

119TH CONGRESS
2D SESSION

H. R. 8840

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

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2026

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 Workforce, the Judiciary, Oversight and Government Reform, Rules, the Budget, Armed Services, and House Administration, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Fair Care Act of 2026”.

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.

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. Access of individuals to protected health information.
- Sec. 323. Advisory group on reducing burden of hospital administrative requirements.
- Sec. 324. Data reporting to improve the transparency regarding how 340B hospital covered entities provide care for patients.
- Sec. 325. Requiring 340B drug discount program reports by DSH hospital covered entities on low-income utilization rate of outpatient hospital services.
- Sec. 326. Employer benefits reports.
- Sec. 327. 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.
- Sec. 356. Provisional approval of new human drugs.

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 the United States.

Subtitle E—Medicare and Medicaid Prescription Drug Reforms

- Sec. 371. Market based part B pricing index.
- Sec. 372. Innovation model testing of Medicare drug payments.

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:

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

11 “(a) DEDUCTION ALLOWED.—In the case of an indi-
 12 vidual who is an eligible individual for any month during
 13 the taxable year, there shall be allowed as a deduction for

1 the taxable year an amount equal to the aggregate amount
2 paid in cash during such taxable year by or on behalf of
3 such individual to a health savings account of such indi-
4 vidual.

5 “(b) LIMITATIONS.—

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

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

18 “(3) INCREASE IN LIMIT FOR INDIVIDUALS BE-
19 COMING ELIGIBLE INDIVIDUALS AFTER THE BEGIN-
20 NING OF THE YEAR.—

21 “(A) IN GENERAL.—For purposes of com-
22 puting the limitation under paragraph (1) for
23 any taxable year, an individual who is an eligi-
24 ble individual during the last month of such
25 taxable year shall be treated—

1 “(i) as having been an eligible indi-
2 vidual during each of the months in such
3 taxable year, and

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

10 “(B) FAILURE TO MAINTAIN QUALIFIED
11 PLAN COVERAGE.—

12 “(i) IN GENERAL.—If, at any time
13 during the testing period, the individual is
14 not an eligible individual, then—

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

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

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

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

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

21 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
22 individual’ means, with respect to any month, any
23 individual if such individual is covered under a quali-
24 fied plan as of the 1st day of such month.

25 “(2) QUALIFIED PLAN.—

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

7 “(B) EXCLUSION OF CERTAIN PLANS.—
8 Such term does not include a health plan if
9 substantially all of its coverage is—

10 “(i) coverage for any benefit provided
11 by permitted insurance, or

12 “(ii) coverage (whether through insur-
13 ance or otherwise) for accidents, disability,
14 dental care, vision care, or long-term care.

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

17 “(A) insurance if substantially all of the
18 coverage provided under such insurance relates
19 to—

20 “(i) liabilities incurred under workers’
21 compensation laws,

22 “(ii) tort liabilities,

23 “(iii) liabilities relating to ownership
24 or use of property, or

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

3 “(B) insurance for a specified disease or
4 illness, and

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

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

10 “(d) HEALTH SAVINGS ACCOUNT.—For purposes of
11 this section—

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

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

23 “(i) unless it is in cash, or

24 “(ii) to the extent such contribution,
25 when added to previous contributions to

1 the trust for the calendar year, exceeds the
2 limitation amount specified in paragraph
3 (2)(A), or

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

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

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

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

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

23 “(2) LIMITATIONS.—

24 “(A) ANNUAL LIMITATION.—

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

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

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

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

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

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

22 “(C) INDEXING.—

23 “(i) IN GENERAL.—In the case of any
24 taxable year beginning in a calendar year
25 after 2026, each dollar amount contained

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

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

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

14 “(II) such component of the C–
15 CPI–U (as so defined) for August of
16 2025.

17 “(iii) ROUNDING.—

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

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

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

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

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

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

3 “(3) QUALIFIED MEDICAL EXPENSES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 “(e) TAX TREATMENT OF ACCOUNTS.—

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

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

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

9 “(f) TAX TREATMENT OF DISTRIBUTIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 “(B) OTHER CASES.—

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

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

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

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

3 “(ii) SPECIAL RULES.—

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

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

22 “(g) COST-OF-LIVING ADJUSTMENT.—

23 “(1) IN GENERAL.—In the case of any taxable
24 year beginning after December 31, 2026, 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 ‘2025’ for ‘2016’ in sub-
8 paragraph (A)(ii) thereof.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(B) RULES RELATED TO CLASS SIZE.—

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

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

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

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

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

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

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

18 “(i) number of dependents,

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

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

1 “(5) COORDINATION WITH ACA PROVISIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 (3) REPEAL OF EXCLUSIONS FROM INCOME FOR
10 ARCHER MSAS AND FSAS.—Section 106 of such Code
11 is amended by striking 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 redес-
8 ignating subsection (h) as subsection (i) and by inserting
9 after subsection (g) the following new subsection:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(1) IN GENERAL.—Notwithstanding any pre-
16 ceding provision of this section, a State may apply
17 to the Secretary for the waiver of any requirement
18 of subsection (a)(2) with respect to health insurance
19 coverage within that State for plan years beginning
20 on or after January 1, 2026, 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 2026 through 2030.

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, 2026, may be made through December
25 31, 2026.

1 “(3) LIMITATION.—Amounts appropriated
2 under paragraph (1) for each of plan years 2026
3 through 2030 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 **Subtitle B—Assistance to Health**
9 **Savings Accounts**

10 **SEC. 111. ONE-TIME APPLICATION OF SAVER’S CREDIT TO**
11 **CONTRIBUTIONS TO HEALTH SAVINGS AC-**
12 **COUNTS.**

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

18 (b) APPLICABLE TAXABLE YEAR.—For purposes of
19 this section, the term “applicable taxable year” means any
20 taxable year elected by the taxpayer (at such time and
21 in such manner as the Secretary of the Treasury may pro-
22 vide) which begins during the 3-year period beginning 1
23 year after the date of the enactment of this Act. A tax-
24 payer may not elect not more than 1 applicable taxable
25 year under this subsection.

1 **SEC. 112. GRANTS FOR HEALTH SAVINGS ACCOUNT ASSIST-**
2 **ANCE AND OUTREACH.**

3 (a) IN GENERAL.—The Administrator shall establish
4 a grant program to provide assistance to eligible entities
5 to carry out the activities described in subsection (c).

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

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

16 (1) distribute fair and impartial information to
17 consumers about health savings accounts, including
18 the availability of such accounts and how such ac-
19 counts may be utilized;

20 (2) conduct activities to raise public awareness
21 of health savings accounts;

22 (3) facilitate enrollment in health savings ac-
23 counts; and

24 (4) refer individuals enrolled in a health savings
25 account to the appropriate official, organization, or
26 State agency for the purpose of addressing a com-

1 plaint, grievance, or other question with respect to
2 such health savings account.

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

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

11 (f) DEFINITIONS.—In this section:

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

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

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

20 (A) A State.

21 (B) Trade.

22 (C) Industry.

23 (D) Professional associations.

24 (E) Commercial fishing industry organiza-
25 tions.

1 (F) Ranching and farming organizations.

2 (G) Community and consumer-focused
3 nonprofit groups.

4 (H) Chambers of commerce.

5 (I) Unions.

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

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

11 (4) HEALTH SAVINGS ACCOUNT.—The term
12 “health savings account” has the meaning given
13 such term in section 223 of the Internal Revenue
14 Code of 1986.

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

19 **SEC. 113. NEW CORPORATIONS REQUIRED TO USE HEALTH**
20 **SAVINGS ACCOUNTS.**

21 Notwithstanding any other provision of law, a cor-
22 poration incorporated after December 31, 2026, may not
23 receive tax benefits for offering employees health insur-
24 ance. The previous sentence shall not apply to health sav-
25 ings account contributions offered by such a corporation.

1 **SEC. 114. FEDERAL EMPLOYEE HEALTH BENEFITS AND**
2 **HEALTH SAVINGS ACCOUNTS.**

3 (a) IN GENERAL.—Section 1312(d)(3)(D) of the Pa-
4 tient Protection and Affordable Care Act (42 U.S.C.
5 18032(d)(3)(D)) is amended—

6 (1) in the subparagraph heading, by striking
7 “MEMBERS OF CONGRESS” and inserting “PRESI-
8 DENT, VICE PRESIDENT, MEMBERS OF CONGRESS,
9 AND FEDERAL EMPLOYEES”;

10 (2) in clause (i), in the matter preceding sub-
11 clause (I)—

12 (A) by striking “Members of Congress and
13 congressional staff” and inserting “the Presi-
14 dent, Vice President, Members of Congress, and
15 Federal employees”; and

16 (B) by striking “a Member of Congress or
17 congressional staff” and inserting “the Presi-
18 dent, the Vice President, a Member of Con-
19 gress, or a Federal employee”; and

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

22 “(II) FEDERAL EMPLOYEE.—The
23 term ‘Federal employee’ means—

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

1 “(bb) includes an individual
2 to whom subsection (c) or (f) of
3 such section 2105 pertains
4 (whether or not such individual
5 satisfies item (aa)).”.

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

12 **TITLE II—IMPROVING PRIVATE**
13 **HEALTH INSURANCE**
14 **Subtitle A—Maintaining Protec-**
15 **tions for Patients With Pre-**
16 **existing Conditions**

17 **SEC. 201. GUARANTEED AVAILABILITY OF COVERAGE; PRO-**
18 **HIBITING DISCRIMINATION.**

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

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

24 “(a) GUARANTEED ISSUANCE OF COVERAGE IN THE
25 INDIVIDUAL AND GROUP MARKET.—Subject to sub-

1 sections (b) through (d), each health insurance issuer that
2 offers health insurance coverage in the individual or group
3 market in a State must accept every employer and indi-
4 vidual in the State that applies for such coverage.

5 “(b) ENROLLMENT.—

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

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

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

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

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

24 “(A) limit the employers that may apply
25 for such coverage to those with eligible individ-

1 uals who live, work, or reside in the service area
2 for such network plan; and

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

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

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

20 “(2) 180-DAY SUSPENSION UPON DENIAL OF
21 COVERAGE.—An issuer, upon denying health insur-
22 ance coverage in any service area in accordance with
23 paragraph (1)(B), may not offer coverage in the
24 group or individual market within such service area

1 for a period of 180 days after the date such cov-
2 erage is denied.

3 “(d) APPLICATION OF FINANCIAL CAPACITY LIM-
4 ITS.—

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

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

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

21 “(2) 180-DAY SUSPENSION UPON DENIAL OF
22 COVERAGE.—A health insurance issuer upon denying
23 health insurance coverage in connection with group
24 health plans in accordance with paragraph (1) in a
25 State may not offer coverage in connection with

1 group health plans in the group or individual market
2 in the State for a period of 180 days after the date
3 such coverage is denied or until the issuer has dem-
4 onstrated to the applicable State authority, if re-
5 quired under applicable State law, that the issuer
6 has sufficient financial reserves to underwrite addi-
7 tional coverage, whichever is later. An applicable
8 State authority may provide for the application of
9 this subsection on a service-area-specific basis.

10 “(e) DEFINITIONS.—In this section and in sections
11 197 through 199A:

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

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

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

22 “(a) PROHIBITING DISCRIMINATORY PREMIUM
23 RATES.—

24 “(1) IN GENERAL.—With respect to the pre-
25 mium rate charged by a health insurance issuer for

1 health insurance coverage offered in the individual
2 or small group market—

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

6 “(i) whether such plan or coverage
7 covers an individual or family;

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

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

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

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

20 “(2) RATING AREA.—

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

1 “(B) SECRETARIAL REVIEW.—The Sec-
2 retary shall review the rating areas established
3 by each State under subparagraph (A) to en-
4 sure the adequacy of such areas for purposes of
5 carrying out the requirements of this title. If
6 the Secretary determines a State’s rating areas
7 are not adequate, or that a State does not es-
8 tablish such areas, the Secretary may establish
9 rating areas for that State.

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

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

1 **“SEC. 198. PROHIBITING DISCRIMINATION AGAINST INDI-**
2 **VIDUAL PARTICIPANTS AND BENEFICIARIES**
3 **BASED ON HEALTH STATUS.**

4 “(a) IN GENERAL.—A group health plan and a health
5 insurance issuer offering group or individual health insur-
6 ance coverage may not establish rules for eligibility (in-
7 cluding continued eligibility) of any individual to enroll
8 under the terms of the plan or coverage based on any of
9 the following health status-related factors in relation to
10 the individual or a dependent of the individual:

11 “(1) Health status.

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

14 “(3) Claims experience.

15 “(4) Receipt of health care.

16 “(5) Medical history.

17 “(6) Genetic information.

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

20 “(8) Disability.

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

23 “(b) IN PREMIUM CONTRIBUTIONS.—

24 “(1) IN GENERAL.—A group health plan, and a
25 health insurance issuer offering group or individual
26 health insurance coverage, may not require any indi-

1 vidual (as a condition of enrollment or continued en-
2 rollment under the plan) to pay a premium or con-
3 tribution which is greater than such premium or
4 contribution for a similarly situated individual en-
5 rolled in the plan on the basis of any health status-
6 related factor in relation to the individual or to an
7 individual enrolled under the plan as a dependent of
8 the individual.

9 “(2) CONSTRUCTION.—Nothing in paragraph
10 (1) shall be construed—

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

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

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

1 “(A) IN GENERAL.—For purposes of this
2 section, a group health plan, and health insur-
3 ance issuer offering group health insurance cov-
4 erage in connection with a group health plan,
5 may not adjust premium or contribution
6 amounts for the group covered under such plan
7 on the basis of genetic information.

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

20 “(c) GENETIC TESTING.—

21 “(1) LIMITATION ON REQUESTING OR REQUIR-
22 ING GENETIC TESTING.—A group health plan, and a
23 health insurance issuer offering health insurance
24 coverage in connection with a group health plan,

1 shall not request or require an individual or a family
2 member of such individual to undergo a genetic test.

3 “(2) RULE OF CONSTRUCTION.—Paragraph (1)
4 shall not be construed to limit the authority of a
5 health care professional who is providing health care
6 services to an individual to request that such indi-
7 vidual undergo a genetic test.

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

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

22 “(B) LIMITATION.—For purposes of sub-
23 paragraph (A), a group health plan, or a health
24 insurance issuer offering health insurance cov-
25 erage in connection with a group health plan,

1 may request only the minimum amount of in-
2 formation necessary to accomplish the intended
3 purpose.

4 “(4) RESEARCH EXCEPTION.—Notwithstanding
5 paragraph (1), a group health plan, or a health in-
6 surance issuer offering health insurance coverage in
7 connection with a group health plan, may request,
8 but not require, that a participant or beneficiary un-
9 dergo a genetic test if each of the following condi-
10 tions is met:

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

17 “(B) The plan or issuer clearly indicates to
18 each participant or beneficiary, or in the case of
19 a minor child, to the legal guardian of such
20 beneficiary, to whom the request is made that—

21 “(i) compliance with the request is
22 voluntary; and

23 “(ii) noncompliance will have no effect
24 on enrollment status or premium or con-
25 tribution amounts.

1 “(C) No genetic information collected or
2 acquired under this paragraph shall be used for
3 underwriting purposes.

4 “(D) The plan or issuer notifies the Sec-
5 retary in writing that the plan or issuer is con-
6 ducting activities pursuant to the exception pro-
7 vided for under this paragraph, including a de-
8 scription of the activities conducted.

9 “(E) The plan or issuer complies with such
10 other conditions as the Secretary may by regu-
11 lation require for activities conducted under this
12 paragraph.

13 “(d) PROHIBITION ON COLLECTION OF GENETIC IN-
14 FORMATION.—

15 “(1) IN GENERAL.—A group health plan, and a
16 health insurance issuer offering health insurance
17 coverage in connection with a group health plan,
18 shall not request, require, or purchase genetic infor-
19 mation for underwriting purposes.

20 “(2) PROHIBITION ON COLLECTION OF GE-
21 NETIC INFORMATION PRIOR TO ENROLLMENT.—A
22 group health plan, and a health insurance issuer of-
23 fering health insurance coverage in connection with
24 a group health plan, shall not request, require, or
25 purchase genetic information with respect to any in-

1 dividual prior to such individual’s enrollment under
2 the plan or coverage in connection with such enroll-
3 ment.

4 “(3) INCIDENTAL COLLECTION.—If a group
5 health plan, or a health insurance issuer offering
6 health insurance coverage in connection with a group
7 health plan, obtains genetic information incidental to
8 the requesting, requiring, or purchasing of other in-
9 formation concerning any individual, such request,
10 requirement, or purchase shall not be considered a
11 violation of paragraph (2) if such request, require-
12 ment, or purchase is not in violation of paragraph
13 (1).

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

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

22 “(2) with respect to an individual or family
23 member utilizing an assisted reproductive tech-
24 nology, include genetic information of any embryo le-
25 gally held by the individual or family member.

1 “(f) PROGRAMS OF HEALTH PROMOTION OR DIS-
2 EASE PREVENTION.—

3 “(1) GENERAL PROVISIONS.—

4 “(A) GENERAL RULE.—For purposes of
5 subsection (b)(2)(B), a program of health pro-
6 motion or disease prevention (referred to in this
7 subsection as a ‘wellness program’) shall be a
8 program offered by an employer that is de-
9 signed to promote health or prevent disease
10 that meets the applicable requirements of this
11 subsection.

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

23 “(C) CONDITIONS BASED ON HEALTH STA-
24 TUS FACTOR.—If any of the conditions for ob-
25 taining a premium discount or rebate or other

1 reward for participation in a wellness program
2 is based on an individual satisfying a standard
3 that is related to a health status factor, such
4 wellness program shall not violate this section if
5 the requirements of paragraph (3) are complied
6 with.

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

21 “(A) A program that reimburses all or
22 part of the cost for memberships in a fitness
23 center.

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

4 “(C) A program that encourages preven-
5 tive care related to a health condition through
6 the waiver of the copayment or deductible re-
7 quirement under a group health plan for the
8 costs of certain items or services related to a
9 health condition (such as prenatal care or well-
10 baby visits).

11 “(D) A program that reimburses individ-
12 uals for the costs of smoking cessation pro-
13 grams without regard to whether the individual
14 quits smoking.

15 “(E) A program that provides a reward to
16 individuals for attending a periodic health edu-
17 cation seminar.

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

1 “(A) The reward for the wellness program,
2 together with the reward for other wellness pro-
3 grams with respect to the plan that requires
4 satisfaction of a standard related to a health
5 status factor, shall not exceed 30 percent of the
6 cost of employee-only coverage under the plan.
7 If, in addition to employees or individuals, any
8 class of dependents (such as spouses or spouses
9 and dependent children) may participate fully
10 in the wellness program, such reward shall not
11 exceed 30 percent of the cost of the coverage in
12 which an employee or individual and any de-
13 pendents are enrolled. For purposes of this
14 paragraph, the cost of coverage shall be deter-
15 mined based on the total amount of employer
16 and employee contributions for the benefit
17 package under which the employee is (or the
18 employee and any dependents are) receiving
19 coverage. A reward may be in the form of a dis-
20 count or rebate of a premium or contribution,
21 a waiver of all or part of a cost-sharing mecha-
22 nism (such as deductibles, copayments, or coin-
23 surance), the absence of a surcharge, or the
24 value of a benefit that would otherwise not be
25 provided under the plan. The Secretaries of

1 Labor, Health and Human Services, and the
2 Treasury may increase the reward available
3 under this subparagraph to up to 50 percent of
4 the cost of coverage if the Secretaries determine
5 that such an increase is appropriate.

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

16 “(C) The plan shall give individuals eligible
17 for the program the opportunity to qualify for
18 the reward under the program at least once
19 each year.

20 “(D) The full reward under the wellness
21 program shall be made available to all similarly
22 situated individuals. For such purpose, among
23 other things:

1 “(i) The reward is not available to all
2 similarly situated individuals for a period
3 unless the wellness program allows—

4 “(I) for a reasonable alternative
5 standard (or waiver of the otherwise
6 applicable standard) for obtaining the
7 reward for any individual for whom,
8 for that period, it is unreasonably dif-
9 ficult due to a medical condition to
10 satisfy the otherwise applicable stand-
11 ard; and

12 “(II) for a reasonable alternative
13 standard (or waiver of the otherwise
14 applicable standard) for obtaining the
15 reward for any individual for whom,
16 for that period, it is medically inadvis-
17 able to attempt to satisfy the other-
18 wise applicable standard.

19 “(ii) If reasonable under the cir-
20 cumstances, the plan or issuer may seek
21 verification, such as a statement from an
22 individual’s physician, that a health status
23 factor makes it unreasonably difficult or
24 medically inadvisable for the individual to

1 satisfy or attempt to satisfy the otherwise
2 applicable standard.

3 “(E) The plan or issuer involved shall dis-
4 close in all plan materials describing the terms
5 of the wellness program the availability of a
6 reasonable alternative standard (or the possi-
7 bility of waiver of the otherwise applicable
8 standard) required under subparagraph (D). If
9 plan materials disclose that such a program is
10 available, without describing its terms, the dis-
11 closure under this subparagraph shall not be re-
12 quired.

13 **“SEC. 199. PROHIBITION OF PREEXISTING CONDITION EX-**
14 **CLUSIONS OR OTHER DISCRIMINATION**
15 **BASED ON HEALTH STATUS.**

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

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

21 “(1) PREEXISTING CONDITION EXCLUSION.—

22 “(A) IN GENERAL.—The term ‘preexisting
23 condition exclusion’ means, with respect to cov-
24 erage, a limitation or exclusion of benefits relat-
25 ing to a condition based on the fact that the

1 condition was present before the date of enroll-
2 ment for such coverage, whether or not any
3 medical advice, diagnosis, care, or treatment
4 was recommended or received before such date.

5 “(B) TREATMENT OF GENETIC INFORMA-
6 TION.—Genetic information shall not be treated
7 as a condition described in subsection (a)(1) in
8 the absence of a diagnosis of the condition re-
9 lated to such information.

10 “(2) ENROLLMENT DATE.—The term ‘enroll-
11 ment date’ means, with respect to an individual cov-
12 ered under a group health plan or health insurance
13 coverage, the date of enrollment of the individual in
14 the plan or coverage or, if earlier, the first day of
15 the waiting period for such enrollment.

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

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

22 “(B) a special enrollment period under
23 subsection (f).

24 “(4) WAITING PERIOD.—The term ‘waiting pe-
25 riod’ means, with respect to a group health plan and

1 an individual who is a potential participant or bene-
2 ficiary in the plan, the period that must pass with
3 respect to the individual before the individual is eli-
4 gible to be covered for benefits under the terms of
5 the plan.

6 “(c) RULES RELATING TO CREDITING PREVIOUS
7 COVERAGE.—

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

12 “(A) A group health plan.

13 “(B) Health insurance coverage.

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

16 “(D) Title XIX of the Social Security Act,
17 other than coverage consisting solely of benefits
18 under section 1928.

19 “(E) Chapter 55 of title 10, United States
20 Code.

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

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

24 “(H) A health plan offered under chapter
25 89 of title 5, United States Code.

1 “(I) A public health plan (as defined in
2 regulations).

3 “(J) A health benefit plan under section
4 5(e) of the Peace Corps Act (22 U.S.C.
5 2504(e)).

6 Such term does not include coverage consisting sole-
7 ly of coverage of excepted benefits (as defined in sec-
8 tion 2791(c)).

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

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

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

1 in determining the continuous period under
2 subparagraph (A).

3 “(C) TAA-ELIGIBLE INDIVIDUALS.—In the
4 case of plan years beginning before January 1,
5 2014—

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

20 “(ii) DEFINITIONS.—The terms ‘TAA-
21 eligible individual’ and ‘TAA-related loss of
22 coverage’ have the meanings given such
23 terms in section 2205(b)(4).

24 “(3) METHOD OF CREDITING COVERAGE.—

1 “(A) STANDARD METHOD.—Except as oth-
2 erwise provided under subparagraph (B), for
3 purposes of applying subsection (a)(3), a group
4 health plan, and a health insurance issuer offer-
5 ing group or individual health insurance cov-
6 erage, shall count a period of creditable cov-
7 erage without regard to the specific benefits
8 covered during the period.

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

23 “(C) PLAN NOTICE.—In the case of an
24 election with respect to a group health plan
25 under subparagraph (B) (whether or not health

1 insurance coverage is provided in connection
2 with such plan), the plan shall—

3 “(i) prominently state in any disclo-
4 sure statements concerning the plan, and
5 state to each enrollee at the time of enroll-
6 ment under the plan, that the plan has
7 made such election; and

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

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

14 “(i) shall prominently state in any dis-
15 closure statements concerning the cov-
16 erage, and to each employer at the time of
17 the offer or sale of the coverage, that the
18 issuer has made such election; and

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

21 “(4) ESTABLISHMENT OF PERIOD.—Periods of
22 creditable coverage with respect to an individual
23 shall be established through presentation of certifi-
24 cations described in subsection (e) or in such other
25 manner as may be specified in regulations.

1 “(d) EXCEPTIONS.—

2 “(1) EXCLUSION NOT APPLICABLE TO CERTAIN
3 NEWBORNS.—Subject to paragraph (4), a group
4 health plan, and a health insurance issuer offering
5 group or individual health insurance coverage, may
6 not impose any preexisting condition exclusion in the
7 case of an individual who, as of the last day of the
8 30-day period beginning with the date of birth, is
9 covered under creditable coverage.

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

22 “(3) EXCLUSION NOT APPLICABLE TO PREG-
23 NANCY.—A group health plan, and health insurance
24 issuer offering group or individual health insurance
25 coverage, may not impose any preexisting condition

1 exclusion relating to pregnancy as a preexisting con-
2 dition.

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

8 “(e) CERTIFICATIONS AND DISCLOSURE OF COV-
9 ERAGE.—

10 “(1) REQUIREMENT FOR CERTIFICATION OF
11 PERIOD OF CREDITABLE COVERAGE.—

12 “(A) IN GENERAL.—A group health plan,
13 and a health insurance issuer offering group or
14 individual health insurance coverage, shall pro-
15 vide the certification described in subparagraph
16 (B)—

17 “(i) at the time an individual ceases
18 to be covered under the plan or otherwise
19 becomes covered under a COBRA continu-
20 ation provision;

21 “(ii) in the case of an individual be-
22 coming covered under such a provision, at
23 the time the individual ceases to be covered
24 under such provision; and

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

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

10 “(B) CERTIFICATION.—The certification
11 described in this subparagraph is a written cer-
12 tification of—

13 “(i) the period of creditable coverage
14 of the individual under such plan and the
15 coverage (if any) under such COBRA con-
16 tinuation provision; and

17 “(ii) the waiting period (if any) (and
18 affiliation period, if applicable) imposed
19 with respect to the individual for any cov-
20 erage under such plan.

21 “(C) ISSUER COMPLIANCE.—To the extent
22 that medical care under a group health plan
23 consists of group health insurance coverage, the
24 plan is deemed to have satisfied the certification
25 requirement under this paragraph if the health

1 insurance issuer offering the coverage provides
2 for such certification in accordance with this
3 paragraph.

4 “(2) DISCLOSURE OF INFORMATION ON PRE-
5 VIOUS BENEFITS.—In the case of an election de-
6 scribed in subsection (c)(3)(B) by a group health
7 plan or health insurance issuer, if the plan or issuer
8 enrolls an individual for coverage under the plan and
9 the individual provides a certification of coverage of
10 the individual under paragraph (1)—

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

18 “(B) such entity may charge the request-
19 ing plan or issuer for the reasonable cost of dis-
20 closing such information.

21 “(3) REGULATIONS.—The Secretary shall es-
22 tablish rules to prevent an entity’s failure to provide
23 information under paragraph (1) or (2) with respect
24 to previous coverage of an individual from adversely
25 affecting any subsequent coverage of the individual

1 under another group health plan or health insurance
2 coverage.

3 “(f) SPECIAL ENROLLMENT PERIODS.—

4 “(1) INDIVIDUALS LOSING OTHER COVERAGE.—

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

14 “(A) The employee or dependent was cov-
15 ered under a group health plan or had health
16 insurance coverage at the time coverage was
17 previously offered to the employee or dependent.

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

1 the consequences of such requirement) at such
2 time.

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

5 “(i) was under a COBRA continu-
6 ation provision and the coverage under
7 such provision was exhausted; or

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

16 “(D) Under the terms of the plan, the em-
17 ployee requests such enrollment not later than
18 30 days after the date of exhaustion of coverage
19 described in subparagraph (C)(i) or termination
20 of coverage or employer contribution described
21 in subparagraph (C)(ii).

22 “(2) FOR DEPENDENT BENEFICIARIES.—

23 “(A) IN GENERAL.—If—

1 “(i) a group health plan makes cov-
2 erage available with respect to a dependent
3 of an individual;

4 “(ii) the individual is a participant
5 under the plan (or has met any waiting pe-
6 riod applicable to becoming a participant
7 under the plan and is eligible to be enrolled
8 under the plan but for a failure to enroll
9 during a previous enrollment period); and

10 “(iii) a person becomes such a de-
11 pendent of the individual through mar-
12 riage, birth, or adoption or placement for
13 adoption,

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

23 “(B) DEPENDENT SPECIAL ENROLLMENT
24 PERIOD.—A dependent special enrollment pe-
25 riod under this subparagraph shall be a period

1 of not less than 30 days and shall begin on the
2 later of—

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

5 “(ii) the date of the marriage, birth,
6 or adoption or placement for adoption (as
7 the case may be) described in subpara-
8 graph (A)(iii).

9 “(C) NO WAITING PERIOD.—If an indi-
10 vidual seeks to enroll a dependent during the
11 first 30 days of such a dependent special enroll-
12 ment period, the coverage of the dependent
13 shall become effective—

14 “(i) in the case of marriage, not later
15 than the first day of the first month begin-
16 ning after the date the completed request
17 for enrollment is received;

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

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

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

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

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

1 “(ii) ELIGIBILITY FOR EMPLOYMENT
2 ASSISTANCE UNDER MEDICAID OR CHIP.—
3 The employee or dependent becomes eligi-
4 ble for assistance, with respect to coverage
5 under the group health plan or health in-
6 surance coverage, under such Medicaid
7 plan or State child health plan (including
8 under any waiver or demonstration project
9 conducted under or in relation to such a
10 plan), if the employee requests coverage
11 under the group health plan or health in-
12 surance coverage not later than 60 days
13 after the date the employee or dependent is
14 determined to be eligible for such assist-
15 ance.

16 “(B) COORDINATION WITH MEDICAID AND
17 CHIP.—

18 “(i) OUTREACH TO EMPLOYEES RE-
19 GARDING AVAILABILITY OF MEDICAID AND
20 CHIP COVERAGE.—

21 “(I) IN GENERAL.—Each em-
22 ployer that maintains a group health
23 plan in a State that provides medical
24 assistance under a State Medicaid
25 plan under title XIX of the Social Se-

1 curity Act, or child health assistance
2 under a State child health plan under
3 title XXI of such Act, in the form of
4 premium assistance for the purchase
5 of coverage under a group health
6 plan, shall provide to each employee a
7 written notice informing the employee
8 of potential opportunities then cur-
9 rently available in the State in which
10 the employee resides for premium as-
11 sistance under such plans for health
12 coverage of the employee or the em-
13 ployee’s dependents. For purposes of
14 compliance with this subclause, the
15 employer may use any State-specific
16 model notice developed in accordance
17 with section 701(f)(3)(B)(i)(II) of the
18 Employee Retirement Income Security
19 Act of 1974 (29 U.S.C.
20 1181(f)(3)(B)(i)(II)).

21 “(II) OPTION TO PROVIDE CON-
22 CURRENT WITH PROVISION OF PLAN
23 MATERIALS TO EMPLOYEE.—An em-
24 ployer may provide the model notice
25 applicable to the State in which an

1 employee resides concurrent with the
2 furnishing of materials notifying the
3 employee of health plan eligibility,
4 concurrent with materials provided to
5 the employee in connection with an
6 open season or election process con-
7 ducted under the plan, or concurrent
8 with the furnishing of the summary
9 plan description as provided in section
10 104(b) of the Employee Retirement
11 Income Security Act of 1974.

12 “(ii) DISCLOSURE ABOUT GROUP
13 HEALTH PLAN BENEFITS TO STATES FOR
14 MEDICAID AND CHIP ELIGIBLE INDIVID-
15 UALS.—In the case of an enrollee in a
16 group health plan who is covered under a
17 Medicaid plan of a State under title XIX
18 of the Social Security Act or under a State
19 child health plan under title XXI of such
20 Act, the plan administrator of the group
21 health plan shall disclose to the State,
22 upon request, information about the bene-
23 fits available under the group health plan
24 in sufficient specificity, as determined
25 under regulations of the Secretary of

1 Health and Human Services in consulta-
2 tion with the Secretary that require use of
3 the model coverage coordination disclosure
4 form developed under section 311(b)(1)(C)
5 of the Children’s Health Insurance Reau-
6 thorization Act of 2009, so as to permit
7 the State to make a determination (under
8 paragraph (2)(B), (3), or (10) of section
9 2105(c) of the Social Security Act or oth-
10 erwise) concerning the cost-effectiveness of
11 the State providing medical or child health
12 assistance through premium assistance for
13 the purchase of coverage under such group
14 health plan and in order for the State to
15 provide supplemental benefits required
16 under paragraph (10)(E) of such section
17 or other authority.

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

20 “(1) IN GENERAL.—A health maintenance orga-
21 nization which offers health insurance coverage in
22 connection with a group health plan and which does
23 not impose any preexisting condition exclusion al-
24 lowed under subsection (a) with respect to any par-

1 particular coverage option may impose an affiliation pe-
2 riod for such coverage option, but only if—

3 “(A) such period is applied uniformly with-
4 out regard to any health status-related factors;
5 and

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

8 “(2) AFFILIATION PERIOD.—

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

20 “(B) BEGINNING.—Such period shall begin
21 on the enrollment date.

22 “(C) RUNS CONCURRENTLY WITH WAITING
23 PERIODS.—An affiliation period under a plan
24 shall run concurrently with any waiting period
25 under the plan.

1 “(3) ALTERNATIVE METHODS.—A health main-
2 tenance organization described in paragraph (1) may
3 use alternative methods, from those described in
4 such paragraph, to address adverse selection as ap-
5 proved by the State insurance commissioner or offi-
6 cial or officials designated by the State to enforce
7 the requirements of this part for the State involved
8 with respect to such issuer.

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

10 “(a) IN GENERAL.—A group health plan and a health
11 insurance issuer offering group or individual health insur-
12 ance coverage that provides dependent coverage of chil-
13 dren shall continue to make such coverage available for
14 an adult child (who is not married) until the child turns
15 26 years of age. Nothing in this section shall require a
16 health plan or a health insurance issuer described in the
17 preceding sentence to make coverage available for a child
18 of a child receiving dependent coverage.

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

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

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

2 “(a) IN GENERAL.—

3 “(1) 2014.—The cost-sharing incurred under a
4 group health plan or group or individual health in-
5 surance coverage with respect to self-only coverage
6 or coverage other than self-only coverage for a plan
7 year beginning in 2014 shall not exceed the dollar
8 amounts in effect under section 223(c)(2)(A)(ii) of
9 the Internal Revenue Code of 1986 for self-only and
10 family coverage, respectively, for taxable years begin-
11 ning in 2014.

12 “(2) 2015 AND LATER.—In the case of any
13 plan year beginning in a calendar year after 2014,
14 the limitation under this paragraph shall—

15 “(A) in the case of self-only coverage, be
16 equal to the dollar amount under paragraph (1)
17 for self-only coverage for plan years beginning
18 in 2014, increased by an amount equal to the
19 product of that amount and the premium ad-
20 justment percentage under subsection (c) for
21 the calendar year; and

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

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

1 “(b) COST-SHARING.—In this section:

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

4 “(A) deductibles, coinsurance, copayments,
5 or similar charges; and

6 “(B) any other expenditure required of an
7 insured individual which is a qualified medical
8 expense (within the meaning of section
9 223(d)(2) of the Internal Revenue Code of
10 1986) with respect to essential health benefits
11 covered under the plan.

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

15 “(c) PREMIUM ADJUSTMENT PERCENTAGE.—For
16 purposes of subsection (a)(2)(A), the premium adjustment
17 percentage for any calendar year is the percentage (if any)
18 by which the average per capita premium for health insur-
19 ance coverage in the United States for the preceding cal-
20 endar year (as estimated by the Secretary no later than
21 October 1 of such preceding calendar year) exceeds such
22 average per capita premium for 2013 (as determined by
23 the Secretary).

1 **“SEC. 199C. ENFORCEMENT OF CERTAIN HEALTH INSUR-**
2 **ANCE REQUIREMENTS.**

3 “(a) STATE ENFORCEMENT.—

4 “(1) STATE AUTHORITY.—Each State may re-
5 quire that health insurance issuers that issue, sell,
6 renew, or offer health insurance coverage in the
7 State in the individual or group market meet the re-
8 quirements of this part with respect to such issuers.

9 “(2) FAILURE TO IMPLEMENT PROVISIONS.—In
10 the case of a determination by the Secretary that a
11 State has failed to substantially enforce a provision
12 (or provisions) of sections 196 through 199A with
13 respect to health insurance issuers in the State, the
14 Secretary shall enforce such provision (or provisions)
15 under subsection (b) insofar as they relate to the
16 issuance, sale, renewal, and offering of health insur-
17 ance coverage in connection with group health plans
18 or individual health insurance coverage in such
19 State.

20 “(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

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

24 “(A) as provided under such subsection;

25 and

1 “(B) with respect to individual health in-
2 surance coverage or group health plans that are
3 non-Federal governmental plans.

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

6 “(A) IN GENERAL.—Subject to the suc-
7 ceeding provisions of this subsection, any non-
8 Federal governmental plan that is a group
9 health plan and any health insurance issuer
10 that fails to meet a provision of this part appli-
11 cable to such plan or issuer is subject to a civil
12 money penalty under this subsection.

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

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

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

19 “(I) sponsored by 2 or more em-
20 ployers, the plan is liable for such
21 penalty; or

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

24 “(C) AMOUNT OF PENALTY.—

1 “(i) IN GENERAL.—The maximum
2 amount of penalty imposed under this
3 paragraph is \$100 for each day for each
4 individual with respect to which such a
5 failure occurs.

6 “(ii) CONSIDERATIONS IN IMPOSI-
7 TION.—In determining the amount of any
8 penalty to be assessed under this para-
9 graph, the Secretary shall take into ac-
10 count the previous record of compliance of
11 the entity being assessed with the applica-
12 ble provisions of this part and the gravity
13 of the violation.

14 “(iii) LIMITATIONS.—

15 “(I) PENALTY NOT TO APPLY
16 WHERE FAILURE NOT DISCOVERED
17 EXERCISING REASONABLE DILI-
18 GENCE.—No civil money penalty shall
19 be imposed under this paragraph on
20 any failure during any period for
21 which it is established to the satisfac-
22 tion of the Secretary that none of the
23 entities against whom the penalty
24 would be imposed knew, or exercising

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

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

16 “(D) ADMINISTRATIVE REVIEW.—

17 “(i) OPPORTUNITY FOR HEARING.—
18 The entity assessed shall be afforded an
19 opportunity for hearing by the Secretary
20 upon request made within 30 days after
21 the date of the issuance of a notice of as-
22 sessment. In such hearing the decision
23 shall be made on the record pursuant to
24 section 554 of title 5, United States Code.
25 If no hearing is requested, the assessment

1 shall constitute a final and unappealable
2 order.

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

16 “(E) JUDICIAL REVIEW.—

17 “(i) FILING OF ACTION FOR RE-
18 VIEW.—Any entity against whom an order
19 imposing a civil money penalty has been
20 entered after an agency hearing under this
21 paragraph may obtain review by the
22 United States district court for any district
23 in which such entity is located or the
24 United States District Court for the Dis-
25 trict of Columbia by filing a notice of ap-

1 peal in such court within 30 days from the
2 date of such order, and simultaneously
3 sending a copy of such notice by registered
4 mail to the Secretary.

5 “(ii) CERTIFICATION OF ADMINISTRA-
6 TIVE RECORD.—The Secretary shall
7 promptly certify and file in such court the
8 record upon which the penalty was im-
9 posed.

10 “(iii) STANDARD FOR REVIEW.—The
11 findings of the Secretary shall be set aside
12 only if found to be unsupported by sub-
13 stantial evidence as provided by section
14 706(2)(E) of title 5, United States Code.

15 “(iv) APPEAL.—Any final decision,
16 order, or judgment of the district court
17 concerning such review shall be subject to
18 appeal as provided in chapter 83 of title 28
19 of such Code.

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

22 “(i) FAILURE TO PAY ASSESSMENT.—
23 If any entity fails to pay an assessment
24 after it has become a final and
25 unappealable order, or after the court has

1 entered final judgment in favor of the Sec-
2 retary, the Secretary shall refer the matter
3 to the Attorney General who shall recover
4 the amount assessed by action in the ap-
5 propriate United States district court.

6 “(ii) NONREVIEWABILITY.—In such
7 action the validity and appropriateness of
8 the final order imposing the penalty shall
9 not be subject to review.

10 “(G) PAYMENT OF PENALTIES.—Except as
11 otherwise provided, penalties collected under
12 this paragraph shall be paid to the Secretary
13 (or other officer) imposing the penalty and shall
14 be available without appropriation and until ex-
15 pended for the purpose of enforcing the provi-
16 sions with respect to which the penalty was im-
17 posed.

18 “(3) ENFORCEMENT AUTHORITY RELATING TO
19 GENETIC DISCRIMINATION.—

20 “(A) GENERAL RULE.—In the cases de-
21 scribed in paragraph (1), notwithstanding the
22 provisions of paragraph (2)(C), the succeeding
23 subparagraphs of this paragraph shall apply
24 with respect to an action under this subsection
25 by the Secretary with respect to any failure of

1 a health insurance issuer in connection with a
2 group health plan, to meet the requirements of
3 subsection (a)(1)(F), (b)(3), (c), or (d) of sec-
4 tion 196 or section 197 or 196(b)(1) with re-
5 spect to genetic information in connection with
6 the plan.

7 “(B) AMOUNT.—

8 “(i) IN GENERAL.—The amount of
9 the penalty imposed under this paragraph
10 shall be \$100 for each day in the non-
11 compliance period with respect to each par-
12 ticipant or beneficiary to whom such fail-
13 ure relates.

14 “(ii) NONCOMPLIANCE PERIOD.—For
15 purposes of this paragraph, the term ‘non-
16 compliance period’ means, with respect to
17 any failure, the period—

18 “(I) beginning on the date such
19 failure first occurs; and

20 “(II) ending on the date the fail-
21 ure is corrected.

22 “(C) MINIMUM PENALTIES WHERE FAIL-
23 URE DISCOVERED.—Notwithstanding clauses (i)
24 and (ii) of subparagraph (D):

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

4 “(I) which are not corrected be-
5 fore the date on which the plan re-
6 ceives a notice from the Secretary of
7 such violation; and

8 “(II) which occurred or continued
9 during the period involved;

10 the amount of penalty imposed by subpara-
11 graph (A) by reason of such failures with
12 respect to such individual shall not be less
13 than \$2,500.

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

22 “(D) LIMITATIONS.—

23 “(i) PENALTY NOT TO APPLY WHERE
24 FAILURE NOT DISCOVERED EXERCISING
25 REASONABLE DILIGENCE.—No penalty

1 shall be imposed by subparagraph (A) on
2 any failure during any period for which it
3 is established to the satisfaction of the
4 Secretary that the person otherwise liable
5 for such penalty did not know, and exer-
6 cising reasonable diligence would not have
7 known, that such failure existed.

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

12 “(I) such failure was due to rea-
13 sonable cause and not to willful ne-
14 glect; and

15 “(II) such failure is corrected
16 during the 30-day period beginning on
17 the first date the person otherwise lia-
18 ble for such penalty knew, or exer-
19 cising reasonable diligence would have
20 known, that such failure existed.

21 “(iii) OVERALL LIMITATION FOR UN-
22 INTENTIONAL FAILURES.—In the case of
23 failures which are due to reasonable cause
24 and not to willful neglect, the penalty im-
25 posed by subparagraph (A) for failures

1 shall not exceed the amount equal to the
2 lesser of—

3 “(I) 10 percent of the aggregate
4 amount paid or incurred by the em-
5 ployer (or predecessor employer) dur-
6 ing the preceding taxable year for
7 group health plans; or

8 “(II) \$500,000.

9 “(E) WAIVER BY SECRETARY.—In the case
10 of a failure which is due to reasonable cause
11 and not to willful neglect, the Secretary may
12 waive part or all of the penalty imposed by sub-
13 paragraph (A) to the extent that the payment
14 of such penalty would be excessive relative to
15 the failure involved.

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

17 “(1) GOVERNMENTAL PLAN.—The term ‘gov-
18 ernmental plan’ has the meaning given such term
19 under section 3(32) of the Employee Retirement In-
20 come Security Act of 1974 and any Federal govern-
21 mental plan.

22 “(2) FEDERAL GOVERNMENTAL PLAN.—The
23 term “Federal governmental plan” means a govern-
24 mental plan established or maintained for its em-
25 ployees by the Government of the United States or

1 by any agency or instrumentality of such Govern-
2 ment.

3 “(3) NON-FEDERAL GOVERNMENTAL PLAN.—
4 The term ‘non-Federal governmental plan’ means a
5 governmental plan that is not a Federal govern-
6 mental plan.”.

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

“Sec. 196. Guaranteed availability of coverage.

“Sec. 197. Fair health insurance premiums.

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

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

“Sec. 199A. Extension of dependent coverage.

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

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

12 (c) ERISA AND IRC ENFORCEMENT.—

13 (1) ERISA.—Subpart B of part 7 of title I of
14 the Employee Retirement Income Security Act of
15 1974 (29 U.S.C. 1185 et seq.) is amended by adding
16 at the end the following new section:

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

18 “Sections 196 and 197 of the Health Insurance Port-
19 ability and Accountability Act of 1996 shall apply to
20 health insurance issuers providing health insurance cov-
21 erage in connection with group health plans, and sections

1 198 through 199B of such Act shall apply to group health
2 plans and health insurance issuers providing health insur-
3 ance coverage in connection with group health plans, as
4 if included in this subpart, and to the extent that any pro-
5 vision of this part conflicts with a provision of such section
6 196 or 197 with respect to health insurance issuers pro-
7 viding health insurance coverage in connection with group
8 health plans or of such section 198, 199, 199A, or 199B
9 with respect to group health plans or health insurance
10 issuers providing health insurance coverage in connection
11 with group health plans, the provisions of such sections
12 196 through 199B shall apply.”.

13 (2) IRC.—Subchapter B of chapter 100 of sub-
14 title K of title 26 of the Internal Revenue Code of
15 1986 is amended by adding at the end the following
16 new section:

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

18 “Sections 196 and 197 of the Health Insurance Port-
19 ability and Accountability Act of 1996 shall apply to
20 health insurance issuers providing health insurance cov-
21 erage in connection with group health plans, and sections
22 198 through 199B of such Act shall apply to group health
23 plans and health insurance issuers providing health insur-
24 ance coverage in connection with group health plans, as
25 if included in this subchapter, and to the extent that any

1 provision of this chapter conflicts with a provision of such
2 section 196 or 197 with respect to health insurance issuers
3 providing health insurance coverage in connection with
4 group health plans or of such section 198, 199, 199A, or
5 199B with respect to group health plans or health insur-
6 ance issuers providing health insurance coverage in con-
7 nection with group health plans, the provisions of such
8 sections 196 through 199B shall apply.”.

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

14 **Subtitle B—Expanding Coverage** 15 **Options**

16 **SEC. 211. DEFINITION OF “EMPLOYER” UNDER ERISA WITH** 17 **RESPECT TO GROUP HEALTH PLANS.**

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

24 (b) GROUP HEALTH PLANS.—Part 7 of subtitle B
25 of title I of the Employee Retirement Income Security Act

1 of 1974 (29 U.S.C. 1181 et seq.) is amended by adding
2 at the end the following:

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

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

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

11 “(1) The primary purpose of the group or asso-
12 ciation may be to offer and provide health coverage
13 to its employer members and their employees, if
14 such group or association has at least 1 substantial
15 business purpose, as described in subsection (c), un-
16 related to offering and providing health coverage or
17 other employee benefits to its employer members and
18 their employees.

19 “(2) Each employer member of the group or as-
20 sociation participating in the group health plan is a
21 person acting directly as an employer of at least 1
22 employee who is a participant covered under the
23 plan.

24 “(3) The group or association has—

1 “(A) a formal organizational structure
2 with a governing body; and

3 “(B) by-laws or other similar indications of
4 formality.

5 “(4) The functions and activities of the group
6 or association shall be controlled by the employer
7 members of the group or association, and the em-
8 ployer members of the group or association that par-
9 ticipate in the group health plan shall control the
10 plan. Control under this paragraph shall be in form
11 and substance.

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

14 “(6)(A) The group or association shall not
15 make health coverage through the group health plan
16 available other than to—

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

19 “(ii) a former employee of a current em-
20 ployer member of the group or association who
21 became eligible for coverage under the group
22 health plan when the former employee was an
23 employee of the employer; and

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

4 “(B) Notwithstanding subparagraph (A), the
5 group or association shall not make health coverage
6 through the group health plan available to any indi-
7 vidual (or beneficiaries of the individual) for any
8 plan year following the plan year in which the plan
9 determines pursuant to reasonable monitoring proce-
10 dures described in subsection (f)(2)(C) that the indi-
11 vidual ceases to meet the conditions described in
12 subsection (f)(2) for being a working owner (unless
13 the individual again meets those conditions), except
14 as may be required by section 601.

15 “(7) The group or association, and any health
16 coverage offered by the group or association, shall
17 comply with the nondiscrimination provisions under
18 subsection (e).

19 “(8) The group or association shall not be a
20 health insurance issuer, or owned or controlled by
21 such a health insurance issuer or by a subsidiary or
22 affiliate of such a health insurance issuer, other
23 than to the extent such entities participate in the
24 group or association in their capacity as employer
25 members of the group or association.

1 “(c) SUBSTANTIAL BUSINESS PURPOSE.—

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

6 “(2) BUSINESS PURPOSE.—For purposes of
7 subsection (b)(1) and paragraph (1), a business pur-
8 pose shall—

9 “(A) include promoting common business
10 interests of the members of the group or asso-
11 ciation or the common economic interests in a
12 given trade or employer community; and

13 “(B) not be required to be a for-profit ac-
14 tivity.

15 “(d) COMMONALITY OF INTEREST.—

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

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

22 “(B) each employer has a principal place
23 of business in the same region that does not ex-
24 ceed the boundaries of a single State or a met-

1 metropolitan area (even if the metropolitan area in-
2 cludes more than 1 State).

3 “(2) SAME TRADE, INDUSTRY, OR LINE OF
4 BUSINESS.—In the case of a group or association
5 that is sponsoring a group health plan under this
6 section and that is itself an employer member of the
7 group or association, the group or association shall
8 be deemed for purposes of paragraph (1)(A) to be
9 in the same trade, industry, line of business, or pro-
10 fession, as applicable, as the other employer mem-
11 bers of the group or association.

12 “(3) NONDISCRIMINATION.—The standards
13 under paragraph (1) shall not be implemented in a
14 manner that is subterfuge for discrimination as is
15 prohibited under subsection (e).

16 “(e) NONDISCRIMINATION.—

17 “(1) IN GENERAL.—A group or association of
18 employers sponsoring a group health plan under this
19 section, and any health coverage sponsored by such
20 group or association, shall comply with each of the
21 following:

22 “(A) The group or association shall not
23 condition employer membership in the group or
24 association on any health factor of any indi-
25 vidual who is or may become eligible to partici-

1 pate in the group health plan sponsored by the
2 group or association.

3 “(B) The group health plan sponsored by
4 the group or association shall comply with the
5 rules under section 2590.702(b) of title 29,
6 Code of Federal Regulations (as in effect on
7 June 21, 2018), with respect to nondiscrimina-
8 tion in rules for eligibility for benefits, subject
9 to subparagraph (D).

10 “(C) The group health plan sponsored by
11 the group or association shall comply with the
12 rules under section 2590.702(c) of title 29,
13 Code of Federal Regulations (as in effect on
14 June 21, 2018), with respect to nondiscrimina-
15 tion in premiums or contributions required by
16 any participant or beneficiary for coverage
17 under the plan, subject to subparagraph (D).

18 “(D) In applying subparagraphs (B) and
19 (C), the group or association may not treat the
20 employees of different employer members of the
21 group or association as distinct groups of simi-
22 larly situated individuals based on a health fac-
23 tor of 1 or more individuals.

24 “(2) DEFINITION OF HEALTH FACTOR.—For
25 purposes of this subsection, the term ‘health factor’

1 has the meaning given such term in section
2 2590.702(a) of title 29, Code of Federal Regulations
3 (as in effect on June 21, 2018).

4 “(f) DUAL TREATMENT OF WORKING OWNERS AS
5 EMPLOYERS AND EMPLOYEES.—

6 “(1) IN GENERAL.—A person determined in ac-
7 cordance with paragraph (2) to be a working owner
8 of a trade or business may qualify as both an em-
9 ployer and as an employee of the trade or business
10 for purposes of the requirements under subsection
11 (b), including the requirements under paragraphs
12 (2) and (6) of such subsection.

13 “(2) WORKING OWNER.—

14 “(A) ELIGIBILITY.—A person shall qualify
15 as a ‘working owner’ if a responsible fiduciary
16 of the group health plan reasonably determines
17 that the person—

18 “(i) does not have any common law
19 employees;

20 “(ii) has an ownership right of any
21 nature in a trade or business, whether in-
22 corporated or unincorporated, including a
23 partner and other self-employed individual;

24 “(iii) is earning wages or self-employ-
25 ment income from the trade or business

1 for providing personal services to the trade
2 or business; and

3 “(iv) either—

4 “(I) works on average at least 20
5 hours per week, or at least 80 hours
6 per month, providing personal services
7 to the person’s trade or business; or

8 “(II) has wages or self-employ-
9 ment income from such trade or busi-
10 ness that at least equals the person’s
11 cost of coverage for participation by
12 the person, and any covered bene-
13 ficiaries, in the group health plan
14 sponsored by the group or association
15 in which the person is participating.

16 “(B) DETERMINATION.—The determina-
17 tion under subparagraph (A) shall be made
18 when the person first becomes eligible for cov-
19 erage under the group health plan.

20 “(C) REASONABLE MONITORING PROCE-
21 DURES.—A responsible fiduciary of the group
22 health plan shall, through reasonable moni-
23 toring procedures, periodically confirm the con-
24 tinued eligibility of a person to qualify as a
25 working owner under subparagraph (A) for pur-

1 poses of meeting the requirements under sub-
2 section (b) for the group health plan sponsored
3 under this section.

4 “(g) APPLICABILITY.—

5 “(1) FULLY INSURED.—This section shall apply
6 beginning on September 1, 2026, with respect to a
7 group or association of employers sponsoring a
8 group health plan that is fully insured.

9 “(2) PLANS EXPANDING TO INCLUDE BROADER
10 GROUP.—This section shall apply beginning on Jan-
11 uary 1, 2026, with respect to a group or association
12 of employers sponsoring a group health plan that—

13 “(A) is not fully insured;

14 “(B) is in existence on June 21, 2025;

15 “(C) meets the requirements that applied
16 with respect to such plan before June 21, 2025;
17 and

18 “(D) chooses to be a plan sponsored under
19 this section (and subject to the requirements
20 under subsections (b) through (f)).

21 “(3) OTHER ASSOCIATION HEALTH PLANS.—
22 This section shall apply beginning on April 1, 2026,
23 with respect to any other group or association of em-
24 ployers sponsoring a group health plan.

1 “(4) OTHER CRITERIA IN ADVISORY OPIN-
2 IONS.—The criteria under this section shall not in-
3 validate any criteria provided in an advisory opinion,
4 in effect on or after the date of enactment of the
5 Fair Care Act of 2026, that the Secretary may use
6 to determine if a group or association of employers
7 is an employer under section 3(5) for purposes of
8 sponsoring a group health plan.

9 “(h) DETERMINATION OF EMPLOYER OR JOINT EM-
10 PLOYER STATUS.—

11 “(1) IN GENERAL.—Participating in or facili-
12 tating a group health plan sponsored by a bona fide
13 group or association of employers pursuant to sub-
14 section (a) shall not be construed as establishing an
15 employer or joint employer relationship under any
16 Federal or State law.

17 “(2) APPLICATION OF PROVISION.—Paragraph
18 (1) shall apply to a group health plan sponsored or
19 facilitated by a franchisor and any franchisee, by
20 multiple franchisors for the benefit of the employees
21 of such franchisors and their franchisees, by mul-
22 tiple franchisees for the benefit of the employees of
23 such franchisees, by a franchisor whose franchisee or
24 franchisees participate or participates in the plan, or
25 by a person or entity that contracts with any indi-

1 vidual as an independent contractor for whom the
2 plan benefits.

3 “(i) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed as repealing or otherwise limiting
5 the application of this Act (including section 712 relating
6 to mental health parity) to group health plans and em-
7 ployee welfare benefit plans.”.

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

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

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

21 (b) **GUARANTEED RENEWABILITY.**—Section 2703 of
22 the Public Health Service Act (42 U.S.C. 300gg–2) is
23 amended—

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

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

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

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

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

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

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

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

4 (c) APPLICABILITY.—The amendments made by sub-
5 sections (a) and (b) shall apply with respect to contracts
6 for short-term limited duration insurance that take effect
7 on or after January 1, 2026.

8 **Subtitle C—Improving Commercial** 9 **Health Insurance**

10 **SEC. 221. INVISIBLE GUARANTEED COVERAGE POOL REIN-** 11 **SURANCE PROGRAM; TAX ON EXCHANGE** 12 **PLANS.**

13 (a) ESTABLISHMENT.—Not later than 2 years after
14 the date of enactment of this Act, the Secretary of Health
15 and Human Services shall establish the Invisible Guar-
16 teed Coverage Pool Reinsurance Program (in this section
17 referred to as the “IGCPR program”).

18 (b) STATE GRANTS.—Under the IGCPR program,
19 the Secretary shall, from amounts appropriated under
20 subsection (f) for a fiscal year, award grants to States for
21 such fiscal year, in amounts determined in accordance
22 with the allocation methodology specified under subsection
23 (d). Such grants shall be used for the purpose of estab-
24 lishing or maintaining a qualifying Invisible Guaranteed
25 Coverage Pool for the State.

1 (c) FEDERAL DEFAULT.—

2 (1) IN GENERAL.—In the case of a State that
3 does not, by a date and in a manner specified by the
4 Secretary, choose to be awarded a grant under sub-
5 section (b) for a fiscal year to operate a qualifying
6 Invisible Guaranteed Coverage Pool for the State,
7 the Secretary shall, from amounts appropriated
8 under subsection (f) for such fiscal year, use the al-
9 location determined for the State under subsection
10 (d) for participation of such State in the Federal de-
11 fault qualifying Invisible Guaranteed Coverage Pool
12 described in paragraph (2).

13 (2) FEDERAL DEFAULT QUALIFYING INVISIBLE
14 GUARANTEED COVERAGE POOL.—The Federal de-
15 fault qualifying high risk pool is, with respect to
16 each State that chooses not to be awarded a grant
17 under subsection (b) with respect to a fiscal year for
18 which funds are appropriated under subsection (f),
19 an Invisible Guaranteed Coverage Pool under which
20 health insurance issuers participating in the Ex-
21 change of such a State, with respect to designated
22 individuals who are enrolled in health insurance cov-
23 erage and are expected to experience higher than av-
24 erage health costs as determined by the insurer, cede
25 risk to the pool, without affecting the premium paid

1 by the designated individuals or their terms of cov-
2 erage. With respect to such pool—

3 (A) high-risk individuals designated for
4 cession to the pool shall be designated by the
5 ceding issuer;

6 (B) the premium amount the ceding issuer
7 shall pay to the reinsurance pool shall be 90
8 percent of the premium paid to the issuer for
9 the coverage;

10 (C) the ceding issuer shall retain the same
11 risk under the ceded policies as under any other
12 policy of the issuer with respect to the first
13 \$10,000 of benefits for each ceded policy in-
14 volved and will not retain any risk under ceded
15 policies after such first \$10,000 of benefits; and

16 (D) after a ceding issuer, with respect to
17 a ceded policy, no longer retains risk under
18 such policy pursuant to subparagraph (C), the
19 negotiated rate under such policy for items and
20 services shall be payable at the reimbursement
21 rate under the Medicare program under title
22 XVIII of the Social Security Act for such items
23 and services, or in the case of items and serv-
24 ices for which payment is available under the

1 policy but not the Medicare program, at a rate
2 determined by the Secretary.

3 (d) ALLOCATION METHODOLOGY.—Not later than six
4 months after the establishment of the IG CPR program,
5 the Secretary shall specify an allocation methodology for
6 determining the amount of funds appropriated under sub-
7 section (f) for a fiscal year to be allocated for each State
8 for purposes of subsections (b) and (c). Such methodology
9 shall be based on the number of residents of each State
10 and the general health status of such residents.

11 (e) QUALIFYING INVISIBLE GUARANTEED COVERAGE
12 POOL.—For purposes of this section, the term “qualifying
13 Invisible Guaranteed Coverage Pool” means, with respect
14 to a State, a method of designation under which health
15 insurance issuers identify individuals who experience high-
16 er than average health costs as determined by the State
17 and are enrolled in health insurance coverage offered in
18 the individual market, and cede the risk of spending more
19 than \$10,000 on health care services for a single indi-
20 vidual to the pool without affecting the premium paid by
21 the designated individuals or their terms of coverage. With
22 respect to such pool, the State, or an entity operating the
23 pool on behalf of the State, shall establish—

24 (1) the premium amount the ceding issuer shall
25 pay to the reinsurance pool;

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

8 (3) the mechanism by which high-risk individ-
 9 uals are designated for cession to the pool, which
 10 may include a list of designated high-cost health
 11 conditions.

12 (f) APPROPRIATIONS.—There is appropriated to the
 13 Secretary of Health and Human Services
 14 \$200,000,000,000 to carry out this section for the period
 15 of the first 10 years after the establishment of the IGCP
 16 program.

17 (g) TAX ON HEALTH INSURANCE PLANS SOLD ON
 18 EXCHANGES.—

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

22 **“Subchapter C—Additional Tax on Health In-**
 23 **surance Plans Sold by Insurers Offering**
 24 **Plans on Exchanges**

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

1 **“SEC. 4401. ADDITIONAL TAX ON HEALTH INSURANCE**
2 **PLANS SOLD BY INSURERS OFFERING PLANS**
3 **ON EXCHANGES.**

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

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

11 (2) CONFORMING AMENDMENT.—The table of
12 subchapters for chapter 34 of the Internal Revenue
13 Code of 1986 is amended by adding at the end the
14 following item:

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

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

18 (h) REPORT.—The Secretary of Health and Human
19 Services, in collaboration with the Comptroller General of
20 the United States, shall submit to Congress, not later than
21 5 years after the date of enactment of this Act, and again
22 5 years thereafter, a report on the status of reinsurance
23 pool funding, along with any recommendations with re-

1 spect to future allocations or funding methods for such
2 pool.

3 **SEC. 222. EMPLOYER HEALTH INSURANCE MANDATE RE-**
4 **PEAL.**

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

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

10 (c) CONFORMING AMENDMENTS.—

11 (1) Section 6724(d)(1)(B) of such Code is
12 amended by inserting “or” at the end of clause
13 (xxiii), by striking “or” at the end of clause (xxiv),
14 and by striking clause (xxv).

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

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

21 (4) The table of sections for subpart D of part
22 III of subchapter A of chapter 61 of such Code is
23 amended by striking the item relating to section
24 6056.

1 (5) Section 1513 of the Patient Protection and
2 Affordable Care Act is amended by striking sub-
3 section (c).

4 (d) EFFECTIVE DATE.—

5 (1) IN GENERAL.—Except as otherwise pro-
6 vided in this subsection, the amendments made by
7 this section shall apply to months and other periods
8 beginning after December 31, 2026.

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

12 **SEC. 223. REFUNDABLE CREDITS FOR COVERAGE UNDER A**
13 **QUALIFIED HEALTH PLAN FOR INDIVIDUALS**
14 **OFFERED EMPLOYER-SPONSORED INSUR-**
15 **ANCE.**

16 (a) IN GENERAL.—Section 36B(c)(2) of the Internal
17 Revenue Code of 1986 is amended—

18 (1) in subparagraph (B)(i), by inserting “or
19 section 5000A(f)(1)(B)”, and

20 (2) by striking subparagraph (C).

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

1 **SEC. 224. INCLUSION IN INCOME OF CERTAIN COSTS OF**
2 **EMPLOYER-PROVIDED COVERAGE UNDER**
3 **HEALTH PLANS.**

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

7 “(h) LIMITATION.—

8 “(1) IN GENERAL.—Subsection (a) shall not
9 apply to the extent that employer-provided coverage
10 under health plans for an employee for a taxable
11 year exceeds—

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

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

14 “(2) IN GENERAL.—In the case of any calendar
15 year after 2026, the dollar amounts in paragraph
16 (1) shall each be increased by an amount equal to—

17 “(A) such dollar amount, multiplied by

18 “(B) the cost-of-living adjustment deter-
19 mined under section 1(f)(3) for such calendar
20 year, determined—

21 “(i) by substituting ‘calendar year
22 2025’ for ‘calendar year 2018’ in subpara-
23 graph (A)(ii) thereof, and

24 “(ii) by substituting for the C–CPI–U
25 referred to in section 1(f)(3)(A) the
26 amount that such CPI would have been if

1 the annual percentage increase in CPI with
2 respect to each year after 2024 and before
3 2034 had been one percentage point great-
4 er.

5 “(3) TERMS RELATED TO CPI.—

6 “(A) ANNUAL PERCENTAGE INCREASE.—
7 For purposes of subparagraph (B)(ii)(II), the
8 term ‘annual percentage increase’ means the
9 percentage (if any) by which C–CPI–U for any
10 year exceeds the C–CPI–U for the prior year.

11 “(B) OTHER TERMS.—Terms used in this
12 paragraph which are also used in section
13 1(f)(3) shall have the same meanings as when
14 used in such section.”.

15 (b) EFFECTIVE DATE.—The amendments made by
16 this section shall apply with respect to taxable years begin-
17 ning after December 31, 2026.

18 **SEC. 225. CHANGE IN PERMISSIBLE AGE VARIATION IN**
19 **HEALTH INSURANCE PREMIUM RATES.**

20 Section 2701(a)(1)(A)(iii) of the Public Health Serv-
21 ice Act (42 U.S.C. 300gg(a)(1)(A)(iii)) is amended by in-
22 serting after “(consistent with section 2707(c))” the fol-
23 lowing: “or, for plan years beginning on or after January
24 1, 2026, as the Secretary may implement through interim

1 final regulation, 5 to 1 for adults (consistent with section
2 2707(c))”.

3 **SEC. 226. PREMIUM ASSISTANCE ADJUSTMENT TO RE-**
4 **FLECT AGE.**

5 (a) MODIFICATION OF APPLICABLE PERCENTAGE.—
6 Section 36B(b)(3)(A) of the Internal Revenue Code of
7 1986 is amended to read as follows:

8 “(A) APPLICABLE PERCENTAGE.—
9 “(i) IN GENERAL.—The applicable
10 percentage for any taxable year shall be
11 the percentage such that the applicable
12 percentage for any taxpayer whose house-
13 hold income is within an income tier speci-
14 fied in the following table shall increase, on
15 a sliding scale in a linear manner, from the
16 initial percentage to the final percentage
17 specified in such table for such income tier
18 with respect to a taxpayer of the age in-
19 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

1 “(ii) AGE DETERMINATIONS.—

2 “(I) IN GENERAL.—For purposes
3 of clause (i), the age of the taxpayer
4 taken into account under clause (i)
5 with respect to any taxable year is the
6 age attained by such taxpayer before
7 the close of such taxable year.

8 “(II) JOINT RETURNS.—In the
9 case of a joint return, the age of the
10 older spouse shall be taken into ac-
11 count under clause (i).

12 “(iii) INDEXING.—In the case of any
13 taxable year beginning after calendar year
14 2026, the initial and final percentages con-
15 tained in clause (i) shall be adjusted to re-
16 flect—

17 “(I) the excess (if any) of the
18 rate of premium growth for the period
19 beginning with calendar year 2013
20 and ending with calendar year 2025,
21 over the rate of income growth for
22 such period, and

23 “(II) in addition to any adjust-
24 ment under subclause (I), the excess
25 (if any) of the rate of premium

1 growth for calendar year 2025, over
2 the rate of growth in the consumer
3 price index for calendar year 2025.

4 “(iv) FAILSAFE.—Clause (iii)(II) shall
5 apply only if the aggregate amount of pre-
6 mium tax credits under this section and
7 cost-sharing reductions under section 1402
8 of the Patient Protection and Affordable
9 Care Act for the preceding calendar year
10 exceeds an amount equal to 0.504 percent
11 of the gross domestic product for such cal-
12 endar year.”.

13 (b) EXPANSION OF ELIGIBILITY.—Section 36B of the
14 Internal Revenue Code of 1986 is amended—

15 (1) in subsection (c)(1)(A), by striking “400”
16 and inserting “600”; and

17 (2) in subsection (f)(2)(B)(i), by striking “400”
18 each place such reference appears and inserting
19 “600” in each such place.

20 (c) EFFECTIVE DATE.—The amendment made by
21 this section shall apply to taxable years beginning after
22 December 31, 2026.

23 **SEC. 227. PREMIUM ASSISTANCE.**

24 Notwithstanding any other provision of law, the Sec-
25 retary of the Treasury shall calculate the credit allowable

1 under section 36B of the Internal Revenue Code of 1986
2 based on the taxpayer's prior year tax return and the Sec-
3 retary of Health and Human Services shall provide for
4 open enrollment periods that end on April 15.

5 **SEC. 228. ADDING COPPER PLANS TO EXCHANGES.**

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

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

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

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

17 (3) in subsection (d)—

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

20 “(E) COPPER LEVEL.—A plan in the cop-
21 per level shall provide a level of coverage that
22 is designed to provide benefits that are actuari-
23 ally equivalent to 50 percent of the full actu-
24 arial value of the benefits provided under the

1 plan and will have out-of-pocket limits that are
2 30 percent higher than bronze plans.”; and

3 (B) in paragraph (4)—

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

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

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

10 (b) EFFECTIVE DATE.—The amendments made by
11 this section shall apply with respect to plan years begin-
12 ning on or after January 1, 2026.

13 **SEC. 229. COPPER AND BRONZE PLANS.**

14 Notwithstanding any other provision of law, refund-
15 able credits for coverage under a qualified health plan and
16 cost-sharing reductions may be used to purchase bronze
17 and copper plans.

18 **SEC. 230. WAIVERS FOR STATE INNOVATION.**

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

22 (1) in subsection (a)(1)(C), by striking “the
23 law” and inserting “a law or has in effect a certifi-
24 cation”; and

25 (2) in subsection (b)(2)—

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

3 (B) in subparagraph (A)—

4 (i) by striking “A law” and inserting
5 the following:

6 “(i) LAWS.—A law”; and

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

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

18 (C) in subparagraph (B)—

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

21 (ii) by striking “may repeal a law”
22 and all that follows through the period at
23 the end and inserting the following: “may
24 terminate the authority provided under the
25 waiver with respect to the State by—

1 “(i) repealing a law described in sub-
2 paragraph (A)(i); or

3 “(ii) terminating a certification de-
4 scribed in subparagraph (A)(ii), through a
5 certification for such termination signed by
6 the Governor of the State.”.

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

10 (1) in paragraph (1) by striking “180” and in-
11 serting “90”; and

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

13 “(3) EXPEDITED DETERMINATION.—

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

1 section (a)(4) to occur concurrently if such
2 State application—

3 “(i) is submitted in response to an ur-
4 gent situation, with respect to areas in the
5 State that the Secretary determines are at
6 risk for excessive premium increases or
7 having no health plans offered in the appli-
8 cable health insurance market for the cur-
9 rent or following plan year; or

10 “(ii) is for a waiver that is the same
11 or substantially similar to a waiver that
12 the Secretary already has approved for an-
13 other State.

14 “(B) APPROVAL.—

15 “(i) URGENT SITUATIONS.—

16 “(I) PROVISIONAL APPROVAL.—A
17 waiver approved under the expedited
18 determination process under subpara-
19 graph (A)(i) shall be in effect for a
20 period of 3 years, unless the State re-
21 quests a shorter duration.

22 “(II) FULL APPROVAL.—Subject
23 to the requirements for approval oth-
24 erwise applicable under this section,
25 not later than 1 year before the expi-

1 ration of a provisional waiver period
2 described in subclause (I) with respect
3 to an application described in sub-
4 paragraph (A)(i), the Secretary shall
5 make a determination on whether to
6 extend the approval of such waiver for
7 the full term of the waiver requested
8 by the State, for a total approval pe-
9 riod not to exceed 6 years. The Sec-
10 retary may request additional infor-
11 mation as the Secretary determines
12 appropriate to make such determina-
13 tion.

14 “(ii) APPROVAL OF SAME OR SIMILAR
15 APPLICATIONS.—An approval of a waiver
16 under subparagraph (A)(ii) shall be subject
17 to the terms of subsection (e).

18 “(C) GAO STUDY.—Not later than 5 years
19 after the date of enactment of this paragraph,
20 the Comptroller General of the United States
21 shall conduct a review of all waivers approved
22 pursuant to an application under subparagraph
23 (A)(ii) to evaluate whether such waivers met
24 the requirements of subsection (b)(1) and

1 whether the applications should have qualified
2 for such expedited process.”.

3 (c) PROVIDING CERTAINTY FOR STATE-BASED RE-
4 FORMS.—Section 1332(e) of the Patient Protection and
5 Affordable Care Act (42 U.S.C. 18052(e)) is amended by
6 striking “No waiver” and all that follows through the pe-
7 riod at the end and inserting the following: “A waiver
8 under this section—

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

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

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

22 (d) ENSURING PATIENT ACCESS TO MORE FLEXIBLE
23 HEALTH PLANS.—Section 1332(b)(1)(B) of the Patient
24 Protection and Affordable Care Act (42 U.S.C.
25 18052(b)(1)(B)) is amended by striking “at least as af-

1 fordable” and inserting “of comparable affordability, in-
2 cluding for low-income individuals, individuals with serious
3 health needs, and other vulnerable populations,”.

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

7 (1) with respect to applications for waivers
8 under such section 1332 submitted after the date of
9 enactment of this Act and applications for such
10 waivers submitted prior to such date of enactment
11 and under review by the Secretary on the date of en-
12 actment, shall take effect on the date of enactment
13 of this Act; and

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

22 **SEC. 231. ENROLLMENT PERIODS.**

23 (a) EXCHANGES.—Paragraph (7) of section 1311(c)
24 of the Patient Protection and Affordable Care Act (42

1 U.S.C. 18031(e)), as added by section 106, is amended
2 by adding at the end the following new subparagraph:

3 “(B) ENROLLMENTS OTHER THAN DURING
4 INITIAL, OPEN, AND SPECIAL ENROLLMENT PE-
5 RIODS.—Beginning with plan year 2026, an Ex-
6 change may provide for enrollments during pe-
7 riods in addition to open enrollment periods de-
8 scribed in subparagraph (A) or paragraph (6)
9 and special enrollment periods described in
10 paragraph (6).”.

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

14 **“SEC. 2710. ENROLLMENT OUTSIDE OF INITIAL, OPEN, AND**
15 **SPECIAL ENROLLMENT PERIOD.**

16 “Beginning with plan year 2026, a group health plan
17 and a health insurance issuer offering group or individual
18 health insurance coverage may provide for enrollment in
19 such plan or coverage during periods in addition to initial,
20 open, or special enrollment periods. In the case that an
21 individual enrolls in such plan or coverage during a period
22 pursuant to the previous sentence, the plan or issuer may
23 charge the individual a one-time enrollment fee.”.

1 **SEC. 232. STATE-OPERATED EXCHANGES FLEXIBILITY FOR**
 2 **OPEN ENROLLMENT PERIODS.**

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

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

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

10 “(7) FLEXIBILITY FOR ENROLLMENT PERI-
 11 ODS.—

12 “(A) STATE-OPERATED EXCHANGES OPEN
 13 ENROLLMENT PERIODS.—In the case of an Ex-
 14 change operated by a State, beginning with
 15 plan years of 1 year after the date of enactment
 16 of this Act, the Exchange may provide for open
 17 enrollment periods (after the initial enrollment
 18 period) every 12, 24, or 36 months, as deter-
 19 mined by the State.”.

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

22 There are appropriated, out of amounts in the Treas-
 23 ury not otherwise appropriated, \$10,000,000 to be made
 24 available by no later than 1 year after the date of enact-
 25 ment of this Act, to the Center for Medicare & Medicaid
 26 Innovation to fund new research or pilot programs dedi-

1 cated to pursuing viable methods of enrolling individuals
2 in health insurance programs that cross State lines.

3 **TITLE III—COMPETITION,**
4 **TRANSPARENCY AND AC-**
5 **COUNTABILITY**

6 **Subtitle A—Provider and Insurer**
7 **Competition**

8 **SEC. 301. HOSPITAL CONSOLIDATION.**

9 (a) AUTHORIZATION OF APPROPRIATIONS.—There is
10 authorized to be appropriated \$160,000,000 to the Fed-
11 eral Trade Commission to hire staff to investigate, as con-
12 sistent with the Sherman Antitrust Act and other relevant
13 Federal laws, anti-competitive mergers and practices
14 under such laws to the extent such mergers and practices
15 relate to providers of inpatient and outpatient health care
16 services, as defined by the Secretary of Health and
17 Human Services.

18 (b) MEDICARE ADVANTAGE RATES APPLIED TO CER-
19 TAIN HHI HOSPITALS.—

20 (1) IN GENERAL.—Section 1866(a) of the So-
21 cial Security Act (42 U.S.C. 1395cc(a)) is amend-
22 ed—

23 (A) in paragraph (1)—

24 (i) in subparagraph (X), by striking
25 “and” at the end;

1 (ii) in subparagraph (Y), by striking
2 the period at the end and inserting “;
3 and”;

4 (iii) by inserting after subparagraph
5 (Y) the following new subparagraph:

6 “(Z) subject to paragraph (4), beginning
7 in 2028, in the case of a hospital located in a
8 county whose population density is above the
9 median population density for all counties in
10 the United States with respect to which there
11 is a Herfindahl-Hirschman Index (HHI) of
12 greater than 4,000, to apply the average reim-
13 bursement rate (or, with respect to years before
14 2032, the percent specified in paragraph (4)(C)
15 of such average rate) with respect to individuals
16 (regardless of whether such an individual is en-
17 titled to or eligible for benefits under this title,
18 but excluding individuals eligible for medical as-
19 sistance under a State plan under title XIX)
20 furnished items and services at such hospital
21 that would be billable under this title for such
22 items and services if furnished by such hospital
23 to an individual enrolled under part C.”;

24 (B) by adding at the end the following new
25 paragraph:

1 “(4)(A) The requirement under paragraph
2 (1)(Z) shall not apply in the case of a hospital in a
3 hospital referral region if—

4 “(i) the HRR market share of such hos-
5 pital (as determined under subparagraph (B))
6 is less than 0.15; or

7 “(ii) the hospital is located in a rural area
8 (as defined in section 1886(d)(2)(D)).

9 “(B) For purposes of subparagraph (A), the
10 HRR market share of a hospital in a hospital refer-
11 ral region is equal to—

12 “(i) the total revenue of the hospital, di-
13 vided by

14 “(ii) the total revenue of all hospitals in
15 the hospital referral region.

16 “(C) For purposes of paragraph (1)(Z), the
17 percent specified in this subparagraph is—

18 “(i) for 2028, 178 percent;

19 “(ii) for 2029, 150 percent;

20 “(iii) for 2030, 130 percent; and

21 “(iv) for 2031, 110 percent.”.

22 (2) EFFECTIVE DATE.—The amendments made
23 by this subsection shall apply with respect to items
24 and services furnished on or after January 1, 2026.

1 (c) GRANTS FOR HOSPITAL INFRASTRUCTURE IM-
2 PROVEMENT.—

3 (1) IN GENERAL.—The Secretary of Health and
4 Human Services shall carry out a grant program
5 under which the Secretary shall provide grants to el-
6 igible States, in accordance with this subsection.

7 (2) USES.—An eligible State receiving a grant
8 under this subsection may use such grant to improve
9 the State hospital infrastructure and to supplement
10 any other funds provided for a purpose authorized
11 under a State or local hospital grant program under
12 State law.

13 (3) ELIGIBILITY.—

14 (A) IN GENERAL.—An eligible State may
15 receive not more than one grant under this sub-
16 section with respect to each qualifying criterion
17 described in subparagraph (B) that is met by
18 the State.

19 (B) ELIGIBLE STATE.—For purposes of
20 this subsection, the term “eligible State” means
21 a State that meets any one or more of the fol-
22 lowing qualifying criteria:

23 (i) The State does not have in effect
24 any State certificate of need law that re-
25 quires a health care provider to provide to

1 a regulatory body a certification that the
2 community needs the services provided by
3 the health care provider.

4 (ii) The State has in effect State
5 scope of practice laws that—

6 (I) allow advanced practice pro-
7 viders (such as nurse practitioners,
8 advanced practice registered nurses,
9 clinical nurse specialists, and physi-
10 cian assistants) to evaluate patients;
11 diagnose, order, and interpret diag-
12 nostic tests; and initiate and manage
13 treatments; or

14 (II) provide that the only jus-
15 tification for limiting the scope of
16 practice of a health care provider is
17 safety to the public.

18 (iii) The State does not have in effect
19 any State laws that require managed care
20 plans to accept into the network of such
21 plan any qualified provider who is willing
22 to accept the terms and conditions of the
23 managed care plan.

24 (iv) The State does not have in effect
25 any Certificate of Public Advantage laws

1 that clearly articulate the State’s intent to
2 displace competition in favor of regulation
3 or that violate State or Federal antitrust
4 laws.

5 (v) The State does not have in effect
6 any network adequacy laws regulating a
7 health plan’s ability to deliver benefits by
8 providing reasonable access to a sufficient
9 number of in-network primary care and
10 specialty physicians, as well as all health
11 care services included under the terms of
12 an insuree’s contract with a health insurer.

13 (4) FUNDING.—There is authorized to be ap-
14 propriated to carry out this subsection
15 \$1,000,000,000 for each of the fiscal years 2026
16 through 2035. Funds appropriated under this para-
17 graph shall remain available until expended.

18 (d) CRITICAL ACCESS HOSPITAL REIMBURSEMENT
19 RATES.—

20 (1) PART A.—Section 1814(l)(1) of the Social
21 Security Act (42 U.S.C. 1395f(l)(1)) is amended by
22 inserting “(or, for 2026, 102, plus 1 percentage
23 point for each subsequent year through 2033, and
24 110 for each subsequent year thereafter)” after
25 “101”.

1 (2) PART B.—Section 1834(g)(1) of such Act
2 (42 U.S.C. 1395m(g)(1)) is amended by inserting
3 “(or, for 2026, 102, plus 1 percentage point for each
4 subsequent year through 2033, and 110 for each
5 subsequent year thereafter)” after “101”.

6 **SEC. 302. AUTHORITY OF FEDERAL TRADE COMMISSION**
7 **OVER CERTAIN TAX-EXEMPT ORGANIZA-**
8 **TIONS.**

9 Section 4 of the Federal Trade Commission Act (15
10 U.S.C. 44) is amended, in the undesignated paragraph re-
11 lating to the definition of the term “Corporation”—

12 (1) by striking “, and any” and inserting “,
13 any”; and

14 (2) by inserting before the period at the end the
15 following: “, and any organization described in sec-
16 tion 501(c)(3) of the Internal Revenue Code of 1986
17 that is exempt from taxation under section 501(a) of
18 such Code”.

19 **SEC. 303. LEVELING THE PLAYING FIELD BETWEEN PAYERS**
20 **AND PROVIDERS.**

21 (a) EXEMPTION.—It shall not be a violation of the
22 antitrust laws for one or more private health insurer
23 issuers or their designated agents to jointly negotiate
24 prices of particular hospital services with a hospital pro-

1 vider with regards to the reimbursement policies of the
2 insurers for those services.

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

4 (1) ANTITRUST LAWS.—The term “antitrust
5 laws” has the meaning given it in subsection (a) of
6 the 1st section of the Clayton Act (15 U.S.C. 12(a)),
7 except that such term includes section 5 of the Fed-
8 eral Trade Commission Act (15 U.S.C. 45) to the
9 extent such section 5 applies to unfair methods of
10 competition.

11 (2) HEALTH INSURANCE ISSUER.—The term
12 “health insurance issuer” means an insurance com-
13 pany, insurance service, or insurance organization
14 (including a health maintenance organization, as de-
15 fined in subparagraph (C)) which is licensed to en-
16 gage in the business of insurance in a State and
17 which is subject to State law which regulates insur-
18 ance (within the meaning of section 514(b)(2) of the
19 Employee Retirement Income Security Act of 1974
20 (29 U.S.C. 1144(b)(2))). Such term does not include
21 a group health plan.

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

1 (A) a Federally qualified health mainte-
2 nance organization (as defined in section
3 300e(a) of title 42 of the United States Code),

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 (c) EFFECTIVE DATE.—This section shall take effect
11 on the date of the enactment of this Act but shall not
12 apply with respect to conduct that occurs before such date.

13 **SEC. 304. BANNING ANTICOMPETITIVE TERMS IN FACILITY**
14 **AND INSURANCE CONTRACTS THAT LIMIT AC-**
15 **CESS TO HIGHER QUALITY, LOWER COST**
16 **CARE.**

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

20 “(b) PROTECTING HEALTH PLANS NETWORK DE-
21 SIGN FLEXIBILITY.—

22 “(1) IN GENERAL.—A group health plan or a
23 health insurance issuer offering group or individual
24 health insurance coverage shall not enter into an
25 agreement with a provider, network or association of

1 providers, or other service provider offering access to
2 a network of service providers if such agreement, di-
3 rectly or indirectly—

4 “(A) restricts the group health plan or
5 health insurance issuer from—

6 “(i) directing or steering enrollees to
7 other health care providers; or

8 “(ii) offering incentives to encourage
9 enrollees to utilize specific health care pro-
10 viders;

11 “(B) requires the group health plan or
12 health insurance issuer to enter into any addi-
13 tional contract with an affiliate of the provider,
14 such as an affiliate of the provider, as a condi-
15 tion of entering into a contract with such pro-
16 vider;

17 “(C) requires the group health plan or
18 health insurance issuer to agree to payment
19 rates or other terms for any affiliate not party
20 to the contract of the provider involved; or

21 “(D) restricts other group health plans or
22 health insurance issuers not party to the con-
23 tract from paying a lower rate for items or
24 services than the contracting plan or issuer
25 pays for such items or services.

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

13 “(3) EXCEPTION FOR CERTAIN GROUP MODEL
14 ISSUERS.—Paragraph (1)(A) shall not apply to a
15 group health plan or health insurance issuer offering
16 group or individual health insurance coverage with
17 respect to—

18 “(A) a health maintenance organization
19 (as defined in section 2791(b)(3)), if such
20 health maintenance organization operates pri-
21 marily through exclusive contracts with multi-
22 specialty physician groups, nor to any arrange-
23 ment between such a health maintenance orga-
24 nization and its affiliates; or

1 “(B) a value-based network arrangement,
2 such as an exclusive provider network, account-
3 able care organization, center of excellence, a
4 provider sponsored health insurance issuer that
5 operates primarily through aligned multi-spe-
6 cialty physician group practices or integrated
7 health systems, or such other similar network
8 arrangements as determined by the Secretary
9 through rulemaking.

10 “(4) ATTESTATION.—A group health plan or
11 health insurance issuer offering group or individual
12 health insurance coverage shall annually submit to,
13 as applicable, the applicable authority described in
14 section 2723 or the Secretary of Labor, an attesta-
15 tion that such plan or issuer is in compliance with
16 the requirements of this subsection.

17 “(c) MAINTENANCE OF EXISTING HIPAA, GINA,
18 AND ADA PROTECTIONS.—Nothing in this section shall
19 modify, reduce, or eliminate the existing privacy protec-
20 tions and standards provided by reason of State and Fed-
21 eral law, including the requirements of parts 160 and 164
22 of title 45, Code of Federal Regulations (or any successor
23 regulations).

24 “(d) REGULATIONS.—The Secretary, not later than
25 1 year after the date of enactment of the Fair Care Act

1 of 2026, shall promulgate regulations to carry out this sec-
2 tion.

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

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

15 (b) EFFECTIVE DATE.—Section 2729B of the Public
16 Health Service Act (as added by section 301 and amended
17 by subsection (a)) shall apply with respect to any contract
18 entered into on or after the date that is 18 months after
19 the date of enactment of this Act. With respect to an ap-
20 plicable contract that is in effect on the date of enactment
21 of this Act, such section 2729B shall apply on the earlier
22 of the date of renewal of such contract or 3 years after
23 such date of enactment.

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

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

5 (b) EFFECTIVE DATE.—The amendment made by
6 subsection (a) shall take effect on January 1, 2026.

7 **SEC. 306. REPEAL OF HEALTH CARE REFORM PROVISIONS**
8 **LIMITING MEDICARE EXCEPTION TO THE**
9 **PROHIBITION ON CERTAIN PHYSICIAN RE-**
10 **FERRALS FOR HOSPITALS.**

11 Sections 6001 and 10601 of the Patient Protection
12 and Affordable Care Act (Public Law 111–148; 124 Stat.
13 684, 1005) and section 1106 of the Health Care and Edu-
14 cation Reconciliation Act of 2010 (Public Law 111–152;
15 124 Stat. 1049) are repealed and the provisions of law
16 amended by such sections are restored as if such sections
17 had never been enacted.

18 **SEC. 307. ALTERNATIVE PAYMENT MODEL FOR CERTAIN**
19 **SHOPPABLE PROCEDURES.**

20 (a) IN GENERAL.—A group health plan and a health
21 insurance issuer offering group or individual health insur-
22 ance coverage (as such terms are defined in section 2791
23 of the Public Health Service Act (42 U.S.C. 300gg–91))
24 may elect, with respect to a plan year, to provide a set
25 payment amount to an enrollee under such plan or cov-
26 erage for certain shoppable procedures (as defined in sub-

1 section (b)) in accordance with the provisions of this sec-
2 tion in lieu of otherwise providing coverage for such a pro-
3 cedure under such plan or coverage, but only if the en-
4 rollee so agrees to such set payment amount.

5 (b) DEFINITION.—For purposes of this section, the
6 term “shoppable procedure” means a procedure specified
7 by the Secretary of Health and Human Services (in this
8 section referred to as the “Secretary”) with respect to
9 which individuals may be expected to compare prices for
10 such procedure of health care providers and facilities, in-
11 cluding primary and preventive services, prenatal care and
12 childbirth, common surgeries that can be scheduled, and
13 other similar services.

14 (c) SET PAYMENT RULES.—A set payment described
15 in subsection (a) under a group health plan or group or
16 individual health insurance coverage offered by a health
17 insurance issuer shall—

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

21 (2) be the same amount with respect to the
22 same shoppable procedure furnished in a geographic
23 area (as defined by the Secretary);

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

4 (4) be made available to an enrollee under such
5 plan or such coverage regardless of the provider or
6 facility furnishing the shoppable procedure;

7 (5) represent the entirety of the payment obli-
8 gation of such plan or such issuer with respect to
9 such procedure; and

10 (6) may be retained by such enrollee to the ex-
11 tent that the amount of such payment exceeds the
12 amount charged by such provider or facility for such
13 procedure.

14 (d) PROVISION OF PRICE INFORMATION.—Each
15 health care provider and facility that may furnish a
16 shoppable procedure during a year shall post in a public
17 area a notice containing the prices that will be charged
18 by such provider of facility with respect to each such pro-
19 cedure to individuals making payment for such services
20 pursuant to a set payment amount described in subsection
21 (a).

22 (e) EHB WAIVER AUTHORITY.—The Secretary may
23 waive such provisions of section 1302(b) of the Patient
24 Protection and Affordable Care Act (42 U.S.C. 18022(b))
25 with respect to a group health plan, health insurance

1 issuer offering group or individual health insurance cov-
2 erage, and a plan year as the Secretary determines nec-
3 essary to allow for the provision of set payment amounts
4 described in subsection (a).

5 **Subtitle B—Price Transparency**

6 **SEC. 321. PRICE TRANSPARENCY REQUIREMENTS.**

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

10 (1) by striking “Each hospital” and inserting
11 the following:

12 “(1) IN GENERAL.—Each hospital”;

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

16 (3) by inserting “, along with such additional
17 information as the Secretary may require with re-
18 spect to such charges for purposes of promoting
19 public awareness of hospital pricing in advance of
20 receiving a hospital item or service” before the pe-
21 riod; and

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

23 “(2) DEFINITION OF STANDARD CHARGES.—
24 Notwithstanding any other provision of law, for pur-
25 poses of paragraph (1), the term ‘standard charges’

1 means the rates hospitals, including providers or en-
2 tities that contract with or practice at a hospital,
3 charge for all items and services at a minimum,
4 chargemaster rates, rates that hospitals negotiate
5 with third party payers across all plans, including
6 those related to a patient’s specific plan, discounted
7 cash prices, and other rates determined by the Sec-
8 retary.

9 “(3) ENFORCEMENT.—In addition to any other
10 enforcement actions or penalties that may apply
11 under subsection (b)(3) or another provision of law,
12 a hospital that fails to provide the information re-
13 quired by this subsection and has not completed a
14 corrective action plan to comply with the require-
15 ments of such subsection shall be subject to a civil
16 monetary penalty of an amount not to exceed \$300
17 per day that the violation is ongoing as determined
18 by the Secretary. Such penalty shall be imposed and
19 collected in the same manner as civil money pen-
20 alties under subsection (a) of section 1128A of the
21 Social Security Act are imposed and collected.”.

22 (b) TRANSPARENCY IN COVERAGE.—Section
23 1311(e)(3) of the Patient Protection and Affordable Care
24 Act (42 U.S.C. 18031(e)(3)) is amended—

25 (1) in subparagraph (A)—

1 (A) in clause (vii), by inserting before the
2 period the following: “, including, for all items
3 and services covered under the plan, aggregate
4 information on specific payments the plan has
5 made to out-of-network health care providers on
6 behalf of plan enrollees”;

7 (B) by designating clause (ix) as clause
8 (x); and

9 (C) by inserting after clause (viii), the fol-
10 lowing:

11 “(ix) Information on the specific nego-
12 tiated payment rates between the plan and
13 health care providers for all items and
14 services covered under the plan.”;

15 (2) in subparagraph (B)—

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

18 (B) by inserting “, as applicable,” after
19 “English proficiency”; and

20 (C) by inserting after the second sentence,
21 the following: “The Secretary shall establish
22 standards for electronic delivery and access to
23 such information by individuals, free of charge,
24 in machine readable format, through an Inter-
25 net website and via open APIs.”;

1 (3) in subparagraph (C)—

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

5 (B) in the second sentence, by striking
6 “through an Internet website” and inserting
7 “free of charge, in machine readable format,
8 through an Internet website, and via open
9 APIs, in accordance with standards established
10 by the Secretary,”; and

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

18 (4) in subparagraph (D) by striking “subpara-
19 graph (A)” and inserting “subparagraphs (A), (B),
20 and (C)”.

21 **SEC. 322. ACCESS OF INDIVIDUALS TO PROTECTED HEALTH**
22 **INFORMATION.**

23 The provisions of section 164.524 of title 45, Code
24 of Federal Regulations, as in effect on the day before the

1 date of the enactment of this Act, shall have the force and
2 effect of law.

3 **SEC. 323. ADVISORY GROUP ON REDUCING BURDEN OF**
4 **HOSPITAL ADMINISTRATIVE REQUIREMENTS.**

5 (a) IN GENERAL.—Not later than January 1, 2026,
6 the Secretary of Health and Human Services shall convene
7 an advisory group to provide, in accordance with this sec-
8 tion, recommendations on ways the Federal Government
9 could reduce the burden of administrative requirements on
10 hospitals.

11 (b) RECOMMENDATIONS.—Not later than January 1,
12 2027, the advisory board convened under this section
13 shall—

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

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

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

24 (1) Three representatives of companies that
25 have—

- 1 (A) geographically distributed workforces;
- 2 (B) at least 10,000 employees; and
- 3 (C) no more than 10 percent of such em-
4 ployees in any single State.

5 (2) Three representatives of health insurance
6 issuers and health plans, consisting of—

7 (A) one representative of for-profit health
8 insurance issuers and health plans with at least
9 20,000,000 enrollees in the employer-sponsored
10 market;

11 (B) one representative of non-profit health
12 insurance issuers and health plans operating in
13 at least 5 States; and

14 (C) one representative of non-profit health
15 insurance issuers and health plans operating in
16 a rural State (as defined by the Census Bu-
17 reau).

18 (3) Seven public policy experts in the field of
19 hospital consolidation.

1 **SEC. 324. DATA REPORTING TO IMPROVE THE TRANS-**
2 **PARENCY REGARDING HOW 340B HOSPITAL**
3 **COVERED ENTITIES PROVIDE CARE FOR PA-**
4 **TIENTS.**

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

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

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

19 “(A) The following information:

20 “(i) With respect to such covered enti-
21 ty and with respect to each child site of
22 such entity (as referenced in paragraph
23 (11)), the number and percentage of indi-
24 viduals who are dispensed or administered
25 drugs that are subject to an agreement
26 under this section, organized by form of

1 health insurance coverage of such individ-
2 uals (including at least by the Medicare
3 program under title XVIII of the Social
4 Security Act, the Medicaid program under
5 title XIX of such Act, health insurance
6 coverage offered in the individual or group
7 market or a group health plan (as such
8 terms are defined in section 2791), and
9 uninsured).

10 “(ii) With respect to each such child
11 site of such entity, the total costs incurred
12 at each such site and the cost incurred at
13 each such site for charity care as defined
14 in line 23 of worksheet S-10 to the Medi-
15 care cost report or in any successor form.

16 “(B) The aggregate amount of gross reim-
17 bursement received by each such covered entity
18 (including child sites of such entity) described
19 in such subparagraph (L) or (M) for all drugs
20 purchased that are subject to an agreement
21 under this section and the entity’s aggregate
22 acquisition cost for such drugs.

23 “(C) In the case of covered entity de-
24 scribed in subparagraph (L) of subsection
25 (a)(4), at the time of application and recertifi-

1 cation (and at least annually thereafter), the
2 contract that is the basis for eligibility under
3 the requirement under clause (i) of such sub-
4 paragraph and any modifications to such con-
5 tract for purposes of review by the Secretary.

6 “(D) With respect to such covered entity
7 and with respect to each child site of such enti-
8 ty, the name of all third-party vendors or other
9 similar entities that the covered entity contracts
10 with to provide services associated with the pro-
11 gram under this section.

12 “(2) AVAILABILITY OF INFORMATION.—

13 “(A) IN GENERAL.—The Secretary shall
14 make data reported by covered entities under
15 subparagraphs (A), (C), and (D) of paragraph
16 (1) available on the public website of the De-
17 partment of Health and Human Services in an
18 electronic and searchable format, which may in-
19 clude the 340B Office of Pharmacy Affairs In-
20 formation System or a successor to such sys-
21 tem.

22 “(B) FORMAT.—Data made available
23 under subparagraph (A) shall be made available
24 in a manner that shows each category of data
25 reported both in the aggregate and identified by

1 covered entities described in subparagraphs (L)
2 and (M) of subsection (a)(4) and child sites of
3 such covered entities. In carrying out this para-
4 graph, with respect to data reported pursuant
5 to paragraph (1)(C), the Secretary shall ensure
6 that any proprietary information shall be re-
7 dacted from contracts submitted pursuant to
8 such paragraph (1)(C) before posting such
9 data.

10 “(3) INTERIM FINAL REGULATIONS.—The Sec-
11 retary shall issue interim final regulations no later
12 than the date that is 6 months after the date of the
13 enactment of this subsection, to carry out this sub-
14 section and shall finalize such regulations prior to
15 the end of the moratorium period to which sub-
16 section (a)(11) applies.

17 “(4) REPORTS TO CONGRESS.—

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

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

3 “(B) GAO REPORTS.—

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

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

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

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

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

13 **SEC. 325. REQUIRING 340B DRUG DISCOUNT PROGRAM RE-**
14 **PORTS BY DSH HOSPITAL COVERED ENTITIES**
15 **ON LOW-INCOME UTILIZATION RATE OF OUT-**
16 **PATIENT HOSPITAL SERVICES.**

17 (a) IN GENERAL.—Section 340B(d)(2) of the Public
18 Health Service Act (42 U.S.C. 256b(d)(2)) is amended—

19 (1) in subparagraph (B)(i), by inserting before
20 the period at the end the following: “, including,
21 with respect to such updates made on or after one
22 year after the date of enactment of the Act, by re-
23 quiring covered entities described in subsection
24 (a)(4)(L) to submit (and to so regularly update) in-
25 formation described in subparagraph (C)”;

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

3 “(C) INFORMATION ON LOW-INCOME UTI-
4 LIZATION RATE OF OUTPATIENT HOSPITAL
5 SERVICES.—

6 “(i) IN GENERAL.—For purposes of
7 subparagraph (B)(i), the information de-
8 scribed in this subparagraph, with respect
9 to a covered entity described in subsection
10 (a)(4)(L) and an update under such sub-
11 paragraph (B)(i), is—

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

15 “(II) the low-income outpatient
16 utilization rate of off-site outpatient
17 facilities, clinics, eligible off-site loca-
18 tions, and associated sites of such en-
19 tity identified as child sites of such
20 entity pursuant to the identification
21 system under subparagraph (B)(iv)
22 for the most recent fiscal year.

23 “(ii) LOW-INCOME OUTPATIENT UTI-
24 LIZATION RATE DEFINED.—In this sub-
25 paragraph, the term ‘low-income outpatient

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

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

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

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

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

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

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

20 (b) ANNUAL REPORTS.—Not later than 1 year after
21 the date of enactment of this Act, and annually thereafter,
22 the Administrator of the Health Resources and Services
23 Administration shall submit to Congress a report on infor-
24 mation submitted by covered entities for the previous year
25 pursuant to the amendments made by subsection (a).

1 **SEC. 326. 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. 327. 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 Workforce and the
9 Committee on Energy and Commerce of the House of
10 Representatives.

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 redesignig-
2 nated—

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)

1 or (j) of this section or section 351(k) of
2 the Public Health Service Act before the
3 Secretary has taken final agency action on
4 the petition within the meaning of sub-
5 paragraph (C), the court shall dismiss
6 without prejudice the action for failure to
7 exhaust administrative remedies.”; and

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

12 (3) in paragraph (4)—

13 (A) by striking “EXCEPTIONS” and all that
14 follows through “This subsection does” and in-
15 serting “EXCEPTIONS.—This subsection does”;

16 (B) by striking subparagraph (B); and

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

20 **SEC. 344. PREEMPTION OF STATE BARRIERS TO THE SUB-**
21 **STITUTION OF BIOSIMILAR PRODUCTS.**

22 No State, or any political subdivision thereof, may,
23 under any circumstances, prohibit a pharmacy or phar-
24 macist from dispensing, in place of a biological reference
25 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 subparagraph (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. 355e(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 ensure 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-

1 tion shall make each such repeal or amendment. In mak-
2 ing such an amendment or repeal, the Food and Drug Ad-
3 ministration shall comply with the requirements of sub-
4 chapter II of chapter 5, but the Food and Drug Adminis-
5 tration may consolidate proceedings under subchapter II
6 (of chapter 5) with proceedings on the new rule.

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

8 “(a) ANNUAL REVIEW.—Beginning on the date that
9 is 6 months after the date of enactment of this section
10 and annually thereafter for the 9 years following, the Food
11 and Drug Administration shall designate not less than 10
12 percent of eligible rules made by the Food and Drug Ad-
13 ministration for review, and shall submit a report includ-
14 ing each such eligible rule in the same manner as a report
15 under section 811(a)(1). Section 811, section 812, and
16 section 813 shall apply to each such rule, subject to sub-
17 section (c) of this section. No eligible rule previously des-
18 ignated may be designated again.

19 “(b) SUNSET FOR ELIGIBLE RULES NOT EX-
20 TENDED.—Beginning after the date that is 10 years after
21 the date of enactment of this section, if Congress has not
22 enacted a joint resolution of approval for that eligible rule,
23 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 **SEC. 356. PROVISIONAL APPROVAL OF NEW HUMAN DRUGS.**

7 (a) IN GENERAL.—Subchapter A of chapter V of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
9 et seq.) is amended by adding at the end the following:
10 **“SEC. 524B. PROVISIONAL APPROVAL OF NEW HUMAN**
11 **DRUGS.**

12 “(a) PRIORITY REVIEW AND EVALUATION OF APPLI-
13 CATIONS.—

14 “(1) IN GENERAL.—The Secretary shall estab-
15 lish a priority review system to evaluate applications
16 submitted under this pathway for provisional ap-
17 proval within 90 days of receipt of a completed ap-
18 plication.

19 “(2) REVIEW OF APPLICATIONS DURING
20 EPIDEMICS AND PANDEMICS.—In the case of an epi-
21 demic or pandemic, including with respect to
22 COVID–19, the Secretary shall accept and review
23 various portions of an application submitted under
24 the pathway under this section for provisional ap-
25 proval on a rolling basis, and the review of any part

1 of an application so submitted shall be completed
2 not later than 3 weeks after submission.

3 “(3) OTHER DESIGNATIONS.—If a drug sub-
4 mitted for review under the pathway under this sec-
5 tion is eligible for a special designation by the Sec-
6 retary under this Act, including as a drug for a rare
7 disease or condition under section 526, all benefits
8 of such other designation shall be available for use
9 under provisional approval, including any tax credits
10 and waiving of fees under chapter VII.

11 “(b) ELIGIBILITY.—A drug may be eligible for provi-
12 sional approval under this section if the Secretary deter-
13 mines that the drug is intended for the treatment, preven-
14 tion, or medical diagnosis of—

15 “(1) a serious or life-threatening disease or con-
16 dition for which there is a reasonable likelihood that
17 premature death will occur without early medical
18 intervention for an individual contracting or being
19 diagnosed with such disease or condition; or

20 “(2) a disease or condition that poses a threat
21 of epidemic or pandemic.

22 “(c) STANDARD OF REVIEW FOR APPROVAL.—

23 “(1) REQUIREMENTS.—An application for pro-
24 visional approval under this section may be approved
25 only if the Secretary determines that—

1 “(A) there is substantial evidence of safety
2 for the drug, such that there is evidence con-
3 sisting of adequate and well-controlled inves-
4 tigations, including clinical investigations, by
5 experts qualified by scientific training and expe-
6 rience to evaluate the safety of the drug in-
7 volved, on the basis of which it could fairly and
8 responsibly be concluded that the drug will have
9 the effect it purports or is represented to have
10 under the conditions of use prescribed, rec-
11 ommended, or suggested in the labeling or pro-
12 posed labeling; and

13 “(B) there is relevant early evidence based
14 on adequate and well-controlled investigations,
15 including early-stage clinical investigations, to
16 establish that—

17 “(i) the drug provides a positive
18 therapeutic outcome; and

19 “(ii) the outcome of the drug is con-
20 sistent with or greater than currently mar-
21 keted on-label therapies, with equal or
22 fewer side effects, if there are currently
23 marketed on-label therapies.

24 “(2) PROTOCOLS.—The Secretary shall promul-
25 gate rules that establish the appropriate protocols

1 for a sponsor of an application for provisional ap-
2 proval under this section and the Commissioner to
3 follow to enable rolling, real-time, mid-trial submis-
4 sion while preserving the integrity of the ongoing
5 trial and without penalizing the sponsor for making
6 use of this pathway.

7 “(3) REAL WORLD EVIDENCE.—The Secretary
8 shall allow the use of real world evidence (as defined
9 in section 505F(b)), including real world data used
10 to generate real world evidence, to support an appli-
11 cation for provisional approval under this section,
12 and to fulfill the follow-up requirements and support
13 applications for full approval as described under sec-
14 tion 505 or section 351 of the Public Health Service
15 Act, as applicable.

16 “(4) USE OF SCIENTIFICALLY SUBSTANTIATED
17 SURROGATES.—

18 “(A) IN GENERAL.—The sponsor of an ap-
19 plication for provisional approval under this sec-
20 tion may use scientifically substantiated surro-
21 gates to support such application.

22 “(B) DEFINITION.—In subparagraph (A),
23 the term ‘scientifically substantiated surrogates’
24 means surrogate endpoints to predict clinical

1 benefit other than such endpoints previously
2 validated by the Secretary, based on—

3 “(i) epidemiologic, therapeutic, patho-
4 physiologic, or other evidence; or

5 “(ii) an effect on a clinical endpoint
6 other than survival or irreversible mor-
7 bidity of interest.

8 “(d) TRANSPARENCY AND PATIENT MONITORING
9 REQUIREMENTS.—

10 “(1) REGISTRIES.—

11 “(A) IN GENERAL.—The sponsor of a drug
12 provisionally approved under this section shall
13 require that all patients who use such drug par-
14 ticipate in an observational registry and consent
15 to the sponsor’s collection, and submission to
16 the registry, of data related to the patient’s use
17 of such drug until such drug receives full ap-
18 proval under section 505 or section 351 of the
19 Public Health Service Act, or the provisional
20 approval is rescinded.

21 “(B) REQUIREMENTS FOR REGISTRIES.—

22 An observational registry described in subpara-
23 graph (A) may be run by a third party, such as
24 a government, for profit, or non-profit organiza-

1 tion, and shall track all patients who use the
2 provisionally approved drug.

3 “(C) ACCESSIBILITY.—An observational
4 registry described in subparagraph (A) shall be
5 easily accessible for—

6 “(i) all patients who are participating
7 in any registry related to a provisionally
8 approved drug that allows for easy, unre-
9 stricted (or transparent) access for such
10 patients to their patient data and related
11 information regarding their usage of the
12 provisionally approved drug; and

13 “(ii) approved researchers and med-
14 ical professionals who may access data
15 maintained in the registry, which access
16 shall be for public health research and only
17 in a de-identified, aggregated manner.

18 “(2) FUNDING.—An observational registry
19 under this subsection shall be maintained, as appli-
20 cable—

21 “(A) by the sponsor of the drug provision-
22 ally approved under this section that is the sub-
23 ject of the registry;

24 “(B) by a third party, such as a govern-
25 ment, for profit, or nonprofit organization; or

1 “(C) the Federal Government, in the case
2 of any drug so approved that is intended to
3 treat a disease or condition associated with an
4 epidemic or pandemic.

5 “(3) SPONSOR REQUIREMENTS.—

6 “(A) IN GENERAL.—For any drug applica-
7 tion provisionally approved under this section,
8 the Secretary shall notify the sponsor of the
9 exact data such sponsor is required to submit
10 to an observational registry.

11 “(B) ANNUAL REVIEW OF THE REGISTRY;
12 PENALTIES.—The Secretary shall conduct an
13 annual review of observational registries estab-
14 lished under this subsection. If, at such an an-
15 nual review, less than 90 percent of patients are
16 participating in an observational registry with
17 respect to a drug approved under this section,
18 the Secretary shall issue to the sponsor of such
19 drug a civil monetary penalty of not more than
20 \$100,000. If a violation of this section is not
21 corrected within the 30-day period following no-
22 tification, the sponsor shall, in addition to any
23 penalty under this subparagraph be subject to
24 a civil monetary penalty of not more than
25 \$10,000 for each day of the violation after such

1 period until the violation is corrected. If appli-
2 cation patient participation in an observational
3 registry is not at or above 90 percent within 6
4 months of issuance of such penalty, the provi-
5 sional approval shall be withdrawn.

6 “(4) ANNUAL REPORT TO CONGRESS.—The
7 Secretary shall submit an annual report to Congress
8 on all drugs granted provisional approval under this
9 section. Such report shall include—

10 “(A) the number of patients treated with
11 each such drug, and the number of patients
12 tracked in an observational registry with re-
13 spect to each such drug;

14 “(B) a discussion of the minimum amount
15 of data required in the registries, including pa-
16 tient treatments and uses, length of use, side
17 effects encountered, relevant biomarkers or sci-
18 entifically substantiated surrogates, scan re-
19 sults, cause of death and how long the patient
20 lived, and adverse drug effects;

21 “(C) a list of all such drugs for which an
22 application for full approval under section 505
23 of this Act or section 351 of the Public Health
24 Service Act, or an application for an extension

1 of provisional approval under this section, has
2 been submitted; and

3 “(D) a list of all applications denied provi-
4 sional approval under this section, together with
5 an explanation for the decisions to deny each
6 such application.

7 “(e) WITHDRAWAL OF PROVISIONAL APPROVAL.—

8 “(1) IN GENERAL.—The Secretary shall with-
9 draw provisional approval under this section if there
10 are a significant numbers of patients who experience
11 serious adverse effects, compared to the other cur-
12 rently marketed on-label therapies that are available
13 for the applicable disease or condition.

14 “(2) EFFECT OF WITHDRAWAL.—If a provi-
15 sional approval is withdrawn under this subsection,
16 the sponsor may not make the drug available to any
17 new patients, but may be allowed to continue to
18 make such drug available to patients who started
19 taking the drug prior to the date of withdrawal, for
20 as long a period as dictated by patient need, as de-
21 termined by the Secretary.

22 “(f) TRANSPARENCY.—Any scientific, medical, aca-
23 demic, or health care journal publishing an article explain-
24 ing, releasing, conveying or announcing research findings
25 which were funded by the Department of Health and

1 Human Services shall be prohibited from publishing such
2 research unless—

3 “(1) such article conveying research findings is
4 made publicly available on the journal’s internet
5 website without a paywall or charge not later than
6 3 months after the date on which such article was
7 first provided to subscribers of such journal (or first
8 made available for purchase); and

9 “(2) the article’s author or researcher or au-
10 thor’s institution (or, in the case of multiple authors,
11 researchers, or institutions, all such authors, re-
12 searchers, or institutions) received less than 30 per-
13 cent of funding for such research from the Depart-
14 ment of Health and Human Services throughout the
15 period of time the research was conducted.

16 “(g) INFORMED CONSENT.—Prior to receiving a drug
17 provisionally approved under this section, the sponsor of
18 the drug shall receive from each patient, or the patient’s
19 representative, informed consent, through a signed in-
20 formed consent form, acknowledging that such patient un-
21 derstands that the drug did not undergo the usual process
22 for full approval of a drug by the Food and Drug Adminis-
23 tration, and that such patient is willing to accept the risks
24 involved in taking such drug.

25 “(h) POSTMARKET CONTROLS AND LABELING.—

1 “(1) FDA ANNUAL REVIEW OF REGISTRY
2 DATA.—The Secretary shall annually review the data
3 made available through the observational registries
4 under subsection (d) and make a determination re-
5 garding whether the side effect profile of any drug
6 approved under this pathway does not support the
7 benefit provided, or the data shows the benefit is
8 less than the benefits offered through other, fully
9 approved drugs.

10 “(2) LABELING.—The sponsor of the provision-
11 ally approved drug shall ensure that all labeling and
12 promotional materials for the drug bear the state-
13 ment ‘provisionally approved by the FDA pending a
14 full demonstration of effectiveness under application
15 number _____’ (specifying the application
16 number assigned by the Secretary in place of the
17 blank). All promotional, educational and marketing
18 materials for provisionally approved products shall
19 be reviewed and approved by the Secretary before
20 such materials are distributed.

21 “(3) RESCISSION OF PROVISIONAL AP-
22 PROVAL.—If the Secretary determines that the side
23 effect profile of any drug included in such observa-
24 tional registries does not support the benefit pro-
25 vided by such drug, or that the data shows that the

1 benefit is less than the benefits offered through
2 other, fully approved drugs, the Secretary shall re-
3 scind such provisional approval.

4 “(i) DURATION OF PROVISIONAL APPROVAL; RE-
5 QUIREMENT TO BRING DRUG TO MARKET.—

6 “(1) DURATION; RENEWALS.—The period of
7 provisional approval for a drug approved under this
8 section is effective for a 2-year period. The sponsor
9 may request renewal for provisional approval status
10 for up to 3 subsequent 2-year periods by the Sec-
11 retary. Provisional approval status with respect to a
12 drug shall not exceed a total of 6 years from the ini-
13 tial date the sponsor was awarded provisional ap-
14 proval status.

15 “(2) MARKETING REQUIREMENT.—If any drug
16 that receives provisional approval status under this
17 section is not brought to market within 180 days of
18 the approval, such approval shall be rescinded.

19 “(j) LIMITATION ON LIABILITY.—With respect to any
20 claim under State law alleging that a drug sold or other-
21 wise made available pursuant to a grant of provisional ap-
22 proval under this section is unsafe or ineffective, no liabil-
23 ity in a cause of action shall lie against a sponsor or manu-
24 facturer, unless the relevant conduct constitutes reckless

1 or willful misconduct, gross negligence, or an intentional
2 tort under any applicable State law.

3 “(k) APPLYING FOR FULL APPROVAL.—

4 “(1) IN GENERAL.—Except as provided under
5 paragraph (2), the sponsor of a drug granted provi-
6 sional approval pursuant to this section may, at any
7 point, submit an application for full approval of such
8 drug under section 505 of this Act or section 351
9 of the Public Health Service Act, as applicable.

10 “(2) EFFECT OF RECESSION ON APPROVAL AND
11 AUTOMATIC APPROVAL.—

12 “(A) IN GENERAL.—The sponsor of a drug
13 granted provisional approval pursuant to this
14 section that has been rescinded under sub-
15 section (h)(3), may submit an application for
16 full approval of such drug under section 505 of
17 this Act or section 351 of the Public Health
18 Service Act at any time.

19 “(B) AUTOMATIC APPROVAL.—Such full
20 approval may be awarded at any time for any
21 drug granted provisional approval pursuant to
22 this section if the sponsor of the drug estab-
23 lishes a 15 percent improvement in an impor-
24 tant endpoint, including surrogate endpoints

1 not validated by the Food and Drug Adminis-
2 tration, compared to a standard drug.

3 “(3) REAL-TIME EPIDEMIC AND PANDEMIC VAC-
4 CINE APPROVAL.—

5 “(A) IN GENERAL.—In the case of a vac-
6 cine developed in response to an epidemic or
7 pandemic, including COVID–19, the Secretary
8 shall share data information regarding the ap-
9 proval of the vaccine with the Advisory Com-
10 mittee on Immunization Practices of the Cen-
11 ters for Disease Control and Prevention as the
12 review nears completion.

13 “(B) EVALUATION.—Any vaccine that has
14 been approved by the Secretary for an epidemic
15 or pandemic-related disease, including COVID–
16 19, shall be evaluated by the Advisory Com-
17 mittee on Immunization Practices of the Cen-
18 ters for Disease Control and Prevention not
19 later than 1 week after the date of submission
20 to the Advisory Committee by the Secretary of
21 the vaccine.

22 “(1) PATIENT ADVOCATE GENERAL.—Not later than
23 6 months after the date of enactment of the Promising
24 Pathway Act, the Secretary shall establish within the Of-
25 fice of the Commissioner, the position of Patient Advocate

1 General, who shall provide assistance to patients and their
2 families who use drugs under evaluation in this pathway
3 or drugs reviewed or approved under section 505 or sec-
4 tion 351 of the Public Health Service Act. Such assistance
5 shall include providing bi-informational communication
6 about maintaining patient health, delivery of proper in-
7 formed consent, participating in clinical investigations,
8 completing required documentation in order to participate
9 in the applicable programs, and providing other informa-
10 tion.”.

11 (b) CONFORMING AMENDMENT.—Section 505(a) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355(a)) is amended by inserting “, or there is in effect
14 a provisional approval under section 524B with respect to
15 such drug” before the period.

16 (c) REIMBURSEMENT.—

17 (1) PRIVATE HEALTH INSURERS.—Section
18 2719A of the Public Health Service Act (42 U.S.C.
19 300gg–19a) is amended by adding at the end the
20 following:

21 “(e) TREATMENT OF CERTAIN DRUGS.—A group
22 health plan or health insurance issuer of group or indi-
23 vidual health insurance coverage shall not deny coverage
24 of any drug provisionally approved under section 524B of
25 the Federal Food, Drug, and Cosmetic Act on the basis

1 of such drug being experimental. In determining coverage
2 under the applicable plan or coverage, a group health plan
3 or health insurance issuer shall treat a drug provisionally
4 approved under such section in the same manner as such
5 plan or coverage would treat a drug approved under sec-
6 tion 505 of the Federal Food, Drug, and Cosmetic Act
7 or section 351 of this Act. Nothing in this subsection shall
8 be construed to require a group health plan or health in-
9 surance issuer to cover any specific drug provisionally ap-
10 proved under such section 524B.”.

11 (2) FEDERAL HEALTH CARE PROGRAMS.—The
12 requirement under subsection (e) of section 2719A
13 of the Public Health Service Act (as added by para-
14 graph (1)) shall apply with respect to coverage de-
15 terminations under a Federal health care program
16 (as defined in section 1128B(f) of the Social Secu-
17 rity Act (42 U.S.C. 1320a–7b(f))) in the same man-
18 ner such requirement applies under such subsection
19 (e).

20 (3) CONFORMING AMENDMENT.—Section
21 1927(k)(2)(A)(i) of the Social Security Act (42
22 U.S.C. 1396r–8(k)(2)(A)(i)) is amended—

23 (A) by striking “or which” and inserting “,
24 which”; and

1 (B) by inserting “, or which is provision-
2 ally approved under section 524B of such Act”
3 before the semicolon.

4 **Subtitle D—Prescription Drug and**
5 **Pharmacy Benefit Manager**
6 **Transparency**

7 **SEC. 361. PATENT DISCLOSURE REQUIREMENTS.**

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

11 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
12 TO PATENTS.—

13 “(1) APPROVED APPLICATION HOLDER LISTING
14 REQUIREMENTS.—

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

22 “(B) PREVIOUSLY APPROVED OR LI-
23 CENSED BIOLOGICAL PRODUCTS.—

24 “(i) PRODUCTS APPROVED UNDER
25 SECTION 351 OF THE PHSA.—Not later

1 than 30 days after the date of enactment
2 of the Fair Care Act of 2026, the holder
3 of a biological product license that was ap-
4 proved under subsection (a) or (k) before
5 the date of enactment of such Act shall
6 submit to the Secretary a list of each pat-
7 ent required to be disclosed (as described
8 in paragraph (3)).

9 “(ii) PRODUCTS APPROVED UNDER
10 SECTION 505 OF THE FFDCA.—Not later
11 than 30 days after March 23, 2026, the
12 holder of an approved application for a bio-
13 logical product under section 505 of the
14 Federal Food, Drug, and Cosmetic Act
15 that is deemed to be a license for the bio-
16 logical product under this section on
17 March 23, 2026, shall submit a list of each
18 patent required to be disclosed (as de-
19 scribed in paragraph (3)).

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

24 “(i) any patent first required to be
25 disclosed (as described in paragraph (3))

1 after the submission under subparagraph
2 (A) or (B), as applicable, within 30 days of
3 the earlier of—

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

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

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

17 “(2) PUBLICATION OF INFORMATION.—

18 “(A) IN GENERAL.—Within 1 year of the
19 date of enactment of the Fair Care Act of
20 2026, the Secretary shall publish and make
21 available to the public a single, easily search-
22 able, list that includes—

23 “(i) the official and proprietary name
24 of each biological product licensed under
25 subsection (a) or (k), and of each biological

1 product application approved under section
2 505 of the Federal Food, Drug, and Cos-
3 metic Act and deemed to be a license for
4 the biological product under this section on
5 March 23, 2026;

6 “(ii) with respect to each biological
7 product described in clause (i), each patent
8 submitted in accordance with paragraph
9 (1);

10 “(iii) the date of licensure and appli-
11 cation number for each such biological
12 product;

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

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

21 “(vi) any period of any exclusivity
22 under subsection (k)(7)(A) or subsection
23 (k)(7)(B) of this section or section 527 of
24 the Federal Food, Drug, and Cosmetic
25 Act, and any extension of such period in

1 accordance with subsection (m) of this sec-
2 tion with respect to each such biological
3 product, and the date on which such exclu-
4 sivity expires;

5 “(vii) information regarding any de-
6 termination related to biosimilarity or
7 interchangeability for each such biological
8 product; and

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

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

17 “(i)(I) each biological product licensed
18 under subsection (a) or (k) during the 30-
19 day period; and

20 “(II) with respect to each biological
21 product described in subclause (I), the in-
22 formation described in clauses (i) through
23 (viii) of subparagraph (A); and

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

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

5 In this section, a ‘patent required to be disclosed’ is
6 any patent for which the holder of a biological prod-
7 uct license approved under subsection (a) or (k), or
8 a biological product application approved under sec-
9 tion 505 of the Federal Food, Drug, and Cosmetic
10 Act and deemed to be a license for a biological prod-
11 uct under this section on March 23, 2026, believes
12 a claim of patent infringement could reasonably be
13 asserted by the holder, or by a patent owner that
14 has granted an exclusive license to the holder with
15 respect to the biological product that is the subject
16 of such license, if a person not licensed by the holder
17 engaged in the making, using, offering to sell, sell-
18 ing, or importing into the United States of the bio-
19 logical product that is the subject of such license.”.

20 (b) DISCLOSURE OF PATENTS.—Section
21 351(l)(3)(A)(i) of the Public Health Service Act (42
22 U.S.C. 262(l)(3)(A)(i)) is amended by inserting “included
23 in the list provided by the reference product sponsor under
24 subsection (o)(1)” after “a list of patents”.

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

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

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

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

21 **SEC. 362. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
22 **TION DRUG BENEFITS.**

23 (a) IN GENERAL.—Subpart II of part A of title
24 XXVII of the Public Health Service Act (42 U.S.C.

1 300gg–11 et seq.) is amended by adding at the end the
2 following:

3 **“SEC. 2729A. REQUIREMENTS WITH RESPECT TO PRESCRIP-**
4 **TION DRUG BENEFITS.**

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

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

16 “(2) any such other remuneration is a flat fee-
17 based service fee that a manufacturer of prescription
18 drugs pays to a pharmacy benefit manager for serv-
19 ices rendered to the manufacturer that relate to ar-
20 rangements by the pharmacy benefit manager to
21 provide pharmacy benefit management services to a
22 health plan or health insurance issuer, if certain
23 conditions established by the Secretary are met, in-
24 cluding requirements that the fees are transparent
25 to the health plan or health insurance issuer.”.

1 (b) EFFECTIVE DATE.—Section 2729A of the Public
2 Health Service Act, as added by subsection (a), shall take
3 effect on January 1, 2026.

4 **SEC. 363. PBM TRANSPARENCY AND ELIMINATION OF DIR**
5 **FEES.**

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

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

14 “(iv) PROHIBITING RETROACTIVE RE-
15 Ductions IN PAYMENTS ON CLEAN
16 CLAIMS.—Each contract entered into with
17 a PDP sponsor under this part with re-
18 spect to a prescription drug plan offered
19 by such sponsor shall provide that after
20 the date of receipt of a clean claim sub-
21 mitted by a pharmacy, the PDP sponsor
22 (or an agent of the PDP sponsor) may not
23 retroactively reduce payment on such claim
24 directly or indirectly through aggregated
25 effective rate or otherwise except in the

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

13 (2) EFFECTIVE DATE.—The amendment made
14 by subsection (a) shall apply with respect to con-
15 tracts entered into on or after January 1, 2026.

16 (b) ELIMINATION OF DIR FEES.—

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

20 (A) IN GENERAL.—Section 1860D–12(b)
21 of the Social Security Act (42 U.S.C. 1395w–
22 112(b)) is amended by adding at the end the
23 following new paragraph:

24 “(7) PHARMACY BENEFITS MANAGER TRANS-
25 PARENCY REQUIREMENTS.—Each contract entered

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

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

22 “(B) The PBM may not require that a
23 plan enrollee use a retail pharmacy, mail order
24 pharmacy, specialty pharmacy, or other phar-
25 macy entity providing pharmacy services in

1 which the PBM has an ownership interest or
2 that has an ownership interest in the PBM, or
3 provide an incentive to a plan enrollee to en-
4 courage the enrollee to use a retail pharmacy,
5 mail order pharmacy, specialty pharmacy, or
6 other pharmacy entity providing pharmacy serv-
7 ices in which the PBM has an ownership inter-
8 est or that has an ownership interest in the
9 PBM, if the incentive is applicable only to such
10 pharmacies.”.

11 (B) REGULAR UPDATE OF PRESCRIPTION
12 DRUG PRICING STANDARD.—Paragraph (6) of
13 section 1860D–12(b) of the Social Security Act
14 (42 U.S.C. 1395w–112(b)) is amended to read
15 as follows:

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

18 “(A) IN GENERAL.—If the PDP sponsor of
19 a prescription drug plan (or MA organization
20 offering an MA–PD plan) uses a standard for
21 reimbursement (as described in subparagraph
22 (B)) of pharmacies based on the cost of a drug,
23 each contract entered into with such sponsor
24 under this part (or organization under part C)

1 with respect to the plan shall provide that the
2 sponsor (or organization) shall—

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

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

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

20 “(iv) establish a process to appeal, in-
21 vestigate, and resolve disputes regarding
22 individual drug prices that are less than
23 the pharmacy acquisition price for such
24 drug, which must be adjudicated within 7
25 days of the pharmacy filing its appeal; and

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

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

18 (C) EFFECTIVE DATE.—The amendments
19 made by this section shall apply to plan years
20 beginning on or after January 1, 2026.

21 (2) REGULAR UPDATE OF PRESCRIPTION DRUG
22 PRICING STANDARD UNDER TRICARE RETAIL PHAR-
23 MACY PROGRAM.—Section 1074g(d) of title 10,
24 United States Code, is amended by adding at the
25 end the following new paragraph:

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

9 (3) PRESCRIPTION DRUG TRANSPARENCY IN
10 THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-
11 GRAM.—

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

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

22 “(1) The PBM may not transmit any personally
23 identifiable utilization, protected health information,
24 or claims data with respect to an individual enrolled
25 under such contract or plan to a pharmacy owned by

1 the PBM if the individual has not voluntarily elected
2 in writing or via secure electronic means to fill that
3 particular prescription at such a pharmacy.

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

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

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

1 “(B) disclose to applicable pharmacies and the
2 contracting entities of such pharmacies the sources
3 used for making any such update immediately with-
4 out requirement of request;

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

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

16 “(E) provide all such pricing data in an .xml
17 spreadsheet format or a comparable easily accessible
18 and complete spreadsheet format.

19 “(2) For purposes of paragraph (1), a standard for
20 reimbursement of a pharmacy is any methodology or for-
21 mula for varying the pricing of a drug or drugs during
22 the term of the pharmacy reimbursement contract that is
23 based on the cost of the drug involved, including drug prie-
24 ing references and amounts that are based upon average
25 wholesale price, wholesale average cost, average manufac-

1 turer price, average sales price, maximum allowable cost,
2 or other costs, whether publicly available or not.”.

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

8 **SEC. 364. HEALTH PLAN OVERSIGHT OF PHARMACY BEN-**
9 **EFIT MANAGER SERVICES.**

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

14 **“SEC. 2729E. HEALTH PLAN OVERSIGHT OF PHARMACY**
15 **BENEFIT MANAGER SERVICES.**

16 “(a) IN GENERAL.—A group health plan or health
17 insurance issuer offering group health insurance coverage
18 or an entity or subsidiary providing pharmacy benefits
19 management services shall not enter into a contract with
20 a drug manufacturer, distributor, wholesaler, subcon-
21 tractor, rebate aggregator, or any associated third party
22 that limits the disclosure of information to plan sponsors
23 in such a manner that prevents the plan or coverage, or
24 an entity or subsidiary providing pharmacy benefits man-

1 agement services on behalf of a plan or coverage from
2 making the reports described in subsection (b).

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

4 “(1) IN GENERAL.—Beginning with the first
5 plan year that begins after the date of enactment of
6 the Fair Care Act of 2026, not less frequently than
7 once every 6 months, a health insurance issuer offer-
8 ing group health insurance coverage or an entity
9 providing pharmacy benefits management services
10 on behalf of a group health plan shall submit to the
11 plan sponsor (as defined in section 3(16)(B) of the
12 Employee Retirement Income Security Act of 1974)
13 of such group health plan or health insurance cov-
14 erage a report in accordance with this subsection
15 and make such report available to the plan sponsor
16 in a machine-readable format. Each such report
17 shall include, with respect to the applicable group
18 health plan or health insurance coverage—

19 “(A) information collected from drug man-
20 ufacturers by such issuer or entity on the total
21 amount of copayment assistance dollars paid, or
22 copayment cards applied, that were funded by
23 the drug manufacturer with respect to the en-
24 rollees in such plan or coverage;

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

5 “(i) the brand name, chemical entity,
6 and National Drug Code;

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

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

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

24 “(v) for any drug for which gross
25 spending of the group health plan or

1 health insurance coverage exceeded
2 \$10,000 during the reporting period—

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

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

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

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

23 “(ii) the number of enrollees who
24 filled a prescription for a drug in that cat-
25 egory or class;

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

6 “(iv) the total out-of-pocket spending
7 by enrollees, including enrollee spending
8 through copayments, coinsurance, and
9 deductibles; and

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

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

18 “(aa) to be paid by drug
19 manufacturers for claims in-
20 curred during the reporting pe-
21 riod; or

22 “(bb) that is related to utili-
23 zation of drugs, in such thera-
24 peutic category or class;

1 “(II) the total net spending, after
2 deducting rebates, price concessions,
3 alternative discounts or other remun-
4 eration from drug manufacturers, by
5 the health plan or health insurance
6 coverage on that category or class of
7 drugs; and

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

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

20 “(E) total amount received, or expected to
21 be received, by the health plan or health insur-
22 ance coverage in drug manufacturer rebates,
23 fees, alternative discounts, and all other remun-
24 eration received from the manufacturer or any
25 third party, other than the plan sponsor, re-

1 lated to utilization of drug or drug spending
2 under that health plan or health insurance cov-
3 erage during the reporting period;

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

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

13 “(2) PRIVACY REQUIREMENTS.—Health insur-
14 ance issuers offering group health insurance cov-
15 erage and entities providing pharmacy benefits man-
16 agement services on behalf of a group health plan
17 shall provide information under paragraph (1) in a
18 manner consistent with the privacy, security, and
19 breach notification regulations promulgated under
20 section 264(c) of the Health Insurance Portability
21 and Accountability Act of 1996 (or successor regula-
22 tions), and shall restrict the use and disclosure of
23 such information according to such privacy regula-
24 tions.

25 “(3) DISCLOSURE AND REDISCLOSURE.—

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

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

19 “(C) LIMITED FORM OF REPORT.—The
20 Secretary shall define through rulemaking a
21 limited form of the report under paragraph (1)
22 required of plan sponsors who are drug manu-
23 facturers, drug wholesalers, or other direct par-
24 ticipants in the drug supply chain, in order to
25 prevent anti-competitive behavior.

1 “(c) LIMITATIONS ON SPREAD PRICING.—

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

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

1 or individual health insurance coverage may not ex-
2 ceed the lesser of—

3 “(A) the amount paid to the pharmacy for
4 acquisition of the drug; or

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

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

24 “(A) an explanation of any benefit design
25 parameters that encourage enrollees in the plan

1 or coverage to fill prescriptions at mail order,
2 specialty, or retail pharmacies that are wholly
3 or partially owned by that issuer or entity;

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

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

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

21 “(ii) the median amount charged to
22 the plan or coverage, per course of treat-
23 ment or 30-day supply, including amounts
24 paid by the enrollee, when the same drug
25 is dispensed by other pharmacies that are

1 not wholly or partially owned by the issuer
2 or entity and that are included in the
3 pharmacy network of that plan or cov-
4 erage;

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

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

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

20 “(1) IN GENERAL.—A pharmacy benefits man-
21 ager, a third-party administrator of a group health
22 plan, a health insurance issuer offering group health
23 insurance coverage, or an entity providing pharmacy
24 benefits management services under such health
25 plan or health insurance coverage shall remit 100

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

7 “(2) FORM AND MANNER OF REMITTANCE.—

8 Such rebates, fees, alternative discounts, and other
9 remuneration shall be—

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

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

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

21 “(D) returned to the issuer or entity pro-
22 viding pharmacy benefits management services
23 by the group health plan if audits by such
24 issuer or entity indicate that the amounts re-

1 ceived are incorrect after such amounts have
2 been paid to the group health plan.

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

13 “(e) ENFORCEMENT.—

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

17 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
18 TION.—A health insurance issuer or an entity pro-
19 viding pharmacy benefit management services that
20 violates subsection (a), fails to provide information
21 required under subsection (b), engages in spread
22 pricing as defined in subsection (c), or fails to com-
23 ply with the requirements of subsection (d), or a
24 drug manufacturer that fails to provide information
25 under subsection (b)(1)(A), in a timely manner shall

1 be subject to a civil monetary penalty in the amount
2 of \$10,000 for each day during which such violation
3 continues or such information is not disclosed or re-
4 ported.

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

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

21 “(5) SAFE HARBOR.—The Secretary may waive
22 penalties under paragraph (2), or extend the period
23 of time for compliance with a requirement of this
24 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 THE**
21 **UNITED 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. MARKET BASED PART B PRICING INDEX.**

16 Notwithstanding any provision of part B of title
17 XVIII of the Social Security Act, the Secretary of Health
18 and Human Services may make payments for drugs pay-
19 able under such part based on an international pricing
20 index. In using such an index, the Secretary shall take
21 into account whether the market of each country included
22 in such index is a price-controlled or free market and give
23 more weight under such index to countries with market-
24 based drug policies.

1 **SEC. 372. 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 **Subtitle F—Medical Malpractice**
9 **Reform**

10 **SEC. 381. DEFINITIONS.**

11 In this Act:

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

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

1 (3) COLLATERAL SOURCE BENEFITS.—The
2 term “collateral source benefits” means any amount
3 paid or reasonably likely to be paid in the future to
4 or on behalf of the claimant, or any service, product,
5 or other benefit provided or reasonably likely to be
6 provided in the future to or on behalf of the claim-
7 ant, as a result of the injury or wrongful death, pur-
8 suant to—

9 (A) any State or Federal health, sickness,
10 income-disability, accident, or workers’ com-
11 pensation law;

12 (B) any health, sickness, income-disability,
13 or accident insurance that provides health bene-
14 fits or income-disability coverage;

15 (C) any contract or agreement of any
16 group, organization, partnership, or corporation
17 to provide, pay for, or reimburse the cost of
18 medical, hospital, dental, or income-disability
19 benefits; and

20 (D) any other publicly or privately funded
21 program.

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

1 (5) ECONOMIC DAMAGES.—The term “economic
2 damages” means objectively verifiable monetary
3 losses incurred as a result of the provision or use of
4 (or failure to provide or use) health care services or
5 medical products, such as past and future medical
6 expenses, loss of past and future earnings, cost of
7 obtaining domestic services, loss of employment, and
8 loss of business or employment opportunities, unless
9 otherwise defined under applicable State law. In no
10 circumstances shall damages for health care services
11 or medical products exceed the amount actually paid
12 or incurred by or on behalf of the claimant.

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

18 (7) HEALTH CARE LAWSUIT.—The term
19 “health care lawsuit” means any health care liability
20 claim concerning the provision of goods or services
21 for which coverage was provided in whole or in part
22 via a Federal program, subsidy or tax benefit, or
23 any health care liability action concerning the provi-
24 sion of goods or services for which coverage was pro-
25 vided in whole or in part via a Federal program,

1 subsidy or tax benefit, brought in a State or Federal
2 court or pursuant to an alternative dispute resolu-
3 tion system, against a health care provider regard-
4 less of the theory of liability on which the claim is
5 based, or the number of claimants, plaintiffs, de-
6 fendants, or other parties, or the number of claims
7 or causes of action, in which the claimant alleges a
8 health care liability claim. Such term does not in-
9 clude a claim or action which is based on criminal
10 liability; which seeks civil fines or penalties paid to
11 Federal, State, or local government; or which is
12 grounded in antitrust.

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

22 (9) HEALTH CARE LIABILITY CLAIM.—The
23 term “health care liability claim” means a demand
24 by any person, whether or not pursuant to ADR,
25 against a health care provider, including, but not

1 limited to, third-party claims, cross-claims, counter-
2 claims, or contribution claims, which are based upon
3 the provision or use of (or the failure to provide or
4 use) health care services or medical products, re-
5 gardless of the theory of liability on which the claim
6 is based, or the number of plaintiffs, defendants, or
7 other parties, or the number of causes of action.

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

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

1 the assessment or care of the health of human
2 beings.

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

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

1 (14) RECOVERY.—The term “recovery” means
2 the net sum recovered after deducting any disburse-
3 ments or costs incurred in connection with prosecu-
4 tion or settlement of the claim, including all costs
5 paid or advanced by any person. Costs of health care
6 incurred by the plaintiff and the attorneys’ office
7 overhead costs or charges for legal services are not
8 deductible disbursements or costs for such purpose.

9 (15) REPRESENTATIVE.—The term “represent-
10 ative” means a legal guardian, attorney, person des-
11 ignated to make decisions on behalf of a patient
12 under a medical power of attorney, or any person
13 recognized in law or custom as a patient’s agent.

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

21 **SEC. 382. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

22 (a) STATUTE OF LIMITATIONS.—

23 (1) IN GENERAL.—Except as provided in para-
24 graph (2), the time for the commencement of a

1 health care lawsuit shall be, whichever occurs first of
2 the following:

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

5 (B) Three years after the date the medical
6 or health care treatment that is the subject of
7 the claim is completed.

8 (C) One year after the claimant discovers,
9 or through the use of reasonable diligence
10 should have discovered, the injury.

11 (2) TOLLING.—In no event shall the time for
12 commencement of a health care lawsuit exceed 3
13 years after the date of the occurrence of the breach
14 or tort or 3 years after the date the medical or
15 health care treatment that is the subject of the claim
16 is completed (whichever occurs first) unless tolled
17 for any of the following—

18 (A) upon proof of fraud;

19 (B) intentional concealment; or

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

23 (3) ACTIONS BY A MINOR.—Actions by a minor
24 shall be commenced within 3 years after the date of
25 the occurrence of the breach or tort or 3 years after

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

17 (b) STATE FLEXIBILITY.—No provision of subsection
18 (a) 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—

21 (1) specifies a time period of less than 3 years
22 after the date of injury or less than 1 year after the
23 claimant discovers, or through the use of reasonable
24 diligence should have discovered, the injury, for the
25 filing of a health care lawsuit;

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

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

5 (4) establishes a statute of repose for the filing
6 of a health care lawsuit.

7 **SEC. 383. COMPENSATING PATIENT INJURY.**

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

13 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
14 health care lawsuit, the amount of noneconomic damages,
15 if available, shall not exceed \$250,000, regardless of the
16 number of parties against whom the action is brought or
17 the number of separate claims or actions brought with re-
18 spect to the same injury.

19 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
20 DAMAGES.—For purposes of applying the limitation in
21 subsection (b), future noneconomic damages shall not be
22 discounted to present value. The jury shall not be in-
23 formed about the maximum award for noneconomic dam-
24 ages. An award for noneconomic damages in excess of
25 \$250,000 shall be reduced either before the entry of judg-

1 ment, or by amendment of the judgment after entry of
2 judgment, and such reduction shall be made before ac-
3 counting for any other reduction in damages required by
4 law. If separate awards are rendered for past and future
5 noneconomic damages and the combined awards exceed
6 \$250,000, the future noneconomic damages shall be re-
7 duced first.

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

20 (e) STATE FLEXIBILITY.—No provision of this sec-
21 tion shall be construed to preempt any State law (whether
22 effective before, on, or after the date of the enactment of
23 this Act) that specifies a particular monetary amount of
24 economic or noneconomic damages (or the total amount
25 of damages) that may be awarded in a health care lawsuit,

1 regardless of whether such monetary amount is greater
2 or lesser than is provided for under this section.

3 **SEC. 384. MAXIMIZING PATIENT RECOVERY.**

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

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

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

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

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

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

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

18 **SEC. 385. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
19 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
20 **SUITS.**

21 (a) IN GENERAL.—In any health care lawsuit, if an
22 award of future damages, without reduction to present
23 value, equaling or exceeding \$50,000 is made against a
24 party with sufficient insurance or other assets to fund a
25 periodic payment of such a judgment, the court shall, at

1 the request of any party, enter a judgment ordering that
2 the future damages be paid by periodic payments, in ac-
3 cordance with the Uniform Periodic Payment of Judg-
4 ments Act promulgated by the National Conference of
5 Commissioners on Uniform State Laws.

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

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

15 **SEC. 386. PRODUCT LIABILITY FOR HEALTH CARE PRO-**
16 **VIDERS.**

17 A health care provider who prescribes, or who dis-
18 penses pursuant to a prescription, a medical product ap-
19 proved, licensed, or cleared by the Food and Drug Admin-
20 istration shall not be named as a party to a product liabil-
21 ity lawsuit involving such product and shall not be liable
22 to a claimant in a class action lawsuit against the manu-
23 facturer, distributor, or seller of such product.

24 **SEC. 387. EFFECT ON OTHER LAWS.**

25 (a) **VACCINE INJURY.**—

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

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

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

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

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

21 **SEC. 388. LIMITATION ON EXPERT WITNESS TESTIMONY.**

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

1 (1) the recognized standard of acceptable pro-
2 fessional practice and the specialty thereof, if any,
3 that the defendant practices, which shall be the type
4 of acceptable professional practice recognized in the
5 defendant's community or in a community similar to
6 the defendant's community that was in place at the
7 time the alleged injury or wrongful action occurred;

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

11 (3) that as a proximate result of the defend-
12 ant's negligent act or omission, the claimant suf-
13 fered injuries which would not otherwise have oc-
14 curred,

15 unless the person was licensed to practice, in the State
16 or a contiguous bordering State, a profession or specialty
17 which would make the person's expert testimony relevant
18 to the issues in the case and had practiced this profession
19 or specialty in one of these States during the year pre-
20 ceding the date that the alleged injury or wrongful act
21 occurred.

22 (b) APPLICABILITY.—The requirements set forth in
23 subsection (a) shall also apply to expert witnesses testi-
24 fying for the defendant as rebuttal witnesses.

1 (c) WAIVER AUTHORITY.—The court may waive the
2 requirements in this subsection if it determines that the
3 appropriate witnesses otherwise would not be available.

4 **SEC. 389. EXPERT WITNESS QUALIFICATIONS.**

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

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

21 (2) During the 1-year period immediately pre-
22 ceding the occurrence of the action that gave rise to
23 the lawsuit, the expert witness shall have devoted a
24 majority of the individual's professional time to one
25 or more of the following:

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

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

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

18 (A) Active clinical practice as a general
19 practitioner.

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

24 (b) LAWSUITS AGAINST ENTITIES.—If the defendant
25 in a health care lawsuit is an entity that employs a person

1 against whom or on whose behalf the testimony is offered,
2 the provisions of subsection (a) apply as if the person were
3 the party or defendant against whom or on whose behalf
4 the testimony is offered.

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

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

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

18 **SEC. 390. COMMUNICATIONS FOLLOWING UNANTICIPATED**
19 **OUTCOME.**

20 (a) PROVIDER COMMUNICATIONS.—In any health
21 care liability action, any and all statements, affirmations,
22 gestures, or conduct expressing apology, fault, sympathy,
23 commiseration, condolence, compassion, or a general sense
24 of benevolence which are made by a health care provider
25 or an employee of a health care provider to the patient,

1 a relative of the patient, or a representative of the patient
2 and which relate to the discomfort, pain, suffering, injury,
3 or death of the patient as the result of the unanticipated
4 outcome of medical care shall be inadmissible for any pur-
5 pose as evidence of an admission of liability or as evidence
6 of an admission against interest.

7 (b) STATE FLEXIBILITY.—No provision of this sec-
8 tion shall be construed to preempt any State law (whether
9 effective before, on, or after the date of the enactment of
10 this Act) that makes additional communications inadmis-
11 sible as evidence of an admission of liability or as evidence
12 of an admission against interest.

13 **SEC. 391. AFFIDAVIT OF MERIT.**

14 (a) REQUIRED FILING.—Subject to subsection (b),
15 the plaintiff in a health care lawsuit alleging negligence
16 or, if the plaintiff is represented by an attorney, the plain-
17 tiff's attorney shall file simultaneously with the health
18 care lawsuit an affidavit of merit signed by a health pro-
19 fessional who meets the requirements for an expert wit-
20 ness under section 242 of this Act. The affidavit of merit
21 shall certify that the health professional has reviewed the
22 notice and all medical records supplied to him or her by
23 the plaintiff's attorney concerning the allegations con-
24 tained in the notice and shall contain a statement of each
25 of the following:

1 (1) The applicable standard of practice or care.

2 (2) The health professional's opinion that the
3 applicable standard of practice or care was breached
4 by the health professional or health facility receiving
5 the notice.

6 (3) The actions that should have been taken or
7 omitted by the health professional or health facility
8 in order to have complied with the applicable stand-
9 ard of practice or care.

10 (4) The manner in which the breach of the
11 standard of practice or care was the proximate cause
12 of the injury alleged in the notice.

13 (5) A listing of the medical records reviewed.

14 (b) FILING EXTENSION.—Upon motion of a party for
15 good cause shown, the court in which the complaint is filed
16 may grant the plaintiff or, if the plaintiff is represented
17 by an attorney, the plaintiff's attorney an additional 28
18 days in which to file the affidavit required under sub-
19 section (a).

20 (c) STATE FLEXIBILITY.—No provision of this sec-
21 tion shall be construed to preempt any State law (whether
22 effective before, on, or after the date of the enactment of
23 this Act) that establishes additional requirements for the
24 filing of an affidavit of merit or similar pre-litigation docu-
25 mentation.

1 **SEC. 392. NOTICE OF INTENT TO COMMENCE LAWSUIT.**

2 (a) **ADVANCE NOTICE.**—A person shall not com-
3 mence a health care lawsuit against a health care provider
4 unless the person has given the health care provider 90
5 days written notice before the action is commenced.

6 (b) **EXCEPTIONS.**—A health care lawsuit against a
7 health care provider filed within 6 months of the statute
8 of limitations expiring as to any claimant, or within 1 year
9 of the statute of repose expiring as to any claimant, shall
10 be exempt from compliance with this section.

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 establishes a different time period for the
15 filing of written notice.

16 **SEC. 393. LIMITATION ON LIABILITY FOR VOLUNTEER**
17 **HEALTH CARE PROFESSIONALS.**

18 (a) **IN GENERAL.**—Title II of the Public Health Serv-
19 ice Act (42 U.S.C. 202 et seq.) is amended by inserting
20 after section 224 the following:

21 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**
22 **HEALTH CARE PROFESSIONALS.**

23 “(a) **LIMITATION ON LIABILITY.**—A physician shall
24 not be liable under Federal or State law in any civil action
25 for any harm caused by an act or omission of such physi-

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

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

6 “(2) was not grossly negligent.

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

12 “(c) DEFINITIONS.—In this section:

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

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

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

1 **SEC. 394. RULES OF CONSTRUCTION.**

2 (a) HEALTH CARE LAWSUITS.—Unless otherwise
3 specified in this subtitle, the provisions governing health
4 care lawsuits set forth in this subtitle preempt, subject to
5 subsections (b) and (c), State law to the extent that State
6 law prevents the application of any provisions of law estab-
7 lished by or under this subtitle. The provisions governing
8 health care lawsuits set forth in this subtitle supersede
9 chapter 171 of title 28, United States Code, to the extent
10 that such chapter—

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

16 (2) prohibits the introduction of evidence re-
17 garding collateral source benefits, or mandates or
18 permits subrogation or a lien on collateral source
19 benefits.

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

25 (c) STATE FLEXIBILITY.—No provision of this sub-
26 title shall be construed to preempt any defense available

1 to a party in a health care lawsuit under any other provi-
 2 sion of State or Federal law.

3 **SEC. 395. EFFECTIVE DATE.**

4 This subtitle shall apply to any health care lawsuit
 5 brought in a Federal or State court, or subject to an alter-
 6 native dispute resolution system, that is initiated on or
 7 after the date of the enactment of this subtitle, except that
 8 any health care lawsuit arising from an injury occurring
 9 prior to the date of the enactment of this subtitle shall
 10 be governed by the applicable statute of limitations provi-
 11 sions in effect at the time the cause of action accrued.

12 **TITLE IV—MEDICARE AND**

13 **MEDICAID REFORMS**

14 **Subtitle A—Medicaid Reforms**

15 **SEC. 401. MEDICAID PAYMENT REFORM.**

16 (a) IN GENERAL.—Title XIX of the Social Security
 17 Act (42 U.S.C. 1396 et seq.) is amended by inserting after
 18 section 1903 the following section:

19 **“SEC. 1903A. REFORMED PAYMENT TO STATES.**

20 **“(a) REFORMED PAYMENT SYSTEM.—**

21 **“(1) IN GENERAL.—**For quarters beginning on
 22 or after the implementation date (as defined in sub-
 23 section (k)(1)), in the case of a State that elects (in
 24 a time and manner specified by the Secretary) to
 25 apply this section, in lieu of amounts otherwise pay-

1 able to such State under this title (including any
2 payments attributable to section 1923), except as
3 otherwise provided in this section, the amount pay-
4 able to such State shall be equal to the sum of the
5 following:

6 “(A) ADJUSTED AGGREGATE BENE-
7 FICIARY-BASED AMOUNT.—The aggregate bene-
8 ficiary-based amount specified in subsection (b)
9 for the quarter and the State, adjusted under
10 subsection (e).

11 “(B) CHRONIC CARE QUALITY BONUS.—
12 The amount (if any) of the chronic care quality
13 bonus payment specified in subsection (f) for
14 the quarter for the State.

15 “(2) REQUIREMENT OF STATE SHARE.—

16 “(A) IN GENERAL.—A State shall make,
17 from non-Federal funds, expenditures in an
18 amount equal to its State share (as determined
19 under subparagraph (B)) for a quarter for
20 items, services, and other costs for which, but
21 for paragraph (1), Federal funds would have
22 been payable under this title.

23 “(B) STATE SHARE.—The State share for
24 a State for a quarter in a fiscal year is equal
25 to the product of—

1 “(i) the aggregate beneficiary-based
2 amount specified in subsection (b) for the
3 quarter and the State; and

4 “(ii) the ratio of—

5 “(I) the State percentage de-
6 scribed in subparagraph (D)(ii) for
7 such State and fiscal year; to

8 “(II) the Federal percentage de-
9 scribed in subparagraph (D)(i) for
10 such State and fiscal year.

11 “(C) NONPAYMENT FOR FAILURE TO PAY
12 STATE SHARE.—

13 “(i) IN GENERAL.—If a State fails to
14 expend the amount required under sub-
15 paragraph (A) for a quarter in a fiscal
16 year, the amount payable to the State
17 under paragraph (1) shall be reduced by
18 the product of the amount by which the
19 State payment is less than the State share
20 and the ratio of—

21 “(I) the Federal percentage de-
22 scribed in subparagraph (D)(i) for
23 such State and fiscal year; to

1 “(II) the State percentage de-
2 scribed in subparagraph (D)(ii) for
3 such State and fiscal year.

4 “(ii) GRACE PERIOD.—A State shall
5 not be considered to have failed to provide
6 payment of its required State share for a
7 quarter under subparagraph (A) if the ag-
8 gregate State payment towards the State’s
9 required State share for the 4-quarter pe-
10 riod beginning with such quarter exceeds
11 the required State share amount for such
12 4-quarter period.

13 “(D) FEDERAL AND STATE PERCENT-
14 AGES.—In this paragraph, with respect to a
15 State and a fiscal year:

16 “(i) FEDERAL PERCENTAGE.—The
17 Federal percentage described in this clause
18 is 75 percent or, if higher, the Federal
19 medical assistance percentage for such
20 State for such fiscal year.

21 “(ii) STATE PERCENTAGE.—The State
22 percentage described in this clause is 100
23 percent minus the Federal percentage de-
24 scribed in clause (i).

1 “(E) RULES FOR CREDITING TOWARD
2 STATE SHARE.—

3 “(i) GENERAL LIMITATION TO MATCH-
4 ABLE EXPENDITURES.—A payment for ex-
5 penditures shall not be counted toward the
6 State share under subparagraph (A) unless
7 Federal payments may be used for such
8 expenditures consistent with paragraph
9 (3)(B).

10 “(ii) FURTHER LIMITATIONS ON AL-
11 LOWABLE EXPENDITURES.—A payment for
12 expenditures shall not be counted towards
13 the State share under subparagraph (A) if
14 the expenditure is for any of the following:

15 “(I) ABORTION.—Expenditures
16 for an abortion.

17 “(II) INTERGOVERNMENTAL
18 TRANSFERS.—An expenditure that is
19 attributable to an intergovernmental
20 transfer.

21 “(III) CERTIFIED PUBLIC EX-
22 PENDITURES.—An expenditure that is
23 attributable to certified public expend-
24 itures.

1 “(iii) CREDITING FRAUD AND ABUSE
2 RECOVERIES.—Amounts recovered by a
3 State through the operation of its Medicaid
4 fraud and abuse control unit described in
5 section 1903(q) shall be fully counted to-
6 ward the State share under subparagraph
7 (A).

8 “(F) CONSTRUCTION.—Nothing in the
9 paragraph shall be construed as preventing a
10 State from expending, from non-Federal funds,
11 an amount under this title in excess of the
12 amount of the State share.

13 “(G) DETERMINATION BASED UPON SUB-
14 MITTED CLAIMS.—In applying this paragraph
15 with respect to expenditures of a State for a
16 quarter, the determination of the expenditures
17 for such State for such quarter shall be made
18 after the end of the period (which, as of the
19 date of the enactment of this section, is 2
20 years) for which the Secretary accepts claims
21 for payment under this title with respect to
22 such quarter.

23 “(3) USE OF FEDERAL PAYMENTS.—

24 “(A) APPLICATION OF MEDICAID LIMITA-
25 TIONS.—A State may only use Federal pay-

1 ments received under subsection (a) for expend-
2 itures for which Federal funds would have been
3 payable under this title but for this section.

4 “(B) LIMITATION FOR CERTAIN ELIGI-
5 BLES.—

6 “(i) APPLICATION OF 100 PERCENT
7 FEDERAL POVERTY LINE LIMIT ON ELIGI-
8 BILITY.—Subject to clause (iii), a State
9 may not use such Federal payments to
10 provide medical assistance for an indi-
11 vidual who has an income (as determined
12 under clause (ii)) that exceeds 100 percent
13 of the poverty line (as defined in section
14 2110(c)(5)) applicable to a family of the
15 size involved.

16 “(ii) DETERMINATION OF INCOME
17 USING MODIFIED ADJUSTED GROSS IN-
18 COME WITHOUT ANY 5 PERCENT IN-
19 CREASE.—In determining income for pur-
20 poses of clause (i) under section
21 1902(e)(14) (relating to modified adjusted
22 gross income), the following rules shall
23 apply:

24 “(I) APPLICATION OF SPEND
25 DOWN.—The State shall take into ac-

1 count the costs incurred for medical
2 care or for any other type of remedial
3 care recognized under State law in the
4 same manner and to the same extent
5 that such State takes such costs into
6 account for purposes of section
7 1902(a)(17).

8 “(II) DISREGARD OF 5 PERCENT
9 INCREASE.—Subparagraph (I) of sec-
10 tion 1902(e)(14) (relating to a 5 per-
11 cent reduction) shall not apply.

12 “(iii) EXCEPTION.—Clause (i) shall
13 not apply to an individual who is—

14 “(I) a woman described in clause
15 (i) of section 1903(v)(4)(A);

16 “(II) a child who is an individual
17 described in clause (i) of section
18 1905(a);

19 “(III) enrolled in a State plan
20 under this title as of the date of the
21 enactment of this section for the pe-
22 riod of continuous enrollment; or

23 “(IV) described in section
24 1902(e)(14)(D) (relating to modified
25 adjusted gross income).

1 “(iv) CLARIFICATION RELATED TO
2 COMMUNITY SPOUSE.—Nothing in this
3 subparagraph shall supersede the applica-
4 tion of section 1924 (related to community
5 spouse income and assets).

6 “(4) EXCEPTIONS FOR PASS-THROUGH PAY-
7 MENTS.—

8 “(A) IN GENERAL.—Paragraph (1) shall
9 not apply, and amounts shall continue to be
10 payable under this title (and not under sub-
11 section (a)), in the case of the following pay-
12 ments (and related administrative costs and ex-
13 penditures):

14 “(i) PAYMENTS TO TERRITORIES.—
15 Payments to a State other than the 50
16 States and the District of Columbia.

17 “(ii) MEDICARE COST-SHARING.—
18 Payments attributable to Medicare cost-
19 sharing under section 1905(p).

20 “(iii) PEDIATRIC VACCINES.—Pay-
21 ments attributable to section 1928.

22 “(iv) EMERGENCY SERVICES FOR CER-
23 TAIN INDIVIDUALS.—Payments for treat-
24 ment of emergency medical conditions at-

1 tributable to the application of section
2 1903(v)(2).

3 “(v) INDIAN HEALTH CARE FACILI-
4 TIES.—Payments for medical assistance
5 described in the third sentence of section
6 1905(b).

7 “(vi) EMPLOYER-SPONSORED INSUR-
8 ANCE (ESI).—Payments for medical assist-
9 ance attributable to payments to employers
10 for employer-sponsored health benefits cov-
11 erage.

12 “(vii) OTHER POPULATIONS WITH
13 LIMITED BENEFIT COVERAGE.—Other pay-
14 ments that are determined by the Sec-
15 retary to be related to a specified popu-
16 lation for which the medical assistance
17 under this title is limited and does not in-
18 clude any inpatient, nursing facility, or
19 long-term care services.

20 “(B) CERTAIN EXPENSES.—Paragraph (1)
21 shall not apply, and amounts shall continue to
22 be payable under this title (and not under sub-
23 section (a)), in the case of the following:

24 “(i) ADMINISTRATION OF MEDICARE
25 PRESCRIPTION DRUG BENEFIT.—Expendi-

1 tures described in section 1935(b) (relating
2 to administration of the Medicare prescrip-
3 tion drug benefit).

4 “(ii) PAYMENTS FOR HIT BONUSES.—
5 Payments under section 1903(a)(3)(F) (re-
6 lating to payments to encourage the adop-
7 tion and use of certified EHR technology).

8 “(iii) PAYMENTS FOR DESIGN, DEVEL-
9 OPMENT, AND INSTALLATION OF MMIS AND
10 ELIGIBILITY SYSTEMS.—Payments under
11 subparagraphs (A)(i) and (H)(i) of section
12 1903(a)(3) for expenditures for design, de-
13 velopment, and installation of the Medicaid
14 management information systems and
15 mechanized verification and information
16 retrieval systems (related to eligibility).

17 “(5) PAYMENT OF AMOUNTS.—

18 “(A) IN GENERAL.—Except as the Sec-
19 retary may otherwise provide, amounts shall be
20 payable to a State under subsection (a) in the
21 same manner as amounts are payable under
22 subsection (d) of section 1903 to a State under
23 subsection (a) of such section.

24 “(B) INFORMATION AND FORMS.—

1 “(i) SUBMISSION.—As a condition of
2 receiving payment under subsection (a), a
3 State shall submit such information, in
4 such form, and manner, as the Secretary
5 shall specify, including information nec-
6 essary to make the computations under
7 subsections (c)(2)(C) and (e).

8 “(ii) UNIFORM REPORTING.—The
9 Secretary shall develop such forms as may
10 be needed to ensure a system of uniform
11 reporting of such information across
12 States.

13 “(C) REQUIRED REPORTING OF INFORMA-
14 TION ON MEDICAL LOSS RATIOS FOR MANAGED
15 CARE.—The information required to be reported
16 under subparagraph (B)(i) shall include infor-
17 mation on the medical loss ratio with respect to
18 coverage provided under each Medicaid man-
19 aged care plan with a contract with the State
20 under section 1903(m) or 1932.

21 “(b) AGGREGATE BENEFICIARY-BASED AMOUNT.—

22 “(1) IN GENERAL.—The aggregate beneficiary-
23 based amount specified in this subsection for a State
24 for a quarter is equal to the sum of the products,

1 for each of the categories of Medicaid beneficiaries
2 specified in paragraph (2), of the following:

3 “(A) BENEFICIARY-BASED QUARTERLY
4 AMOUNT.—The beneficiary-based quarterly
5 amount for such category computed under sub-
6 section (c) for such State for such quarter.

7 “(B) NUMBER OF INDIVIDUALS IN CAT-
8 EGORY.—Subject to subsection (d), the average
9 number of Medicaid beneficiaries enrolled in
10 such category in the State in such quarter.

11 “(2) CATEGORIES.—The categories specified in
12 this paragraph are the following:

13 “(A) ELDERLY.—A category of Medicaid
14 beneficiaries who are 65 years of age or older.

15 “(B) BLIND OR DISABLED.—A category of
16 Medicaid beneficiaries not described in subpara-
17 graph (A) who are described in section
18 1937(a)(2)(B)(ii).

19 “(C) CHILDREN.—A category of Medicaid
20 beneficiaries not described in subparagraph (B)
21 who are under 21 years of age.

22 “(D) OTHER ADULTS.—A category of any
23 Medicaid beneficiaries who are not described in
24 a previous subparagraph of this paragraph.

1 “(c) COMPUTATION OF PER BENEFICIARY, PER CAT-
2 EGORY QUARTERLY AMOUNT.—

3 “(1) IN GENERAL.—For a State, for each cat-
4 egory of beneficiary for a quarter—

5 “(A) FIRST REFORM YEAR.—For quarters
6 in the first reform year (as defined in sub-
7 section (k)(2)), the beneficiary-based quarterly
8 amount is equal to $\frac{1}{4}$ of the base average per
9 beneficiary Federal payments for such State for
10 such category determined under paragraph (2),
11 increased by a factor that reflects the sum of
12 the following:

13 “(i) HISTORICAL MEDICAL CARE COM-
14 PONENT OF CPI THROUGH PREVIOUS RE-
15 FORM YEAR.—The percentage increase in
16 the historical medical care component of
17 the Consumer Price Index for all urban
18 consumers (U.S. city average) from the
19 midpoint of the base fiscal year (as defined
20 in paragraph (6)) to the midpoint of the
21 fiscal year preceding the first reform year.

22 “(ii) PROJECTED MEDICAL CARE COM-
23 PONENT OF CPI FOR THE FIRST REFORM
24 YEAR.—The percentage increase in the
25 projected medical care component of the

1 Consumer Price Index for all urban con-
2 sumers (U.S. city average) from the mid-
3 point of the previous fiscal year referred to
4 in clause (i) to the midpoint of the first re-
5 form year.

6 “(B) SECOND AND THIRD REFORM
7 YEARS.—The beneficiary-based quarterly
8 amount for a State for a category for quarters
9 in the second reform year or the third reform
10 year is equal to the beneficiary-based quarterly
11 amount under this paragraph for such State
12 and category for the previous reform year in-
13 creased by the per beneficiary percentage in-
14 crease (as defined in subparagraph (E)) for
15 such category and reform year.

16 “(C) FOURTH THROUGH TENTH REFORM
17 YEARS.—The beneficiary-based quarterly
18 amount for a State for a category for quarters
19 in a reform year beginning with the fourth re-
20 form year and ending with the tenth reform
21 year is—

22 “(i) in the case of a State that is a
23 high per beneficiary State or a low per
24 beneficiary State (as defined in paragraph
25 (4)(B)(iii)) for the category, the amount

1 determined under clause (i) or (ii) of para-
2 graph (4)(B) for such State, category, and
3 reform year; or

4 “(ii) in the case of any other State,
5 the beneficiary-based quarterly amount
6 under this paragraph for such State and
7 category for the previous reform year in-
8 creased by the per beneficiary percentage
9 increase for such category and reform
10 year.

11 “(D) ELEVENTH REFORM YEAR AND SUB-
12 SEQUENT REFORM YEARS.—The beneficiary-
13 based quarterly amount for a State for a cat-
14 egory for quarters in a reform year beginning
15 with the eleventh reform year is equal to the
16 beneficiary-based quarterly amount under this
17 paragraph for such State and category for the
18 previous reform year increased by the per bene-
19 ficiary percentage increase for such category
20 and reform year.

21 “(E) ANNUAL PERCENTAGE INCREASE BE-
22 GINNING WITH SECOND REFORM YEAR.—For
23 purposes of this subsection, the term ‘per bene-
24 ficiary percentage increase’ means, for a reform
25 year, the sum of—

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

7 “(ii) one percentage point.

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

10 “(A) AVERAGE PER CATEGORY.—

11 “(i) IN GENERAL.—The Secretary
12 shall determine, consistent with this para-
13 graph and paragraph (3), a base per bene-
14 ficiary, per category amount for each of
15 the 50 States and the District of Columbia
16 equal to the average amount, per Medicaid
17 beneficiary, of Federal payments under
18 this title, including payments attributable
19 to disproportionate share hospital pay-
20 ments under section 1923, for each of the
21 categories of beneficiaries under subsection
22 (b)(2) for the base fiscal year for each of
23 the 50 States and the District of Colum-
24 bia.

1 “(ii) BEST AVAILABLE DATA.—The
2 determination under clause (i) shall ini-
3 tially be estimated by the Secretary, based
4 upon the best available data at the time
5 the determination is made.

6 “(iii) UPDATES.—The determination
7 under clause (i) shall be updated by the
8 Secretary on an annual basis based upon
9 improved data. The Secretary shall adjust
10 the amounts under subsection (a)(1)(A) to
11 reflect changes in the amounts so deter-
12 mined based on such updates.

13 “(B) EXCLUSION OF PASS-THROUGH PAY-
14 MENTS.—In computing base per beneficiary,
15 per category amounts under subparagraph
16 (A)(i) the Secretary shall exclude payments de-
17 scribed in subsection (a)(4).

18 “(C) STANDARDIZATION.—

19 “(i) IN GENERAL.—In computing each
20 such amount, the Secretary shall stand-
21 ardize the amount in order to remove the
22 variation attributable to the following:

23 “(I) RISK FACTORS.—Such risk
24 factors as age, health and disability
25 status (including high cost medical

1 conditions), gender, institutional sta-
2 tus, and such other factors as the
3 Secretary determines to be appro-
4 priate, so as to ensure actuarial
5 equivalence.

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

8 “(ii) METHOD OF STANDARDIZA-
9 TION.—

10 “(I) CONSULTATION IN DEVEL-
11 OPMENT OF RISK STANDARDIZA-
12 TION.—In developing the methodology
13 for risk standardization for purposes
14 of clause (i)(I), the Secretary shall
15 consult with the Medicaid and CHIP
16 Payment and Access Commission, the
17 Medicare Payment Advisory Commis-
18 sion, and the National Association of
19 Medicaid Directors.

20 “(II) METHOD FOR RISK STAND-
21 ARDIZATION.—In carrying out clause
22 (i)(I), the Secretary may apply the
23 hierarchal condition category method-
24 ology under section 1853(a)(1)(C). If
25 the Secretary uses such methodology,

1 the Secretary shall adjust the applica-
2 tion of such methodology to take into
3 account the differences in services
4 provided under this title compared to
5 title XVIII, such as the coverage of
6 long term care, pregnancy, and pedi-
7 atric services.

8 “(III) METHOD FOR GEOGRAPHIC
9 STANDARDIZATION.—The Secretary
10 shall apply the standardization under
11 clause (i)(II) in a manner similar to
12 that applied under section
13 1853(e)(4)(A)(iii).

14 “(iii) APPLICATION ON A NATIONAL,
15 BUDGET NEUTRAL BASIS.—The standard-
16 ization under clause (i) shall be designed
17 and implemented on a uniform national
18 basis and shall be budget neutral so as to
19 not result in any aggregate change in pay-
20 ments under subsection (a).

21 “(iv) RESPONSE TO NEW RISK.—Sub-
22 ject to clause (iii), the Secretary may ad-
23 just the standardization under clause (i) to
24 respond promptly to new instances of com-

1 municable diseases and other public health
2 hazards.

3 “(v) REFERENCE TO APPLICATION OF
4 RISK ADJUSTMENT.—For rules related to
5 the application of risk adjustment to
6 amounts under subsection (a)(1)(A), see
7 subsection (e).

8 “(D) ADJUSTMENT FOR TEMPORARY FMAP
9 INCREASES.—In computing each base per bene-
10 ficiary, per category amounts under subpara-
11 graph (A)(i) the Secretary shall disregard por-
12 tions of payments that are attributable to a
13 temporary increase in the Federal matching
14 rates, including those attributable to the fol-
15 lowing:

16 “(i) PPACA DISASTER FMAP.—Sec-
17 tion 1905(aa).

18 “(ii) ARRA.—Section 5001 of the
19 American Recovery and Reinvestment Act
20 of 2009 (42 U.S.C. 1396d note).

21 “(iii) EXTRAORDINARY EMPLOYER
22 PENSION CONTRIBUTION.—Section 614 of
23 the Children’s Health Insurance Program
24 Reauthorization Act of 2009 (42 U.S.C.
25 1396d note).

1 “(3) ALLOCATION OF NONMEDICAL ASSISTANCE
2 PAYMENTS.—The Secretary shall establish rules for
3 the allocation of payments under this title (other
4 than those payments described in paragraph (1) or
5 (5) of section 1903(a) and including such payments
6 attributable to section 1923)—

7 “(A) among different categories of bene-
8 ficiaries; and

9 “(B) between payments included under
10 subsection (a)(1) and payments described in
11 subsection (a)(4).

12 “(4) TRANSITION TO A CORRIDOR AROUND THE
13 NATIONAL AVERAGE.—

14 “(A) DETERMINATION OF NATIONAL AVER-
15 AGE BASE PER BENEFICIARY, PER CATEGORY
16 AMOUNT.—Subject to subparagraph (C), the
17 Secretary shall determine a national average
18 base per beneficiary, per category amount equal
19 to the average of the base per beneficiary, per
20 category amounts for each of the 50 States and
21 the District of Columbia determined under
22 paragraph (2), weighted by the average number
23 of beneficiaries in each such category and State
24 as determined by the Secretary consistent with
25 subsection (d) for the base fiscal year.

1 “(B) TRANSITION ADJUSTMENT.—

2 “(i) HIGH PER BENEFICIARY
3 STATES.—In the case of a high per bene-
4 ficiary State (as defined in clause (iii)(I))
5 for a category, the beneficiary-based quar-
6 terly amount for such State and category
7 for a quarter in a reform year (beginning
8 with the fourth reform year and ending
9 with the tenth reform year) is equal to the
10 sum of—

11 “(I) the product of the State-spe-
12 cific factor for such reform year (as
13 defined in clause (iv)) and the bene-
14 ficiary-based quarterly amount that
15 would otherwise be determined under
16 paragraph (1) for such State and cat-
17 egory if the State were a State de-
18 scribed in clause (ii) of paragraph
19 (1)(C), instead of a State described in
20 clause (i) of such paragraph; and

21 “(II) the product of 1 minus the
22 State-specific factor for such reform
23 year and the beneficiary-based quar-
24 terly amount that would otherwise be
25 determined under paragraph (1) for a

1 State and category if the base per
2 beneficiary, per category amount de-
3 termined under paragraph (2) for the
4 State and category were equal to 110
5 percent of the national average base
6 per beneficiary, per category amount
7 determined under subparagraph (A)
8 for such category.

9 “(ii) LOW PER BENEFICIARY
10 STATES.—In the case of a low per bene-
11 ficiary State (as defined in clause (iii)(II))
12 for a category, the beneficiary-based quar-
13 terly amount for such State and category
14 for a quarter in a reform year (beginning
15 with the fourth reform year and ending
16 with the tenth reform year) is equal to the
17 sum of—

18 “(I) the product of the State-spe-
19 cific factor for such reform year and
20 the beneficiary-based quarterly
21 amount that would otherwise be deter-
22 mined under paragraph (1) for such
23 State and category if the State were
24 a State described in clause (ii) of
25 paragraph (1)(C), instead of a State

1 described in clause (i) of such para-
2 graph; and

3 “(II) the product of 1 minus the
4 State-specific factor for such reform
5 year and the beneficiary-based quar-
6 terly amount that would otherwise be
7 determined under paragraph (1) for a
8 State and category if the base per
9 beneficiary, per category amount de-
10 termined under paragraph (2) for the
11 State and category were equal to 90
12 percent of the national average base
13 per beneficiary, per category amount
14 determined under subparagraph (A)
15 for such category.

16 “(iii) HIGH AND LOW PER BENE-
17 FICIARY STATES DEFINED.—In this sub-
18 paragraph:

19 “(I) HIGH PER BENEFICIARY
20 STATE.—The term ‘high per bene-
21 ficiary State’ means, with respect to a
22 category, a State for which the base
23 per beneficiary, per category amount
24 determined under paragraph (2) for
25 such category is greater than 110 per-

1 cent of the national average base per
2 beneficiary, per category amount de-
3 termined under subparagraph (A) for
4 such category.

5 “(II) LOW PER BENEFICIARY
6 STATE.—The term ‘low per bene-
7 ficiary State’ means, with respect to a
8 category, a State for which the base
9 per beneficiary, per category amount
10 determined under paragraph (2) for
11 such category is less than 90 percent
12 of the national average base per bene-
13 ficiary, per category amount deter-
14 mined under subparagraph (A) for
15 such category.

16 “(iv) STATE-SPECIFIC FACTOR.—In
17 this subparagraph, the term ‘State-specific
18 factor’ means—

19 “(I) for the fourth reform year,
20 $\frac{7}{8}$; and

21 “(II) for a subsequent reform
22 year, the State-specific factor under
23 this clause for the previous reform
24 year minus $\frac{1}{8}$.

25 “(C) NO ADDITIONAL EXPENDITURES.—

1 “(i) DETERMINATION OF INCREASE IN
2 FEDERAL EXPENDITURES.—For each cat-
3 egory for each reform year (beginning with
4 the fourth reform year and ending with the
5 tenth reform year), the Secretary shall de-
6 termine whether the application of this
7 paragraph—

8 “(I) to the category for the re-
9 form year will result in an aggregate
10 increase in the aggregate Federal ex-
11 penditures under subsection (a); and

12 “(II) to all the categories for the
13 reform year will result in a net aggre-
14 gate increase in the aggregate Federal
15 expenditures under subsection (a).

16 “(ii) ADJUSTMENT.—If the Secretary
17 determines under clause (i)(II) that the
18 application of this paragraph to all the cat-
19 egories for a reform year will result in a
20 net aggregate increase in the aggregate
21 Federal expenditures under subsection (a),
22 the Secretary shall reduce the national av-
23 erage base per beneficiary, per category
24 amount computed under subparagraph (A)
25 for each of the categories determined

1 under clause (i)(I) for which there will be
2 an aggregate increase in the aggregate
3 Federal expenditures under subsection (a)
4 by such uniform percentage as will ensure
5 that there is no net aggregate Federal ex-
6 penditure increase described in clause
7 (i)(II) for the reform year.

8 “(5) REPORTS ON PER BENEFICIARY RATES;
9 APPEALS.—

10 “(A) REPORT TO STATES.—Not later than
11 8 months after the date of the enactment of
12 this section, the Secretary shall submit to each
13 State the Secretary’s initial determination of—

14 “(i) the base per beneficiary, per cat-
15 egory amounts under paragraph (2) for
16 such State; and

17 “(ii) the national average base per
18 beneficiary, per category amounts under
19 paragraph (4)(A).

20 “(B) OPPORTUNITY TO APPEAL.—Not
21 later than 3 months after the date a State re-
22 ceives notice of the Secretary’s initial deter-
23 mination of such base per beneficiary, per cat-
24 egory amounts for such State under subpara-
25 graph (A)(i), the State may file with the Sec-

1 retary, in a form and manner specified by the
2 Secretary, an appeal of such determination.

3 “(C) DETERMINATION ON APPEAL.—Not
4 later than 3 months after receiving such an ap-
5 peal, the Secretary shall make a final deter-
6 mination on such amounts for such State. If no
7 such appeal is received for a State, the Sec-
8 retary’s initial determination under subpara-
9 graph (A)(i) shall become final.

10 “(6) BASE FISCAL YEAR DEFINED.—In this
11 section, the term ‘base fiscal year’ means the latest
12 fiscal year, ending before the date of the enactment
13 of this section, for which the Secretary determines
14 that adequate data are available to make the com-
15 putations required under this subsection.

16 “(d) NOT COUNTING INDIVIDUALS TO ACCOUNT FOR
17 EXCLUDED PAYMENTS.—Under rules specified by the
18 Secretary, individuals shall not be counted as Medicaid
19 beneficiaries for purposes of subsection (b)(1)(B) and sub-
20 section (c)(2)(A) to the extent that such individuals—

21 “(1) are receiving medical assistance for which
22 payments described under subsection (a)(4)(A) are
23 made; or

24 “(2) would not have been eligible to enroll
25 under the State plan (or waiver of such plan) in the

1 State in which such individual is so enrolled if the
2 rules for eligibility for enrollment under such plan
3 (or waiver) were the same as such rules for eligi-
4 bility in effect as of January 1, 2009.

5 “(e) RISK ADJUSTMENT.—

6 “(1) IN GENERAL.—The amount under sub-
7 section (a)(1)(A) shall be adjusted under this sub-
8 section in an appropriate manner, specified by the
9 Secretary and consistent with paragraph (2), to take
10 into account—

11 “(A) the factors described in subsection
12 (c)(2)(C)(i)(I) within a category of bene-
13 ficiaries; and

14 “(B) variations in costs on a county-by-
15 county basis for medical assistance and admin-
16 istrative expenses.

17 “(2) METHOD OF ADJUSTMENT.—

18 “(A) IN GENERAL.—The adjustments
19 under paragraph (1) shall be made in a manner
20 similar to the manner in which similar adjust-
21 ments are made under subsection (c)(2)(C) and
22 consistent with the requirements of clause (iii)
23 of such subsection and subparagraph (B).

24 “(B) BIENNIAL UPDATE OF RISK ADJUST-
25 MENT METHODOLOGY.—In applying clause

1 (i)(I) of subsection (c)(2)(C) for purposes of
2 subparagraph (A), the Secretary shall, in con-
3 sultation with the entities described in clause
4 (ii)(I) of such subsection, update the risk ad-
5 justment methodology applied as appropriate
6 not less often than every 2 years.

7 “(f) CHRONIC CARE QUALITY BONUS PAYMENTS.—

8 “(1) DETERMINATION OF BONUS PAYMENTS.—
9 If the Secretary determines that, based on the re-
10 ports under paragraph (5), with respect to cat-
11 egories of chronic disease for which chronic care per-
12 formance targets had been established under para-
13 graph (3) for each category of Medicaid beneficiaries
14 specified under subsection (b)(2) such targets have
15 been met by a State for a reform year, the Secretary
16 shall make an additional payment to such State in
17 the amount specified in paragraph (6) for each quar-
18 ter in the succeeding reform year. Such payments
19 shall be made in a manner specified by the Secretary
20 and may only be used consistent with subsection
21 (a)(3).

22 “(2) IDENTIFICATION OF CATEGORIES OF
23 CHRONIC DISEASE.—The Secretary shall determine
24 the categories of chronic disease for which bonus

1 payments may be available under this subsection for
2 each category of Medicaid beneficiaries.

3 “(3) ADOPTION OF QUALITY MEASUREMENT
4 SYSTEM AND IDENTIFICATION OF PERFORMANCE
5 TARGETS.—

6 “(A) SYSTEM AND DATA.—With respect to
7 the categories of chronic disease under para-
8 graph (2), the Secretary shall adopt a quality
9 measurement system that uses data described
10 in paragraph (4) and is similar to the Five-Star
11 Quality Rating System used to indicate the per-
12 formance of Medicare Advantage plans under
13 part C of title XVIII.

14 “(B) TARGETS.—Using such system and
15 data, the Secretary shall establish for each re-
16 form year the chronic care performance targets
17 for purposes of the payments under paragraph
18 (1). Such performance targets shall be estab-
19 lished in consultation with States, associations
20 representing individuals with chronic illnesses,
21 entities providing treatment to such individuals
22 for such chronic illnesses, and other stake-
23 holders, including the National Association of
24 Medicaid Directors and the National Governors
25 Association.

1 “(4) DATA TO BE USED.—The data to be used
2 under paragraph (3) shall include—

3 “(A) data collected through methods such
4 as—

5 “(i) the ‘Healthcare Effectiveness
6 Data and Information Set’ (also known as
7 ‘HEDIS’) (or an appropriate successor
8 performance measurement tool);

9 “(ii) the ‘Consumer Assessment of
10 Healthcare Providers and Systems’ (also
11 known as ‘CAHPS’) (or an appropriate
12 successor performance measurement tool);
13 and

14 “(iii) the ‘Health Outcomes Survey’
15 (also known as ‘HOS’) (or an appropriate
16 successor performance measurement tool);
17 and

18 “(B) other data collected by the State.

19 “(5) REPORTS.—

20 “(A) IN GENERAL.—Each State shall col-
21 lect, analyze, and report to the Secretary, at a
22 frequency and in a manner to be established by
23 the Secretary, data described in paragraph (4)
24 that permit the Secretary to monitor the State’s
25 performance relative to the chronic care per-

1 performance targets established under paragraph
2 (3).

3 “(B) REVIEW AND VERIFICATION.—The
4 Secretary may review the data collected by the
5 State under subparagraph (A) to verify the
6 State’s analysis of such data with respect to the
7 performance targets under paragraph (3).

8 “(6) AMOUNT OF BONUS PAYMENTS.—

9 “(A) IN GENERAL.—Subject to subpara-
10 graphs (B) and (C), with respect to each cat-
11 egory of Medicaid beneficiaries, in the case of
12 a State that the Secretary determines, based on
13 the chronic care performance targets set under
14 paragraph (3) for a reform year for such cat-
15 egory, performs—

16 “(i) in the top five States in such cat-
17 egory, subject to subparagraph (C)(ii), the
18 amount of the bonus for each quarter in
19 the succeeding reform year shall be 10 per-
20 cent of the payment amount otherwise paid
21 to the State under subsection (a) for indi-
22 viduals enrolled under the plan within such
23 category;

24 “(ii) in the next five States in such
25 category, subject to subparagraph (C)(ii),

1 the amount of the bonus for each such
2 quarter shall be 5 percent of the payment
3 amount otherwise paid to the State under
4 subsection (a) for individuals enrolled
5 under the plan within such category;

6 “(iii) in the next five States in such
7 category, subject to clauses (i) and (iii) of
8 subparagraph (C), the amount of the
9 bonus for each such quarter shall be 3 per-
10 cent of the payment amount otherwise paid
11 to the State under subsection (a) for indi-
12 viduals enrolled under the plan within such
13 category;

14 “(iv) in the next five States in such
15 category, subject to clauses (i) and (iii) of
16 subparagraph (C), the amount of the
17 bonus for each such quarter shall be 2 per-
18 cent of the payment amount otherwise paid
19 to the State under subsection (a) for indi-
20 viduals enrolled under the plan within such
21 category; and

22 “(v) in the next five States in such
23 category, subject to clauses (i) and (iii) of
24 subparagraph (C), the amount of the
25 bonus for each such quarter shall be 1 per-

1 cent of the payment amount otherwise paid
2 to the State under subsection (a) for indi-
3 viduals enrolled under the plan within such
4 category.

5 “(B) AGGREGATE ANNUAL LIMIT FOR
6 EACH CATEGORY OF MEDICAID BENE-
7 FICIARIES.—

8 “(i) IN GENERAL.—In no case may
9 the aggregate amount of bonuses under
10 this subsection for quarters in a reform
11 year for a category of Medicaid bene-
12 ficiaries exceed the limit specified in clause
13 (ii) for the reform year.

14 “(ii) LIMIT.—The limit specified in
15 this clause—

16 “(I) for the second reform year is
17 equal to \$250,000,000; or

18 “(II) for a subsequent reform
19 year is equal to the limit specified in
20 this clause for the previous reform
21 year increased by the per beneficiary
22 percentage increase determined under
23 paragraph (1)(E) of subsection (c).

1 “(C) LIMITATION AND PRORATION OF BO-
2 NUSES BASED ON APPLICATION OF AGGREGATE
3 LIMIT.—

4 “(i) NO BONUS FOR THIRD OR SUBSE-
5 QUENT TIERS UNLESS AGGREGATE LIMIT
6 NOT REACHED ON FIRST TWO TIERS.—No
7 bonus shall be payable under clause (iii),
8 (iv), or (v) of subparagraph (A) for a cat-
9 egory of Medicaid beneficiaries for a quar-
10 ter in a reform year unless the aggregate
11 amount of bonuses under clauses (i) and
12 (ii) of such subparagraph for such category
13 and reform year is less than the limit spec-
14 ified in subparagraph (B)(ii) for the re-
15 form year.

16 “(ii) PRORATION FOR FIRST TWO
17 TIERS.—If the aggregate amount of bo-
18 nuses under clauses (i) and (ii) of subpara-
19 graph (A) for a category of Medicaid bene-
20 ficiaries for quarters in a reform year ex-
21 ceeds the limit specified in subparagraph
22 (B)(ii) for the reform year, the amount of
23 each such bonus shall be prorated in a
24 manner so the aggregate amount of such
25 bonuses is equal to such limit.

1 “(iii) PRORATION FOR NEXT THREE
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 is
6 less than the limit specified in subpara-
7 graph (B)(ii) for the reform year, but the
8 aggregate amount of bonuses under clauses
9 (i) through (v) of subparagraph (A) for the
10 category and such quarters in the reform
11 year exceeds the limit specified in subpara-
12 graph (B)(ii) for the reform year, the
13 amount of each bonus in clauses (iii), (iv),
14 and (v) of subparagraph (A) shall be pro-
15 rated in a manner so the aggregate
16 amount of all the bonuses under subpara-
17 graph (A) is equal to such limit.

18 “(g) STATE OPTION FOR RECEIVING MEDICARE PAY-
19 MENTS FOR FULL-BENEFIT DUAL ELIGIBLE INDIVID-
20 UALS.—

21 “(1) IN GENERAL.—Under this subsection a
22 State may elect for quarters beginning on or after
23 the implementation date in a reform year to receive
24 payment from the Secretary under paragraph (3).
25 As a condition of receiving such payment, the State

1 shall agree to provide to full-benefit dual eligible in-
2 dividuals eligible for medical assistance under the
3 State plan—

4 “(A) the medical assistance to which such
5 eligible individuals would otherwise be entitled
6 under this title; and

7 “(B) any items and services which such eli-
8 gible individuals would otherwise receive under
9 title XVIII.

10 “(2) PROVIDER PAYMENT REQUIREMENT.—

11 “(A) IN GENERAL.—A State electing the
12 option under this subsection shall provide pay-
13 ment to health care providers for the items and
14 services described under paragraph (1)(B) at a
15 rate that is not less than the rate at which pay-
16 ments would be made to such providers for such
17 items and services under title XVIII.

18 “(B) FLEXIBILITY IN PAYMENT METH-
19 ODS.—Nothing in subparagraph (A) shall be
20 construed as preventing a State from using al-
21 ternative payment methodologies (such as bun-
22 dled payments or the use of accountable care
23 organizations (as such term is used in section
24 1899)) for purposes of making payments to
25 health care providers for items and services pro-

1 vided to dual eligible individuals in the State
2 under the option under this subsection.

3 “(3) PAYMENTS TO STATES IN LIEU OF MEDI-
4 CARE PAYMENTS.—With respect to a full-benefit
5 dual eligible individual, in the case of a State that
6 elects the option under paragraph (1) for quarters in
7 a reform year—

8 “(A) the Secretary shall not make any pay-
9 ment under title XVIII for items and services
10 furnished to such individual for such quarters;
11 and

12 “(B) the Secretary shall pay to the State,
13 in addition to the amounts paid to such State
14 under subsection (a), the amount that the Sec-
15 retary would, but for this subsection, otherwise
16 pay under title XVIII for items and services
17 furnished to such an individual in such State
18 for such quarters.

19 “(4) FULL-BENEFIT DUAL ELIGIBLE INDI-
20 VIDUAL DEFINED.—In this subsection, the term
21 ‘full-benefit dual eligible individual’ means an indi-
22 vidual who meets the requirements of section
23 1935(e)(6)(A)(ii).

24 “(h) AUDITS.—The Secretary shall conduct such au-
25 dits on the number and classification of Medicaid bene-

1 ficiaries under such subsections and expenditures under
2 this section as may be necessary to ensure appropriate
3 payments under this section.

4 “(i) TREATMENT OF WAIVERS.—

5 “(1) NO IMPACT ON CURRENT WAIVERS.—In
6 the case of a waiver of requirements of this title pur-
7 suant to section 1115 or other law that is in effect
8 as of the date of the enactment of this section, noth-
9 ing in this section shall be construed to affect such
10 waiver for the period of the waiver as approved as
11 of such date.

12 “(2) APPLICATION OF BUDGET NEUTRALITY TO
13 SUBSEQUENT WAIVERS AND RENEWALS TAKING SEC-
14 TION INTO ACCOUNT.—In the case of a waiver of re-
15 quirements of this title pursuant to section 1115 or
16 other law that is approved or renewed after the date
17 of the enactment of this section, to the extent that
18 such approval or renewal is conditioned upon a dem-
19 onstration of budget neutrality, budget neutrality
20 shall be determined taking into account the applica-
21 tion of this section.

22 “(j) REPORT TO CONGRESS.—Not later than Janu-
23 ary 1 of the second reform year, the Secretary shall submit
24 to Congress a report on the implementation of this section.

25 “(k) DEFINITIONS.—In this section:

1 “(1) IMPLEMENTATION DATE.—The term ‘im-
2 plementation date’ means—

3 “(A) July 1, 2027, if this section is en-
4 acted on or before July 1, 2026; or

5 “(B) July 1, 2028, if this section is en-
6 acted after July 1, 2026.

7 “(2) REFORM YEARS.—

8 “(A) The term ‘reform year’ means a fiscal
9 year beginning with the first reform year.

10 “(B) The term ‘first reform year’ means
11 the fiscal year in which the implementation date
12 occurs.

13 “(C) The terms ‘second’, ‘third’, and suc-
14 cessive similar terms mean, with respect to a
15 reform year, the second, third, or successive re-
16 form year, respectively, succeeding the first re-
17 form year.”.

18 (b) CONFORMING AMENDMENTS.—

19 (1) CONTINUED APPLICATION OF CLAWBACK
20 PROVISIONS.—

21 (A) CONTINUED APPLICATION.—Sub-
22 sections (a) and (c)(1)(C) of section 1935 of
23 such Act (42 U.S.C. 1396u–5) are each amend-
24 ed by inserting “or 1903A(a)” after “1903(a)”.

1 (B) TECHNICAL AMENDMENT.—Section
2 1935(d)(1) of the Social Security Act (42
3 U.S.C. 1396u–5(d)(1)) is amended by inserting
4 “except as provided in section 1903A(g)” after
5 “any other provision of this title”.

6 (2) PAYMENT RULES UNDER SECTION 1903.—

7 (A) Section 1903(a) of the Social Security
8 Act (42 U.S.C. 1396b(a)) is amended, in the
9 matter before paragraph (1), by inserting “and
10 section 1903A” after “except as otherwise pro-
11 vided in this section”.

12 (B) Section 1903(d) of such Act (42
13 U.S.C. 1396b(d)) is amended—

14 (i) in paragraph (1), by inserting
15 “and under section 1903A” after “sub-
16 sections (a) and (b)”;

17 (ii) in paragraph (2)—

18 (I) in subparagraph (A), by in-
19 serting “or section 1903A” after “was
20 made under this section”; and

21 (II) in subparagraph (B), by in-
22 serting “or section 1903A” after
23 “under subsection (a)”;

24 (iii) in paragraph (4)—

1 (I) by striking “under this sub-
2 section” and inserting “, with respect
3 to this section or section 1903A,
4 under this subsection”; and

5 (II) by striking “under this sec-
6 tion” and inserting “under the respec-
7 tive section”; and

8 (iv) in paragraph (5), by inserting “or
9 section 1903A” after “overpayment under
10 this section”.

11 (3) CONFORMING WAIVER AUTHORITY.—Section
12 1115(a)(2)(A) of the Social Security Act (42 U.S.C.
13 1315(a)(2)(A)) is amended by striking “or 1903”
14 and inserting “1903, or 1903A”.

15 (4) REPORT ON ADDITIONAL CONFORMING
16 AMENDMENTS NEEDED.—Not later than 6 months
17 after the date of the enactment of this Act, the Sec-
18 retary of Health and Human Services shall submit
19 to Congress a report that includes a description of
20 any additional technical and conforming amend-
21 ments to law that are required to properly carry out
22 this Act.

1 **SEC. 402. INCOME LIMITATIONS FOR REFUNDABLE CRED-**
2 **ITS FOR COVERAGE UNDER A QUALIFIED**
3 **HEALTH PLAN.**

4 (a) IN GENERAL.—Subparagraphs (A) and (B) of
5 section 36B(c)(1) of the Internal Revenue Code of 1986
6 are amended by inserting after “100 percent” each place
7 such term appears the following: “(or, in the case of a
8 taxpayer enrolled through an Exchange utilized by such
9 State that makes the election described in section 1903A
10 of the Social Security Act, the percentage established by
11 such State under part A of title IV of such Act for pur-
12 poses of eligibility under title XIX of such Act as of Janu-
13 ary 1, 2009)”.

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

17 **SEC. 403. MEDICAID ELIGIBILITY DETERMINATIONS.**

18 (a) STATE FLEXIBILITY TO USE CONTRACTORS TO
19 MAKE ELIGIBILITY DETERMINATIONS ON BEHALF OF
20 STATE.—Section 1902(a)(5) of the Social Security Act
21 (42 U.S.C. 1396a(a)(5)) is amended by inserting before
22 the semicolon at the end the following: “, but such deter-
23 minations of eligibility may be made, at the option of a
24 State, under a contract with another State or local agency
25 or a contractor so long as the contract does not provide
26 incentives for the agency or contractor to delay eligibility

1 determinations or to deny eligibility for individuals other-
2 wise eligible for medical assistance”.

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

7 “(L) FREQUENCY OF ELIGIBILITY REDE-
8 TERMINATIONS.—Beginning on October 1,
9 2026, and notwithstanding subparagraph (H),
10 in the case of an individual whose eligibility for
11 medical assistance under the State plan under
12 this title (or a waiver of such plan) is deter-
13 mined based on the application of modified ad-
14 justed gross income under subparagraph (A)
15 and who is so eligible on the basis of clause
16 (i)(VIII), (ii)(XX), or (ii)(XXIII) of subsection
17 (a)(10)(A), at the option of the State, the State
18 plan may provide that the individual’s eligibility
19 shall be redetermined every 6 months (or such
20 shorter number of months as the State may
21 elect).”.

1 **SEC. 404. LOWERING SAFE HARBOR THRESHOLD WITH RE-**
2 **SPECT TO STATE TAXES ON HEALTH CARE**
3 **PROVIDERS.**

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

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

8 “(I) beginning”; and

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

11 “(II) beginning on or after January 1,
12 2027, and before January 1, 2036, ‘4 percent’
13 shall be substituted for ‘6 percent’ each place it
14 appears;

15 “(III) beginning on or after January 1,
16 2036, and before January 1, 2041, ‘3 percent’
17 shall be substituted for ‘6 percent’ each place it
18 appears;

19 “(IV) beginning on or after January 1,
20 2041, and before January 1, 2046, ‘2 percent’
21 shall be substituted for ‘6 percent’ each place it
22 appears;

23 “(V) beginning on or after January 1,
24 2046, and before January 1, 2051, ‘1 percent’
25 shall be substituted for ‘6 percent’ each place it
26 appears; and

1 “(VI) beginning on or after January 1,
2 2051, ‘0 percent’ shall be substituted for ‘6 per-
3 cent’ each place it appears.”.

4 **SEC. 405. PROVIDING FOR STATE APPROVAL AND IMPLE-**
5 **MENTATION OF SPECIFIED WAIVERS UNDER**
6 **THE MEDICAID PROGRAM.**

7 Section 1115 of the Social Security Act (42 U.S.C.
8 1315) is amended—

9 (1) in subsection (d)—

10 (A) in paragraph (1), by striking “An ap-
11 plication” and inserting “Subject to paragraph
12 (4), an application”; and

13 (B) by adding at the end the following new
14 paragraph:

15 “(4)(A) An experimental, pilot, or demonstra-
16 tion project undertaken under subsection (a) may be
17 approved or renewed by a State if such project is de-
18 scribed in subparagraph (B).

19 “(B) An experimental, pilot, or demonstration
20 project is described in this subparagraph if such
21 project provides for a waiver of requirements with
22 respect to a State plan (or a waiver of such plan)
23 under title XIX such that—

1 “(i) individuals enrolled under such plan
2 (or such waiver) may elect to participate in
3 such project with respect to a year; and

4 “(ii) such individuals who elect to so par-
5 ticipate are furnished with primary care serv-
6 ices (as described in section 223(c)(1)(D)(ii)(I)
7 of the Internal Revenue Code of 1986) through
8 a direct primary care service arrangement (as
9 defined in such section).

10 “(C) For purposes of a State’s approval or re-
11 newal of an experimental, pilot, or demonstration
12 project under subparagraph (A), each reference to
13 ‘the Secretary’ in subsection (a) shall be deemed to
14 be a reference to ‘the State.’”; and

15 (2) in subsection (e), by inserting “(other than
16 such a project that is described in paragraph
17 (4)(B))” before the period at the end.

18 **SEC. 406. DEDUCTION FOR QUALIFIED CHARITY CARE.**

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

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

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

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

3 “(A) the fee (as published on a publicly
4 available website of such physician) for physi-
5 cians’ services that are qualified charity care
6 furnished by such taxpayer during such year,
7 and

8 “(B) for each visit by a patient to such
9 physician during which qualified charity care is
10 furnished, half of so much of the lowest sub-
11 scription fee of such physician that is attrib-
12 utable to a month, and

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

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

17 “(1) UNREIMBURSED MEDICARE-BASED
18 VALUE.—The term ‘unreimbursed Medicare-based
19 value’ means, with respect to physicians’ services,
20 the amount payable for such services under the phy-
21 sician fee schedule established under section 1848 of
22 the Social Security Act.

23 “(2) QUALIFIED CHARITY CARE.—The term
24 ‘qualified charity care’ means physicians’ services
25 that are furnished—

1 “(A) without expectation of reimburse-
2 ment, and

3 “(B) to an individual enrolled—

4 “(i) under a State plan under title
5 XIX of the Social Security Act (or a waiv-
6 er of such plan), or

7 “(ii) under a State child health plan
8 under title XXI of the Social Security Act
9 (or a waiver of such plan).

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

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

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

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

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

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

“Sec. 199B. Qualified charity care.”.

5 **Subtitle B—Medicare Reforms**

6 **SEC. 411. OFF-CAMPUS PROVIDER-BASED DEPARTMENT** 7 **MEDICARE SITE NEUTRAL PAYMENT.**

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

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

13 “(1) IN GENERAL.—With respect to items and
 14 services furnished in an off-campus provider-based
 15 department, payment under this section for such
 16 items and services shall be the amount determined
 17 under the fee schedule under section 1848 for such
 18 items and services furnished if furnished in a physi-
 19 cian office setting.

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

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall apply with respect to items and serv-
3 ices furnished on or after January 1, 2026.

4 **SEC. 412. ELIMINATING FEHBP ELIGIBILITY FOR ANNU-**
5 **ITANTS.**

6 Section 8905(b) of title 5, United States Code, is
7 amended—

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

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

22 **SEC. 413. ELIMINATION OF MEDICARE ELIGIBILITY FOR**
23 **CERTAIN INDIVIDUALS.**

24 (a) ENROLLMENT PROHIBITION.—

1 (1) PART B.—Section 1836 of the Social Secu-
2 rity Act (42 U.S.C. 1395o) is amended by striking
3 the period at the end and inserting “, except that an
4 individual who attains age 65 on or after January
5 1, 2032, and is an individual who, upon attaining
6 such age, has earned \$10,000,000 or more in life-
7 time wages, shall not be eligible to so enroll.”.

8 (2) PART D.—Section 1860D–1(a)(3)(A) of
9 such Act (42 U.S.C. 1395w–101(a)(3)(A)) is amend-
10 ed by striking the period at the end and inserting
11 “, excluding an individual who, upon attaining age
12 65, has earned \$10,000,000 or more in lifetime
13 wages.”.

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

17 “(aa) ADDITIONAL LIMITATION ON NEWLY ELIGI-
18 BLE BENEFICIARIES.—

19 “(1) IN GENERAL.—Notwithstanding any other
20 provision of this section, on or after January 1,
21 2032, a medicare supplemental policy may not be
22 sold or issued to a targeted newly eligible Medicare
23 beneficiary.

24 “(2) TARGETED NEWLY ELIGIBLE MEDICARE
25 BENEFICIARY.—For purposes of this subsection, the

1 term ‘targeted newly eligible Medicare beneficiary’
2 means an individual who, upon attaining the age of
3 65, has earned \$10,000,000 or more in lifetime
4 wages.”.

5 **SEC. 414. MEDICARE PART D TAX DEDUCTION.**

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

12 (b) EFFECTIVE DATE.—The amendment made by
13 this section shall apply to taxable years beginning after
14 December 31, 2026.

15 **SEC. 415. REPEAL OF NET INVESTMENT INCOME TAX.**

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

18 (b) EFFECTIVE DATE.—The amendment made by
19 this section shall apply to taxable years beginning after
20 December 31, 2026.

21 **SEC. 416. MEDICARE COVERAGE OF BAD DEBT.**

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

24 (1) in subparagraph (T)—

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

3 (B) in clause (v)—

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

6 (ii) by striking “or a subsequent fiscal
7 year” and inserting “through 2026”; and

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

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

12 “(vi) for cost reporting periods beginning dur-
13 ing fiscal year 2027 or a subsequent fiscal year, by
14 the percent applicable for cost reporting periods be-
15 ginning during the previous fiscal year, increased
16 (through fiscal year 2029) by 10 percentage
17 points.”;

18 (2) in subparagraph (V)—

19 (A) in clause (i)—

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

22 (ii) in subclause (IV)—

23 (I) by striking “during fiscal
24 year” and inserting “during fiscal
25 years 2017 through 2026”; and

1 (II) by striking the period at the
2 end and inserting “; and”; and

3 (iii) by adding at the end the fol-
4 lowing new subclause:

5 “(V) for cost reporting periods beginning
6 during fiscal year 2027 or a subsequent fiscal
7 year, the percent applicable for cost reporting
8 periods beginning during the previous fiscal
9 year, increased (through fiscal year 2029) by
10 10 percentage points.”; and

11 (B) in clause (ii)—

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

14 (ii) in subclause (IV)—

15 (I) by striking “a subsequent fis-
16 cal year” and inserting “fiscal years
17 2015 through 2026”;

18 (II) by striking the period at the
19 end and inserting “; and”; and

20 (III) by adding at the end the
21 following new subclause:

22 “(V) for cost reporting periods beginning
23 during fiscal year 2027 or a subsequent fiscal
24 year, shall be reduced by the percent applicable
25 for cost reporting periods beginning during the

1 previous fiscal year, increased (through fiscal
2 year 2029) by 10 percentage points.”; and

3 (3) in subparagraph (W)(i)—

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

6 (B) in subclause (III)—

7 (i) by striking “during a subsequent
8 fiscal year” and inserting “during fiscal
9 years 2015 through 2026”; and

10 (ii) by striking the period at the end
11 and inserting “; and”; and

12 (C) by adding at the end the following new
13 subclause:

14 “(IV) for cost reporting periods beginning dur-
15 ing fiscal year 2027 or a subsequent fiscal year, by
16 the percent applicable for cost reporting periods be-
17 ginning during the previous fiscal year, increased
18 (through fiscal year 2029) by 10 percentage
19 points.”.

20 **Subtitle C—Medicare Choice and** 21 **Competition**

22 **SEC. 421. COMPETITIVE BIDDING AND PREMIUMS UNDER** 23 **UNIFIED MEDICARE.**

24 (a) IN GENERAL.—Part E of title XVIII of the Social
25 Security Act, as added by section 101 and amended by

1 section 103, is further amended by adding at the end the
2 following:

3 **“Subpart 3—Competitive Bidding and Premiums**

4 **“SEC. 1860E-31. APPLICATION OF COMPETITIVE BIDDING IN**
5 **ENROLLMENT.**

6 “(a) IN GENERAL.—Notwithstanding any other pro-
7 vision of this title, the Secretary shall, beginning with plan
8 year 2026, establish a method whereby individuals enroll-
9 ing under this title so enroll through an online process
10 designed to highlight enrollment options for such individ-
11 uals and allow such individuals to compare costs of enroll-
12 ment in such options.

13 “(b) ENROLLMENT OPTIONS.—For purposes of sub-
14 section (a), the Secretary shall make the following options
15 available to individuals for enrollment under this title:

16 “(1) Traditional fee-for-service coverage.

17 “(2) Provider-led risk-bearing plans (also
18 known as ACOs).

19 “(3) Medicare Advantage plans.

20 “(c) MEDICARE ADVANTAGE PLAN ACTUARIAL
21 VALUE REQUIREMENT.—Each Medicare Advantage plan
22 offered through the process described in subsection (a)
23 shall have an actuarial value equal to traditional fee-for-
24 service coverage under parts A and B.

1 “(d) MA DIRECT DEPOSIT OF CERTAIN REBATES.—
2 In the case of an Medicare Advantage plan with a bid for
3 a year that involves a premium differential between such
4 bid and the benchmark for such year and plan, such plan
5 shall provide for a direct deposit of such differential if the
6 applicable enrollee in such plan does not elect any supple-
7 mental coverage under such plan.

8 “(e) ENROLLMENT IN PRESCRIPTION DRUG COV-
9 ERAGE.—As part of the method described in subsection
10 (a), the Secretary shall establish a process to allow an in-
11 dividual to enroll in prescription drug coverage. In the
12 case of an individual who enrolls in a Medicare Advantage
13 plan, such coverage shall be provided under such plan. In
14 a case of an individual who enrolls in an ACO, such cov-
15 erage shall be provided under such network. In the case
16 of an individual who enrolls under traditional fee-for-serv-
17 ice coverage, such drug coverage shall be provided through
18 a prescription drug plan.

19 “(f) SUPPLEMENTAL BENEFITS.—

20 “(1) MA PLANS.—An MA plan is allowed to
21 offer two different packages of supplemental benefits
22 (these packages are available only to individuals who
23 select such plans).

1 “(2) ACOs.—ACOs may limit supplemental op-
2 tions for their enrollees to Medigap plans with con-
3 tractual ties.

4 “(3) FEE-FOR-SERVICE.—Fee-for-service indi-
5 viduals may select supplemental coverage from
6 Medigap policies.

7 **“SEC. 1860E-32. COMPETITION.**

8 “(a) BID AREAS.—Market areas used for bid submis-
9 sions for Medicare Advantage plans, ACOs, and for cal-
10 culation per person fee-for-services costs shall be metro-
11 politan statistical regions plus associated regions.

12 “(b) PREMIUMS.—Medicare payment benchmark by
13 market area shall be calculated based on weighted average
14 (by enrollment in previous year) of the premium bids from
15 MA plans, ACOs, and the per person costs of fee-for-serv-
16 ice, less the statutory part B premium.

17 “(c) BENEFICIARY RESPONSIBILITY.—Beneficiaries
18 shall pay the difference between Medicare payment and
19 required premium of the plan they choose, and get 100
20 percent of the savings by choosing a plan with a premium
21 below the benchmark.

22 “(d) TRANSITION.—For beneficiaries who are in fee-
23 for-service at the time of the enactment of this section,
24 there shall be a limit on the amount of a premium increase
25 allowable by year of no more than \$20 per month com-

1 pared to what such premium would have otherwise been
2 if this subpart had not been enacted for each year through
3 the fifth year.

4 “(e) **MULTIYEAR CONTRACTS.**—A Medicare Advan-
5 tage plan may offer to beneficiaries multiyear contracts
6 with guaranteed premiums over such years, bearing the
7 risk of any change in payments from the Secretary in sub-
8 sequent years. A beneficiary enrolling under such a con-
9 tract shall be exempt from the method described in sub-
10 section (a).”.

11 (b) **CONFORMING AMENDMENTS.**—

12 (1) Section 1853(a)(1)(A) of the Social Security
13 Act is amended by striking “and section 1859(e)(4)”
14 and inserting “, section 1859(e)(4), and subpart 3
15 of part E”.

16 (2) Section 1853(j) of such Act is amended by
17 inserting “and subpart 3 of part E” after “sub-
18 section (o)”.

19 (3) Section 1854 of such Act is amended—

20 (A) in subsection (a), after the heading, by
21 inserting “Subject to subpart 3 of part E.”;

22 (B) in subsection (b), after the heading, by
23 inserting “Subject to subpart 3 of part E.”;

1 (C) in subsection (d), after the heading, by
 2 inserting “Subject to subpart 3 of part E.”;
 3 and

4 (D) in subsection (e), after the heading, by
 5 inserting “Subject to subpart 3 of part E.”.

6 **SEC. 422. NEW UNIFIED ELIGIBILITY AND ENROLLMENT**
 7 **RULES.**

8 (a) IN GENERAL.—Title XVIII of the Social Security
 9 Act is amended—

10 (1) by redesignating part E as part F; and

11 (2) by inserting after part D the following new
 12 part:

13 **“PART E—MEDICARE WITH CHOICE AND**
 14 **COMPETITION**

15 **“Subpart 1—Opt-Out and Auto-Enrollment**

16 **“SEC. 1860E-11. PART A OPT-OUT AND MA AUTO-ENROLL-**
 17 **MENT.**

18 “(a) PERMITTING INDIVIDUALS TO OPT OUT OF
 19 PART A COVERAGE WITHOUT LOSING SOCIAL SECURITY
 20 BENEFITS.—

21 “(1) IN GENERAL.—The Secretary shall estab-
 22 lish—

23 “(A) a process by which an individual oth-
 24 erwise entitled to benefits under part A may
 25 elect (at a time and in a manner specified

1 under the process) to waive such entitlement;
2 and

3 “(B) a process by which an individual who
4 elects to waive such entitlement may revoke (at
5 a time and in a manner specified under the
6 process) such waiver.

7 The process under subparagraph (B) shall be coordi-
8 nated with the enrollment process under section
9 1837 for part B.

10 “(2) APPLICATION OF LATE ENROLLMENT PEN-
11 ALTY.—An individual who revokes a waiver under
12 paragraph (1)(B) shall be subject to a late enroll-
13 ment penalty as applied under section 1860E-
14 32(c)(2)(C).

15 “(3) NO IMPACT ON TITLE II BENEFITS.—Not-
16 withstanding any other provision of law, an election
17 of an individual to waive entitlement to benefits
18 under part A under paragraph (1)(A) shall not re-
19 sult in any loss of benefits under title II.

20 “(4) DEEMED OPT-OUT.—

21 “(A) An election of an individual to waive
22 entitlement to benefits under part A under
23 paragraph (1)(A) is also deemed the filing of a
24 notice of termination of benefits under part B
25 pursuant to section 1838(b)(1).

1 “(B) The termination of benefits under
2 part B pursuant to section 1838(b) is also
3 deemed to be a waiver of any entitlement to
4 benefits under part A.

5 “(b) SPECIAL OPEN ENROLLMENT PERIOD WITH-
6 OUT LATE ENROLLMENT PENALTY FOR CURRENT PART
7 A ONLY OR PART B ONLY ENROLLEES.—Notwith-
8 standing any other provision of law, in the case of an indi-
9 vidual who as of the general effective date, is entitled to
10 benefits under part A but not enrolled under part B, or
11 who is enrolled under part B but not entitled to benefits
12 (or enrolled) under part A, beginning as of such date, such
13 individual shall be deemed to be enrolled under part B
14 or part A, respectively, unless such individual elects to be
15 enrolled (or entitled to benefits) under neither of such
16 parts during a special open enrollment period specified by
17 the Secretary. No increase in the monthly premium of an
18 individual pursuant to section 1839(b) or section 1818(c)
19 shall be effected in the case of any such individual who
20 is deemed enrolled under part B or part A pursuant to
21 the previous sentence with respect to any period prior to
22 the date of such enrollment.

23 “(c) AUTO ENROLLMENT OF DUAL ELIGIBLE INDI-
24 VIDUALS UNDER MEDICARE ADVANTAGE PLANS.—

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

15 “(2) RIGHT TO DISENROLL.—Nothing in para-
16 graph (1) shall prevent such an individual from de-
17 clining enrollment in any such plan (and thereby ob-
18 taining coverage under Medicare fee-for-service) or
19 from changing enrollment in such a plan to another
20 MA–PD plan.

21 **“SEC. 1860E–12. COORDINATION WITH PART D.**

22 “(a) DEEMED ENROLLMENT UNDER PART D.—

23 “(1) IN GENERAL.—The Secretary shall estab-
24 lish a process that, beginning as of the general effec-
25 tive date, provides for the enrollment in a prescrip-

1 tion drug plan that has a monthly base beneficiary
2 premium that does not exceed the weighted average
3 of premiums for such plans that provide standard
4 prescription drug coverage (as defined in section
5 1860D–2(b)) with respect to the area involved (on
6 a random basis among all such plans in the applica-
7 ble PDP region) of each Medicare enrollee (as de-
8 fined in section 1860E–51) who—

9 “(A) failed to enroll in such a prescription
10 drug plan during the applicable enrollment or
11 coverage election period under section 1860D–
12 1(b); and

13 “(B) failed to elect not to enroll in such a
14 prescription drug plan during an applicable opt-
15 out period described in paragraph (2).

16 Nothing in the previous sentence shall prevent such
17 an individual from declining or changing such enroll-
18 ment. Such process shall be carried out in the same
19 manner as the process described in section 1860D–
20 1(b)(1)(C).

21 “(2) OPT-OUT PERIODS.—The process under
22 paragraph (1) shall provide for the opportunity to
23 make an election described in subparagraph (B) of
24 such paragraph during an opt-out period that is co-

1 ordinated with the relevant enrollment or coverage
2 election period under section 1860D–1.

3 “(3) LATE ENROLLMENT PENALTIES.—In the
4 case of an individual who makes an election de-
5 scribed in paragraph (1)(B) and then enrolls in a
6 prescription drug plan, the late enrollment penalty
7 under section 1860D–13(b) shall apply to the
8 monthly beneficiary premium of such individual, ex-
9 cept that in applying such section, any reference to
10 the initial enrollment period of such individual shall
11 be deemed to be a reference to the opt-out period
12 under paragraph (2) during which the individual
13 elected not to enroll in a prescription drug plan.

14 “(4) NO LATE ENROLLMENT PENALTY FOR
15 CURRENT FEE-FOR-SERVICE BENEFICIARIES WITH-
16 OUT DRUG COVERAGE.—In the case of an individual
17 who is a Medicare enrollee before the date of enact-
18 ment of this section and who was not enrolled under
19 a prescription drug plan before being enrolled under
20 such a plan pursuant to paragraph (1), there shall
21 be no increase in the base beneficiary premium of an
22 individual under section 1860D–13 by a late enroll-
23 ment penalty under subsection (b) of such section
24 with respect to any period prior to the date of such
25 enrollment.

1 “(b) REFERENCE TO REQUIRED PRESCRIPTION
2 DRUG COVERAGE UNDER PART C.—For provision requir-
3 ing coverage under MA plans to include prescription drug
4 coverage, see section 1860E–26.”.

5 (b) LIMITATION ON MEDICAID BENEFITS FOR FULL-
6 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—Section 1902
7 of the Social Security Act (42 U.S.C. 1396a) is amended
8 by adding at the end the following new subsection:

9 “(ll) LIMITATION ON BENEFITS FOR FULL-BENEFIT
10 DUAL ELIGIBLE INDIVIDUALS.—Effective as of the gen-
11 eral effective date (as specified in section 1860E–62), ex-
12 cept in the case of a State which has elected the option
13 described in section 1944(b)(2), in the case of an indi-
14 vidual described in subparagraph (A)(ii) of section
15 1935(c)(6) (taking into account the application of sub-
16 paragraph (B) of such section), notwithstanding any other
17 provision of law, medical assistance shall not be available
18 under this title for any items and services for which pay-
19 ment may be made under title XVIII.”.

20 (c) MEDICAID MAINTENANCE OF EFFORT AND AL-
21 TERNATIVES.—Title XIX of the Social Security Act is
22 amended by inserting after section 1943 the following new
23 section:

1 “MAINTENANCE OF EFFORT OPTIONS FOR FULL-BENEFIT
2 DUAL ELIGIBLE INDIVIDUALS

3 “SEC. 1944. (a) IN GENERAL.—Effective as of the
4 general effective date (as specified in section 1860E–62),
5 a State shall elect, in a form and manner specified by the
6 Secretary, a maintenance of effort option described in sub-
7 section (b). In the case of a State that fails to make such
8 an election, the State shall be deemed to have elected the
9 option described in subsection (b)(3).

10 “(b) MAINTENANCE OF EFFORT OPTIONS DE-
11 SCRIBED.—The following are maintenance of effort op-
12 tions described in this subsection for a State, which shall
13 apply to all individuals described in subparagraph (A)(ii)
14 of section 1935(c)(6) (taking into account the application
15 of subparagraph (B) of such section) for such State:

16 “(1) ENROLLMENT OF DUAL ELIGIBLES IN
17 COMPREHENSIVE MEDICAID MANAGED CARE PLAN.—

18 “(A) IN GENERAL.—The State enrolls all
19 such individuals in a comprehensive Medicaid
20 managed care plan offered by a managed care
21 entity under section 1932.

22 “(B) PAYMENT OF SUBSIDY AMOUNT TO
23 STATE.—In the case of a State that elects the
24 option under this paragraph with respect to an
25 individual, the Secretary established under sec-

1 tion 1860E–51 shall pay to the State the same
2 amount that the individual would be entitled to
3 have paid as an income-related premium sub-
4 sidy under section 1860E–41(b)(1)(A) plus the
5 amount that the Secretary estimates would
6 have been paid with respect to the individual
7 under part D (including the actuarial value of
8 subsidy payments under sections 1860D–13
9 and 1860D–14). Such payment shall be made
10 in appropriate part from the Federal Hospital
11 Insurance Trust Fund under section 1817 and
12 the Federal Supplementary Medical Insurance
13 Trust Fund under section 1841.

14 “(C) RELATION TO PART D RULES.—In
15 the case of a State that has elected the option
16 under this paragraph, notwithstanding any
17 other provision of law—

18 “(i) the coverage provided under this
19 option shall be in lieu of any coverage that
20 may otherwise be provided under part D;
21 and

22 “(ii) the payment to the State under
23 subparagraph (B) shall be in lieu of any
24 payments otherwise made with respect to
25 such individual under such part.

1 “(2) OTHER INNOVATIVE ALTERNATIVES.—

2 “(A) IN GENERAL.—The State submits to
3 the Secretary, and has approved by the Sec-
4 retary, an innovative alternative proposal relat-
5 ing to coordinating coverage of such individuals
6 under Medicare and the State plan under title
7 XIX.

8 “(B) PROCESS FOR REVIEW.—With re-
9 spect to proposals submitted to the Secretary
10 under subparagraph (A), the Secretary shall ap-
11 prove such a proposal if the State demonstrates
12 with respect to the proposal that—

13 “(i) there would be no increased cost
14 to the Federal Government if it were ap-
15 proved; and

16 “(ii) there would be no reduction in
17 the quality of care provided to such indi-
18 viduals if the proposal were approved.”.

19 (d) CONFORMING AMENDMENTS.—

20 (1) SECTION 226.—Section 226 of the Social
21 Security Act (42 U.S.C. 426) is amended—

22 (A) in subsection (a), in the matter pre-
23 ceeding paragraph (1), by inserting “, subject to
24 section 1860E–11(a)” after “individual who”;

1 (B) in subsection (b), in the matter pre-
2 ceding paragraph (1), by inserting “, subject to
3 section 1860E–11(a)” after “individual who”;
4 and

5 (C) in subsection (c), in the matter pre-
6 ceding paragraph (1), by inserting “, subject to
7 section 1860E–11(a)” after “subsection (a)”.

8 (2) SECTION 226A.—Section 226A(a) of such
9 Act (42 U.S.C. 426–1(a)) is amended, in the matter
10 preceding paragraph (1), by inserting “and subject
11 to section 1860E–11(a)” after “or title XVIII”.

12 (3) SECTION 1932.—Section 1932(a)(2)(B) of
13 the Social Security Act (42 U.S.C. 1396u–
14 2(a)(2)(B)) is amended by striking “A State” and
15 inserting “Except in the case of a State that has
16 elected the maintenance of effort option described in
17 section 1944(b)(2), a State”.

18 **SEC. 423. NEW BENEFIT STRUCTURE UNDER UNIFIED**
19 **MEDICARE.**

20 (a) IN GENERAL.—Part E of title XVIII of the Social
21 Security Act, as added by section 251, is amended by add-
22 ing at the end the following:

“Subpart 2—Out-of-Pocket Limit**2 “SEC. 1860E-21. OUT-OF-POCKET LIMIT.**

3 “(a) IN GENERAL.—Beginning with 2026, in the case
4 of a Medicare enrollee, if the amount of the out-of-pocket
5 cost-sharing of such enrollee for a calendar year equals
6 or exceeds the catastrophic limit under subsection (b) for
7 that year—

8 “(1) the enrollee shall not be responsible for ad-
9 ditional out-of-pocket cost-sharing incurred during
10 that year; and

11 “(2) the Secretary shall establish procedures
12 under which the Secretary shall, in appropriate part
13 from the Part A Medicare FFS Account under sec-
14 tion 1817 and the Part B Medicare FFS Account
15 under section 1841—

16 “(A) pay on behalf of the enrollee the
17 amount of the additional out-of-pocket cost-
18 sharing described in paragraph (1) attributable
19 to deductibles and coinsurance described in sub-
20 section (c)(1); and

21 “(B) reimburse the enrollee the amount of
22 the additional out-of-pocket cost-sharing de-
23 scribed in paragraph (1) attributable to
24 deductibles and coinsurance described in sub-
25 section (c)(2).

1 “(b) CATASTROPHIC LIMIT.—The amount of the cat-
2 astrophic limit under this subsection for a year shall be
3 the dollar amount in effect under section 223(c)(2)(A)(ii)
4 of the Internal Revenue Code of 1986 for self-only cov-
5 erage for taxable years beginning in such year.

6 “(c) OUT-OF-POCKET COST-SHARING DEFINED.—In
7 this section, the term ‘out-of-pocket cost-sharing’ means,
8 with respect to an individual, the amount of costs incurred
9 by the individual that are attributable to—

10 “(1) deductibles and coinsurance imposed under
11 part A or part B; and

12 “(2) deductibles and coinsurance imposed under
13 standard prescription drug coverage pursuant to sec-
14 tion 1860D–2(b) or alternative prescription drug
15 coverage pursuant to section 1860D–2(c) offered by
16 a prescription drug plan.”.

17 (b) APPLICATION OF OUT-OF-POCKET LIMIT TO MA-
18 PD PLANS.—

19 (1) IN GENERAL.—Section 1852(a)(1)(B) of the
20 Social Security Act (42 U.S.C. 1395w–22(a)(1)(B))
21 is amended—

22 (A) in clause (i), by striking “clause (iii)”
23 and inserting “clauses (iii) and (vi)”; and

24 (B) by adding at the end the following new
25 clause:

1 “(vi) OUT-OF-POCKET LIMIT.—The
2 provisions of section 1860E–21—

3 “(I) shall apply to individuals en-
4 rolled under an MA–PD plan in the
5 same manner as such provisions apply
6 to Medicare enrollees under such sec-
7 tion, except that in lieu of the applica-
8 tion of subsection (a)(2) of such sec-
9 tion the MA–PD plan shall establish
10 procedures to provide for payment of
11 any additional out-of-pocket cost-shar-
12 ing described in subsection (a)(1) of
13 such section incurred by individuals
14 enrolled under the MA–PD plan; and

15 “(II) as applied under subclause
16 (I), may not be waived by application
17 of this subparagraph.

18 In applying subsection (b) of section
19 1860E–21 pursuant to the previous sen-
20 tence, an MA–PD plan may substitute a
21 dollar amount that is less than the dollar
22 amount specified under such subsection.”.

23 (2) EXEMPTING MA–PD PLANS OFFERING AL-
24 TERNATIVE PRESCRIPTION DRUG COVERAGE FROM
25 PART D DEDUCTIBLE AND OUT-OF-POCKET LIMIT

1 REQUIREMENTS.—Section 1860D–2(c) of the Social
2 Security Act (42 U.S.C. 1395w–102(e)) is amend-
3 ed—

4 (A) in paragraph (2), by striking “The de-
5 ductible” and inserting “In the case of a pre-
6 scription drug plan, the deductible”; and

7 (B) in paragraph (3), by striking “The
8 coverage provides” and inserting “In the case
9 of a prescription drug plan, the coverage pro-
10 vides”.

11 (c) PRESCRIPTION DRUG PLANS REQUIRED TO RE-
12 PORT ENROLLEES’ OUT-OF-POCKET COST-SHARING.—
13 Section 1860D–12(b) of the Social Security Act (42
14 U.S.C. 1395w–112(b)) is amended by adding at the end
15 the following new paragraph:

16 “(7) OUT-OF-POCKET COST-SHARING RE-
17 PORTS.—Each contract entered into with a PDP
18 sponsor under this part with respect to a prescrip-
19 tion drug plan offered by such sponsor shall require
20 that, with respect to each claim submitted for items
21 or services furnished to an individual enrolled under
22 the plan pursuant to the contract, the sponsor sub-
23 mits to the Secretary information on the amount of
24 out-of-pocket cost-sharing (as defined in section

1 1860E–23(c)) applicable to such enrollee for such
2 items or services.”.

3 (d) CONFORMING AMENDMENTS.—

4 (1) Section 1813 of the Social Security Act (42
5 U.S.C. 1395e) is amended—

6 (A) in subsection (a), by inserting “Subject
7 to subpart 2 of part E:” before paragraph (1);
8 and

9 (B) in subsection (b), by inserting “Sub-
10 ject to subpart 2 of part E:” before paragraph
11 (1).

12 (2) Section 1833 of such Act (42 U.S.C. 1395l)
13 is amended—

14 (A) in subsection (a), in the matter pre-
15 ceding paragraph (1), by inserting “and sub-
16 part 2 of part E” after “succeeding provisions
17 of this section”;

18 (B) in subsection (b), in the first sentence,
19 by striking “Before applying” and inserting
20 “Subject to subpart 2 of part E, before apply-
21 ing”;

22 (C) in subsection (c)(1), in the matter pre-
23 ceding subparagraph (A), by inserting “subject
24 to subpart 2 of part E,” after “this part,”;

1 (D) in subsection (f), by striking “In es-
2 tablishing” and inserting “Subject to subpart 2
3 of part E, in establishing”; and

4 (E) in subsection (g)(1), by inserting “and
5 subpart 2 of part E” and “paragraphs (4) and
6 (5)”.

7 (3) Section 1882(a)(2) of such Act is amended
8 by striking “No medicare” and inserting “Subject to
9 section 1860E–24(c), no medicare”.

10 **SEC. 424. LATE ENROLLMENT PENALTY NOT TO APPLY FOR**
11 **MONTHS OF ANY HEALTH COVERAGE.**

12 (a) IN GENERAL.—Section 1839(b) of the Social Se-
13 curity Act (42 U.S.C. 1395r) is amended in the second
14 sentence, by inserting before the period at the end the fol-
15 lowing: “or months during which the individual has any
16 other health coverage”.

17 (b) EFFECTIVE DATE.—The amendment made by
18 paragraph (1) shall apply for months of coverage begin-
19 ning after the date of the enactment of this Act.

20 **SEC. 425. MEDIGAP REFORM.**

21 Notwithstanding any provision of section 1882 of the
22 Social Security Act (42 U.S.C. 1395ss), as of the date
23 of the enactment of this Act, no policy may be offered
24 under such section that does not provide guaranteed cov-
25 erage (without regard to an individual’s preexisting condi-

1 tions, if any) to all individuals eligible to enroll under such
2 policy.

3 **SEC. 426. ACO REVISION.**

4 (a) ENROLLMENT.—Enrollment in such an ACO
5 under such title shall be based on the method established
6 under part E of such title. Such a network shall bear full
7 risk in the event payments under such title do not equal
8 or exceed liabilities under such network.

9 (b) DIRECTION OF PAYMENT.—An ACO may direct
10 that any payments under such title be made to a central-
11 ized entity rather than to an individual provider or sup-
12 plier.

13 (c) BIDS.—The Secretary of Health and Human
14 Services shall establish a process whereby such networks
15 compete using a bidding process similar to that described
16 in part E of such title for Medicare Advantage plans.

17 **SEC. 427. PRIMARY CARE OPTIONS.**

18 (a) SELECTION OF PRIMARY CARE PHYSICIAN.—The
19 Secretary shall establish a mechanism under which an in-
20 dividual enrolled under part B of title XVIII of the Social
21 Security Act may select such individual's primary care
22 physician. Such an individual shall not be liable for more
23 than \$5 for each visit to such selected physician.

24 (b) PAYMENT TO PHYSICIAN.—A physician selected
25 under subsection (a) shall receive a monthly fee in lieu

1 of any other payment under such part B for evaluation
2 and monitoring of such individual. The Secretary shall
3 provide a list of standardized benefits that are included
4 in such payment, including telephone and email commu-
5 nications, office visits, preventive care, and vaccinations.

6 **SEC. 428. GENERAL PROVISIONS; EFFECTIVE DATE.**

7 Part E of title XVIII of the Social Security Act, as
8 inserted by section 101(a)(2) and as previously amended,
9 is further amended by adding at the end the following new
10 subpart:

11 **“Subpart 5.—General Provisions**

12 **“SEC. 1860E-51. APPLICABILITY; DEFINITIONS.**

13 “(a) IN GENERAL.—The provisions of this Act are
14 superseded to the extent inconsistent with the provisions
15 of this part.

16 “(b) TERMINOLOGY.—For purposes of this part:

17 “(1) MEDICARE ENROLLEE.—

18 “(A) IN GENERAL.—The term ‘Medicare
19 enrollee’ means—

20 “(i) an individual entitled to (or en-
21 rolled for benefits) under part A and en-
22 rolled under part B; and

23 “(ii) except as otherwise specified, an
24 individual described in section 1860E-
25 11(a)(3).

1 “(B) TREATMENT.—Any reference in this
2 Act (or any other Act) in effect before the date
3 of the enactment of this part, to an individual
4 entitled to benefits under part A or enrolled
5 under part B shall be deemed a reference to a
6 Medicare enrollee.

7 “(2) MEDICARE FEE-FOR-SERVICE.—The term
8 ‘Medicare fee-for-service’ means the original Medi-
9 care fee-for-service program under parts A and B,
10 as modified by this part, and does not include part
11 C or part D.

12 “(3) MEDICARE FEE-FOR-SERVICE EN-
13 ROLLEE.—The term ‘Medicare fee-for-service en-
14 rollee’ means a Medicare enrollee who is not enrolled
15 under a Medicare Advantage plan under part C.

16 **“SEC. 1860E-61. GENERAL EFFECTIVE DATE.**

17 “Except as otherwise specified, the provisions of this
18 part shall apply to items and services furnished on or after
19 January 1, 2026, and to plan years beginning on or after
20 such date (referred to in this title as the ‘general effective
21 date’).”.

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

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

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

8 (1) by striking “and office” and inserting “of-
9 fice”; and

10 (2) by inserting: “respiratory services, audiology
11 services (as defined in section 1861(ll)), outpatient
12 therapy services (including physical therapy, occupa-
13 tional therapy, and speech-language pathology serv-
14 ices)” after “the Secretary)),”.

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

17 (1) in paragraph (1), by striking “or a practi-
18 tioner (described in section 1842(b)(18)(C))” and
19 inserting “, a practitioner (described in section
20 1842(b)(18)(C)), or an applicable professional (as
21 defined in paragraph (4)(G))”;

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

25 (3) in paragraph (3)(A)—

1 (A) in the heading, by striking “PHYSI-
2 CIAN AND PRACTITIONER” and inserting “PHY-
3 SICIAN, PRACTITIONER, AND APPLICABLE PRO-
4 FESSIONAL”; and

5 (B) by striking “physicians or practi-
6 tioners” and inserting “physicians, practi-
7 tioners, or applicable professionals”; and

8 (4) in paragraph (4), by adding at the end the
9 following new subparagraph:

10 “(G) APPLICABLE PROFESSIONAL.—The
11 term ‘applicable professional’ means, with re-
12 spect to services furnished on or after the date
13 that is 6 months after the date of the enact-
14 ment of this subparagraph, a certified diabetes
15 educator or licensed—

16 “(i) respiratory therapist;

17 “(ii) audiologist;

18 “(iii) occupational therapist;

19 “(iv) physical therapist; or

20 “(v) speech language pathologist.”.

21 (c) HOME-BASED MONITORING SERVICES FOR CON-
22 GESTIVE HEART FAILURE AND CHRONIC OBSTRUCTIVE
23 PULMONARY DISEASE.—

24 (1) COVERAGE OF REMOTE PATIENT MONI-
25 TORING SERVICES FOR CERTAIN CHRONIC HEALTH

1 CONDITIONS.—Section 1861(s)(2) of the Social Se-
2 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

3 (A) in subparagraph (GG), by striking
4 “and” at the end;

5 (B) in subparagraph (HH), by inserting
6 “and” at the end; and

7 (C) by inserting after subparagraph (HH)
8 the following new subparagraph:

9 “(II) applicable remote patient monitoring
10 services (as defined in paragraph (1)(A) of sub-
11 section (iii));”.

12 (2) SERVICES DESCRIBED.—Section 1861 of
13 the Social Security Act (42 U.S.C. 1395x) is amend-
14 ed by adding at the end the following new sub-
15 section:

16 “(kkk) REMOTE PATIENT MONITORING SERVICES
17 FOR CHRONIC HEALTH CONDITIONS.—

18 “(1)(A) The term ‘applicable remote patient
19 monitoring services’ means remote patient moni-
20 toring services (as defined in subparagraph (B)) fur-
21 nished to provide for the monitoring, evaluation, and
22 management of an individual with a covered chronic
23 condition (as defined in paragraph (2)), insofar as
24 such services are for the management of such chron-
25 ic condition.

1 “(B) The term ‘remote patient monitoring serv-
2 ices’ means services furnished through remote pa-
3 tient monitoring technology (as defined in subpara-
4 graph (C)).

5 “(C) The term ‘remote patient monitoring tech-
6 nology’ means a coordinated system that uses one or
7 more home-based or mobile monitoring devices that
8 automatically transmit vital sign data or information
9 on activities of daily living and may include re-
10 sponses to assessment questions collected on the de-
11 vices wirelessly or through a telecommunications
12 connection to a server that complies with the Fed-
13 eral regulations (concerning the privacy of individ-
14 ually identifiable health information) promulgated
15 under section 264(c) of the Health Insurance Port-
16 ability and Accountability Act of 1996, as part of an
17 established plan of care for that patient that in-
18 cludes the review and interpretation of that data by
19 a health care professional.

20 “(2) For purposes of paragraph (1), the term
21 ‘covered chronic health condition’ means applicable
22 conditions (as defined in and applied under section
23 1886(q)(5)) when under chronic care management
24 (identified as of July 1, 2015, by HCPCS code

1 99490 (and as subsequently modified by the Sec-
2 retary)).

3 “(3)(A) Payment may be made under this part
4 for applicable remote patient monitoring services
5 provided to an individual during a period of up to
6 90 days and such additional period as provided for
7 under subparagraph (B).

8 “(B) The 90-day period described in subpara-
9 graph (A), with respect to an individual, may be re-
10 newed by the physician who provides chronic care
11 management to such individual if the individual con-
12 tinues to qualify for such management.”.

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

16 (A) in subsection (c)—

17 (i) in paragraph (2)(B)—

18 (I) in clause (ii)(II), by striking
19 “and (v)” and inserting “(v), and
20 (vii)”; and

21 (II) by adding at the end the fol-
22 lowing new clause:

23 “(vii) BUDGETARY TREATMENT OF
24 CERTAIN SERVICES.—The additional ex-
25 penditures attributable to services de-

1 scribed in section 1861(s)(2)(II) shall not
2 be taken into account in applying clause
3 (ii)(II).”; and

4 (ii) by adding at the end the following
5 new paragraph:

6 “(7) TREATMENT OF APPLICABLE REMOTE PA-
7 TIENT MONITORING SERVICES.—

8 “(A) In determining relative value units
9 for applicable remote patient monitoring serv-
10 ices (as defined in section 1861(iii)(1)(A)), the
11 Secretary, in consultation with appropriate phy-
12 sician groups, practitioner groups, and supplier
13 groups, shall take into consideration—

14 “(i) physician or practitioner re-
15 sources, including physician or practitioner
16 time and the level of intensity of services
17 provided, based on—

18 “(I) the frequency of evaluation
19 necessary to manage the individual
20 being furnished the services;

21 “(II) the complexity of the eval-
22 uation, including the information that
23 must be obtained, reviewed, and ana-
24 lyzed; and

1 “(III) the number of possible di-
2 agnoses and the number of manage-
3 ment options that must be considered;
4 “(ii) practice expense costs associated
5 with such services, including the direct
6 costs associated with installation and infor-
7 mation transmission, costs of remote pa-
8 tient monitoring technology (including
9 equipment and software), device delivery
10 costs, and resource costs necessary for pa-
11 tient monitoring and followup (but not in-
12 cluding costs of any related item or non-
13 physician service otherwise reimbursed
14 under this title); and

15 “(iii) malpractice expense resources.

16 “(B) Using the relative value units deter-
17 mined in subparagraph (A), the Secretary shall
18 provide for separate payment for such services
19 and shall not adjust the relative value units as-
20 signed to other services that might otherwise
21 have been determined to include such separately
22 paid remote patient monitoring services.”; and

23 (B) in subsection (j)(3), by inserting
24 “(2)(II),” after “health risk assessment),”.

1 **SEC. 432. EXPANDING THE USE OF TELEHEALTH THROUGH**
2 **THE WAIVER OF CERTAIN REQUIREMENTS.**

3 (a) IN GENERAL.—Section 1834(m) of the Social Se-
4 curity Act (42 U.S.C. 1395m(m)) is amended—

5 (1) in paragraph (4)(C)(i), by striking “and
6 (7)” and inserting “(7), and (8)”; and

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

8 “(8) **AUTHORITY TO WAIVE REQUIREMENTS**
9 **AND LIMITATIONS IF CERTAIN CONDITIONS MET.—**

10 “(A) IN GENERAL.—Notwithstanding the
11 preceding provisions of this subsection, in the
12 case of telehealth services furnished on or after
13 January 1, 2026, 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, 2026, 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 2026, to an eligible telehealth individual at an origi-
7 nating site described in subclause (II), (V), or (VII)
8 of paragraph (4)(C)(ii).”.

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

16 **SEC. 435. IMPROVEMENTS TO THE PROCESS FOR ADDING**
17 **TELEHEALTH SERVICES.**

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

22 (1) implement revisions to the process so that
23 the criteria to add services prioritizes, as appro-
24 priate, improved access to care through telehealth
25 services; and

1 (2) provide clarification on what requests to
2 add telehealth services under such process should in-
3 clude.

4 **SEC. 436. RURAL HEALTH CLINICS AND FEDERALLY QUALI-**
5 **FIED HEALTH CENTERS.**

6 (a) **EXPANSION OF ORIGINATING SITES.**—Section
7 1834(m)(4)(C) of the Social Security Act (42 U.S.C.
8 1395m(m)(4)(C)), as amended by the preceding sections,
9 is amended—

10 (1) in clause (i), by striking “and (10)” and in-
11 serting “and (10), and subject to clause (iii),”;

12 (2) by adding at the end the following new
13 clause:

14 “(iii) **RURAL HEALTH CLINICS AND**
15 **FEDERALLY QUALIFIED HEALTH CEN-**
16 **TERS.**—The term ‘originating site’ shall
17 also include any Federally qualified health
18 center and any rural health clinic (as such
19 terms are defined in section 1861(aa)) at
20 which the eligible telehealth individual is
21 located at the time the service is furnished
22 via a telecommunications system, whether
23 or not the individual is located in an area
24 described in clause (i), insofar as such
25 sites are not otherwise included in the defi-

1 nition of originating site under such
2 clause, subject to applicable State law re-
3 quirements, including State licensure re-
4 quirements.”.

5 (b) EXPANSION OF DISTANT SITES.—Section
6 1834(m) of the Social Security Act (42 U.S.C. 1395m(m))
7 is amended—

8 (1) in the first sentence of paragraph (1)—

9 (A) by striking “or a practitioner (de-
10 scribed in section 1842(b)(18)(C))” and insert-
11 ing “, a practitioner (described in section
12 1842(b)(18)(C)), a Federally qualified health
13 center, or a rural health clinic”; and

14 (B) by striking “or practitioner” and in-
15 sserting “, 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, 2026.

1 **SEC. 437. NATIVE AMERICAN HEALTH FACILITIES.**

2 (a) IN GENERAL.—Section 1834(m)(4)(C) of the So-
3 cial Security Act (42 U.S.C. 1395m(m)(4)(C)), as amend-
4 ed by the preceding sections, is amended—

5 (1) in clause (i), by striking “clause (iii)” and
6 inserting “clauses (iii) and (iv)”; and

7 (2) by adding at the end the following new
8 clause:

9 “(iv) NATIVE AMERICAN HEALTH FA-
10 CILITIES.—The originating site require-
11 ments described in clauses (i) and (ii) shall
12 not apply with respect to a facility of the
13 Indian Health Service, whether operated
14 by such Service, or by an Indian tribe (as
15 that term is defined in section 4 of the In-
16 dian Health Care Improvement Act (25
17 U.S.C. 1603)) or a tribal organization (as
18 that term is defined in section 4 of the In-
19 dian Self-Determination and Education
20 Assistance Act (25 U.S.C. 5304)), or a fa-
21 cility of the Native Hawaiian health care
22 systems authorized under the Native Ha-
23 waiian Health Care Improvement Act (42
24 U.S.C. 11701 et seq.).”.

25 (b) NO ORIGINATING SITE FACILITY FEE FOR NEW
26 SITES.—Section 1834(m)(2)(B)(i) of the Social Security

1 Act (42 U.S.C. 1395m(m)(2)(B)(i)) is amended, in the
2 matter preceding subclause (I), by inserting “(other than
3 an originating site that is only described in clause (iv) of
4 paragraph (4)(C), and does not meet the requirement for
5 an originating site under clause (i) of such paragraph)”
6 after “the originating site”.

7 (c) EFFECTIVE DATE.—The amendments made by
8 this section shall apply to services furnished on or after
9 January 1, 2026.

10 **SEC. 438. WAIVER OF TELEHEALTH RESTRICTIONS DURING**
11 **NATIONAL EMERGENCIES.**

12 Section 1135(b) of the Social Security Act (42 U.S.C.
13 1320b–5(b)) is amended—

14 (1) in paragraph (6), by striking “and” after
15 the semicolon;

16 (2) in paragraph (7), by striking the period at
17 the end and inserting “; and”; and

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

19 “(8) requirements for payment for telehealth
20 services under section 1834(m).”.

21 **SEC. 439. USE OF TELEHEALTH IN RECERTIFICATION FOR**
22 **HOSPICE CARE.**

23 (a) IN GENERAL.—Section 1814(a)(7)(D)(i) of the
24 Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)) is
25 amended by inserting “(including through use of tele-

1 health, notwithstanding the requirements in section
2 1834(m)(4)(C))” after “face-to-face encounter”.

3 (b) GAO REPORT.—Not later than 3 years after the
4 date of enactment of this Act, the Comptroller General
5 of the United States shall submit a report to Congress
6 evaluating the impact of the amendment made by sub-
7 section (a) on—

8 (1) the number and percentage of beneficiaries
9 recertified for the Medicare hospice benefit at 180
10 days and for subsequent benefit periods;

11 (2) the appropriateness for hospice care of the
12 patients recertified through the use of telehealth;
13 and

14 (3) any other factors determined appropriate by
15 the Comptroller General.

16 **SEC. 440. CLARIFICATION FOR FRAUD AND ABUSE LAWS**
17 **REGARDING TECHNOLOGIES PROVIDED TO**
18 **BENEFICIARIES.**

19 Section 1128A(i)(6) of the Social Security Act (42
20 U.S.C. 1320a–7a(i)(6)) is amended—

21 (1) in subparagraph (I), by striking “; or” and
22 inserting a semicolon;

23 (2) in subparagraph (J), by striking the period
24 at the end and inserting “; or”; and

1 (3) by adding at the end the following new sub-
2 paragraph:

3 “(K) the provision of technologies (as de-
4 fined by the Secretary) on or after the date of
5 the enactment of this subparagraph, by a pro-
6 vider of services or supplier (as such terms are
7 defined for purposes of title XVIII) directly to
8 an individual who is entitled to benefits under
9 part A of title XVIII, enrolled under part B of
10 such title, or both, for the purpose of furnishing
11 telehealth services, remote patient monitoring
12 services, or other services furnished through the
13 use of technology (as defined by the Secretary),
14 if—

15 “(i) the technologies are not offered
16 as part of any advertisement or sollicita-
17 tion; and

18 “(ii) the provision of the technologies
19 meets any other requirements set forth in
20 regulations promulgated by the Sec-
21 retary.”.

22 **SEC. 441. STUDY AND REPORT ON INCREASING ACCESS TO**
23 **TELEHEALTH SERVICES IN THE HOME.**

24 (a) **MEDPAC STUDY.**—The Medicare Payment Advi-
25 sory Commission (in this section referred to as the “Com-

1 mission”) shall conduct a study on increasing access under
2 the Medicare program under title XVIII of the Social Se-
3 curity Act (42 U.S.C. 1395 et seq.) to telehealth services
4 in the home. Such study shall include an analysis of the
5 following:

6 (1) How different payers allow the home to be
7 an originating site for telehealth services.

8 (2) Particular types of telehealth services or
9 subgroups of beneficiaries with respect to which al-
10 lowing the home to be an originating site under the
11 Medicare program would be suitable.

12 (b) REPORT.—Not later than 24 months after the
13 date of the enactment of this Act, the Commission shall
14 submit to Congress a report containing the results of the
15 study conducted under subsection (a), together with rec-
16 ommendations for such legislation and administrative ac-
17 tion as the Commission determines appropriate.

18 **SEC. 442. ANALYSIS OF TELEHEALTH WAIVERS IN ALTER-**

19 **NATIVE PAYMENT MODELS.**

20 The second sentence of section 1115A(g) of the So-
21 cial Security Act (42 U.S.C. 1315a(g)) is amended by in-
22 serting “an analysis of waivers under section (d)(1) re-
23 lated to telehealth and the impact on quality and spending
24 under the applicable titles of such waivers,” after “sub-
25 section (c),”.

1 **SEC. 443. MODEL TO ALLOW ADDITIONAL HEALTH PROFES-**
2 **SIONALS TO FURNISH TELEHEALTH SERV-**
3 **ICES.**

4 Section 1115A(b)(2)(B) of the Social Security Act
5 (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the
6 end the following new clause:

7 “(xxviii) Allowing health professionals
8 who are not otherwise eligible under sec-
9 tion 1834(m) to furnish telehealth services
10 to furnish such services.”.

11 **SEC. 444. TESTING OF MODELS TO EXAMINE THE USE OF**
12 **TELEHEALTH UNDER THE MEDICARE PRO-**
13 **GRAM.**

14 Section 1115A(b)(2) of the Social Security Act (42
15 U.S.C. 1315a(b)(2)) is amended by adding at the end the
16 following new subparagraph:

17 “(D) TESTING MODELS TO EXAMINE USE
18 OF TELEHEALTH UNDER MEDICARE.—The Sec-
19 retary shall consider testing under this sub-
20 section models to examine the use of telehealth
21 under title XVIII.”.

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