT ON INCREASING ACCESS TO  
TELEHEALTH SERVICES IN THE HOME.**

(a) MEDPAC STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the “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.”.

○