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AN ACT

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, 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 “Elijah E. Cummings Lower Drug Costs Now Act”.

6 (b) TABLE OF CONTENTS.—The table of contents is
7 as follows:

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE NEGOTIATION

Sec. 101. Providing for lower prices for certain high-priced single source drugs.

Sec. 102. Selected drug manufacturer excise tax imposed during noncompliance periods.

Sec. 103. Fair Price Negotiation Implementation Fund.

TITLE II—MEDICARE PARTS B AND D PRESCRIPTION DRUG INFLATION REBATES

Sec. 201. Medicare part B rebate by manufacturers.

Sec. 202. Medicare part D rebate by manufacturers.

Sec. 203. Provision regarding inflation rebates for group health plans and group health insurance coverage.

Sec. 204. Annual report on drug costs in group health plans and group health insurance coverage.

Sec. 205. Collection of data.

TITLE III—PART D IMPROVEMENTS AND MAXIMUM OUT-OF- POCKET CAP FOR MEDICARE BENEFICIARIES

Sec. 301. Medicare part D benefit redesign.

Sec. 302. Allowing certain enrollees of prescription drugs plans and MA–PD plans under Medicare program to spread out cost-sharing under certain circumstances.

Sec. 303. Establishment of pharmacy quality measures under Medicare part D.

TITLE IV—DRUG PRICE TRANSPARENCY

Sec. 401. Drug price transparency.

TITLE V—PROGRAM IMPROVEMENTS FOR MEDICARE LOW- INCOME BENEFICIARIES

Sec. 501. Dissemination to Medicare part D subsidy eligible individuals of information comparing premiums of certain prescription drug plans.

Sec. 502. Providing for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA–PD plans.

Sec. 503. Expanding eligibility for low-income subsidies under part D of the Medicare program.

Sec. 504. Automatic eligibility of certain low-income territorial residents for premium and cost-sharing subsidies under the Medicare program; Sunset of enhanced allotment program.

Sec. 505. Automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program.

Sec. 506. Providing for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program.

Sec. 507. Reducing cost-sharing and other program improvements for low-income beneficiaries.

TITLE VI—PROVIDING FOR DENTAL, VISION, AND HEARING COVERAGE UNDER THE MEDICARE PROGRAM

- Sec. 601. Dental and oral health care.
- Sec. 602. Providing coverage for hearing care under the Medicare program.
- Sec. 603. Providing coverage for vision care under the Medicare program.

TITLE VII—NIH, FDA, AND OPIOIDS FUNDING

Subtitle A—Biomedical Innovation Expansion

- Sec. 701. NIH Innovation Initiatives.
- Sec. 702. NIH clinical trial.
- Sec. 703. Innovation Network.

Subtitle B—Investing in Safety and Innovation

- Sec. 711. Food and Drug Administration.
- Sec. 712. Study on high-risk, high-reward drugs.

Subtitle C—Opioid Epidemic Response

- Sec. 721. Opioid Epidemic Response Fund.
- Sec. 722. Substance Abuse and Mental Health Services Administration.
- Sec. 723. Centers for Disease Control and Prevention.
- Sec. 724. Food and Drug Administration.
- Sec. 725. National Institutes of Health.
- Sec. 726. Health Resources and Services Administration.
- Sec. 727. Administration for Children and Families.

Subtitle D—Reducing Administrative Costs and Burdens in Health Care

- Sec. 731. Reducing administrative costs and burdens in health care.

TITLE VIII—MISCELLANEOUS

- Sec. 801. Guaranteed issue of certain Medigap policies.
- Sec. 802. Reporting requirements for PDP sponsors regarding point-of-sale rejections under Medicare part D.
- Sec. 803. Providing access to annual Medicare notifications in multiple languages.
- Sec. 804. Temporary increase in Medicare part B payment for certain biosimilar biological products.
- Sec. 805. Waiving medicare coinsurance for colorectal cancer screening tests.
- Sec. 806. Medicare coverage of certain lymphedema compression treatment items.
- Sec. 807. Physician fee update.
- Sec. 808. Additional community health center funding.
- Sec. 809. Grants to improve trauma support services and mental health care for children and youth in educational settings.
- Sec. 810. Pathway to Health Careers Act.
- Sec. 811. Home Visiting to Reduce Maternal Mortality and Morbidity Act.
- Sec. 812. Addition of new measures based on access to biosimilar biological products to the 5-star rating system under medicare advantage.
- Sec. 813. Sense of Congress regarding the impact of the high cost of prescription drugs on communities of color and persons living in rural or sparsely populated areas of the United States.

Sec. 814. Regulations requiring direct-to-consumer advertisements for prescription drugs and biological products to include truthful and not misleading pricing information.

Sec. 815. Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.

Sec. 816. Graduate medical education improvements in rural and underserved communities.

1 TITLE I—LOWERING PRICES 2 THROUGH FAIR DRUG PRICE 3 NEGOTIATION

4 SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN 5 HIGH-PRICED SINGLE SOURCE DRUGS.

6 (a) PROGRAM TO LOWER PRICES FOR CERTAIN
7 HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
8 Social Security Act (42 U.S.C. 1301 et seq.) is amended
9 by adding at the end the following new part:

10 “PART E—FAIR PRICE NEGOTIATION PROGRAM 11 TO LOWER PRICES FOR CERTAIN HIGH- 12 PRICED SINGLE SOURCE DRUGS

13 “SEC. 1191. ESTABLISHMENT OF PROGRAM.

14 “(a) IN GENERAL.—The Secretary shall establish a
15 Fair Price Negotiation Program (in this part referred to
16 as the ‘program’). Under the program, with respect to
17 each price applicability period, the Secretary shall—

18 “(1) publish a list of selected drugs in accord-
19 ance with section 1192;

20 “(2) enter into agreements with manufacturers
21 of selected drugs with respect to such period, in ac-
22 cordance with section 1193;

1 “(3) negotiate and, if applicable, renegotiate
2 maximum fair prices for such selected drugs, in ac-
3 cordance with section 1194; and

4 “(4) carry out the administrative duties de-
5 scribed in section 1196.

6 “(b) DEFINITIONS RELATING TO TIMING.—For pur-
7 poses of this part:

8 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
9 term ‘initial price applicability year’ means a plan
10 year (beginning with plan year 2023) or, if agreed
11 to in an agreement under section 1193 by the Sec-
12 retary and manufacturer involved, a period of more
13 than one plan year (beginning on or after January
14 1, 2023).

15 “(2) PRICE APPLICABILITY PERIOD.—The term
16 ‘price applicability period’ means, with respect to a
17 drug, the period beginning with the initial price ap-
18 plicability year with respect to which such drug is a
19 selected drug and ending with the last plan year
20 during which the drug is a selected drug.

21 “(3) SELECTED DRUG PUBLICATION DATE.—
22 The term ‘selected drug publication date’ means,
23 with respect to each initial price applicability year,
24 April 15 of the plan year that begins 2 years prior
25 to such year.

1 “(4) VOLUNTARY NEGOTIATION PERIOD.—The
2 term ‘voluntary negotiation period’ means, with re-
3 spect to an initial price applicability year with re-
4 spect to a selected drug, the period—

5 “(A) beginning on the sooner of—

6 “(i) the date on which the manufac-
7 turer of the drug and the Secretary enter
8 into an agreement under section 1193 with
9 respect to such drug; or

10 “(ii) June 15 following the selected
11 drug publication date with respect to such
12 selected drug; and

13 “(B) ending on March 31 of the year that
14 begins one year prior to the initial price appli-
15 cability year.

16 “(c) OTHER DEFINITIONS.—For purposes of this
17 part:

18 “(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—The
19 term ‘fair price eligible individual’ means, with re-
20 spect to a selected drug—

21 “(A) in the case such drug is furnished or
22 dispensed to the individual at a pharmacy or by
23 a mail order service—

24 “(i) an individual who is enrolled
25 under a prescription drug plan under part

1 D of title XVIII or an MA–PD plan under
2 part C of such title if coverage is provided
3 under such plan for such selected drug;
4 and

5 “(ii) an individual who is enrolled
6 under a group health plan or health insur-
7 ance coverage offered in the group or indi-
8 vidual market (as such terms are defined
9 in section 2791 of the Public Health Serv-
10 ice Act) with respect to which there is in
11 effect an agreement with the Secretary
12 under section 1197 with respect to such se-
13 lected drug as so furnished or dispensed;
14 and

15 “(B) in the case such drug is furnished or
16 administered to the individual by a hospital,
17 physician, or other provider of services or sup-
18 plier—

19 “(i) an individual who is entitled to
20 benefits under part A of title XVIII or en-
21 rolled under part B of such title if such se-
22 lected drug is covered under the respective
23 part; and

24 “(ii) an individual who is enrolled
25 under a group health plan or health insur-

1 ance coverage offered in the group or indi-
2 vidual market (as such terms are defined
3 in section 2791 of the Public Health Serv-
4 ice Act) with respect to which there is in
5 effect an agreement with the Secretary
6 under section 1197 with respect to such se-
7 lected drug as so furnished or adminis-
8 tered.

9 “(2) MAXIMUM FAIR PRICE.—The term ‘max-
10 imum fair price’ means, with respect to a plan year
11 during a price applicability period and with respect
12 to a selected drug (as defined in section 1192(c))
13 with respect to such period, the price published pur-
14 suant to section 1195 in the Federal Register for
15 such drug and year.

16 “(3) AVERAGE INTERNATIONAL MARKET PRICE
17 DEFINED.—

18 “(A) IN GENERAL.—The terms ‘average
19 international market price’ and ‘AIM price’
20 mean, with respect to a drug, the average price
21 (which shall be the net average price, if prac-
22 ticable, and volume-weighted, if practicable) for
23 a unit (as defined in paragraph (4)) of the drug
24 for sales of such drug (calculated across dif-
25 ferent dosage forms and strengths of the drug

1 and not based on the specific formulation or
2 package size or package type), as computed (as
3 of the date of publication of such drug as a se-
4 lected drug under section 1192(a)) in all coun-
5 tries described in clause (ii) of subparagraph
6 (B) that are applicable countries (as described
7 in clause (i) of such subparagraph) with respect
8 to such drug.

9 “(B) APPLICABLE COUNTRIES.—

10 “(i) IN GENERAL.—For purposes of
11 subparagraph (A), a country described in
12 clause (ii) is an applicable country de-
13 scribed in this clause with respect to a
14 drug if there is available an average price
15 for any unit for the drug for sales of such
16 drug in such country.

17 “(ii) COUNTRIES DESCRIBED.—For
18 purposes of this paragraph, the following
19 are countries described in this clause:

20 “(I) Australia.

21 “(II) Canada.

22 “(III) France.

23 “(IV) Germany.

24 “(V) Japan.

25 “(VI) The United Kingdom.

1 “(4) UNIT.—The term ‘unit’ means, with re-
2 spect to a drug, the lowest identifiable quantity
3 (such as a capsule or tablet, milligram of molecules,
4 or grams) of the drug that is dispensed.

5 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
6 **AS SELECTED DRUGS.**

7 “(a) IN GENERAL.—Not later than the selected drug
8 publication date with respect to an initial price applica-
9 bility year, subject to subsection (h), the Secretary shall
10 select and publish in the Federal Register a list of—

11 “(1)(A) with respect to an initial price applica-
12 bility year during 2023, at least 25 negotiation-eligi-
13 ble drugs described in subparagraphs (A) and (B),
14 but not subparagraph (C), of subsection (d)(1) (or,
15 with respect to an initial price applicability year dur-
16 ing such period beginning after 2023, the maximum
17 number (if such number is less than 25) of such ne-
18 gotiation-eligible drugs for the year) with respect to
19 such year; and

20 “(B) with respect to an initial price applica-
21 bility year during 2024 or a subsequent year, at
22 least 50 negotiation-eligible drugs described in sub-
23 paragraphs (A) and (B), but not subparagraph (C),
24 of subsection (d)(1) (or, with respect to an initial
25 price applicability year during such period, the max-

1 imum number (if such number is less than 50) of
2 such negotiation-eligible drugs for the year) with re-
3 spect to such year;

4 “(2) all negotiation-eligible drugs described in
5 subparagraph (C) of such subsection with respect to
6 such year; and

7 “(3) all new-entrant negotiation-eligible drugs
8 (as defined in subsection (g)(1)) with respect to such
9 year.

10 Each drug published on the list pursuant to the previous
11 sentence shall be subject to the negotiation process under
12 section 1194 for the voluntary negotiation period with re-
13 spect to such initial price applicability year (and the re-
14 negotiation process under such section as applicable for
15 any subsequent year during the applicable price applica-
16 bility period). In applying this subsection, any negotiation-
17 eligible drug that is selected under this subsection for an
18 initial price applicability year shall not count toward the
19 required minimum amount of drugs to be selected under
20 paragraph (1) for any subsequent year, including such a
21 drug so selected that is subject to renegotiation under sec-
22 tion 1194.

23 “(b) SELECTION OF DRUGS.—In carrying out sub-
24 section (a)(1) the Secretary shall select for inclusion on
25 the published list described in subsection (a) with respect

1 to a price applicability period, the negotiation-eligible
2 drugs that the Secretary projects will result in the greatest
3 savings to the Federal Government or fair price eligible
4 individuals during the price applicability period. In making
5 this projection of savings for drugs for which there is an
6 AIM price for a price applicability period, the savings shall
7 be projected across different dosage forms and strengths
8 of the drugs and not based on the specific formulation or
9 package size or package type of the drugs, taking into con-
10 sideration both the volume of drugs for which payment
11 is made, to the extent such data is available, and the
12 amount by which the net price for the drugs exceeds the
13 AIM price for the drugs.

14 “(c) SELECTED DRUG.—For purposes of this part,
15 each drug included on the list published under subsection
16 (a) with respect to an initial price applicability year shall
17 be referred to as a ‘selected drug’ with respect to such
18 year and each subsequent plan year beginning before the
19 first plan year beginning after the date on which the Sec-
20 retary determines two or more drug products—

21 “(1) are approved or licensed (as applicable)—

22 “(A) under section 505(j) of the Federal
23 Food, Drug, and Cosmetic Act using such drug
24 as the listed drug; or

1 “(B) under section 351(k) of the Public
2 Health Service Act using such drug as the ref-
3 erence product; and

4 “(2) continue to be marketed.

5 “(d) NEGOTIATION-ELIGIBLE DRUG.—

6 “(1) IN GENERAL.—For purposes of this part,
7 the term ‘negotiation-eligible drug’ means, with re-
8 spect to the selected drug publication date with re-
9 spect to an initial price applicability year, a quali-
10 fying single source drug, as defined in subsection
11 (e), that meets any of the following criteria:

12 “(A) COVERED PART D DRUGS.—The drug
13 is among the 125 covered part D drugs (as de-
14 fined in section 1860D–2(e)) for which there
15 was an estimated greatest net spending under
16 parts C and D of title XVIII, as determined by
17 the Secretary, during the most recent plan year
18 prior to such drug publication date for which
19 data are available.

20 “(B) OTHER DRUGS.—The drug is among
21 the 125 drugs for which there was an estimated
22 greatest net spending in the United States (in-
23 cluding the 50 States, the District of Columbia,
24 and the territories of the United States), as de-
25 termined by the Secretary, during the most re-

1 cent plan year prior to such drug publication
2 date for which data are available.

3 “(C) INSULIN.—The drug is a qualifying
4 single source drug described in subsection
5 (e)(3).

6 “(2) CLARIFICATION.—In determining whether
7 a qualifying single source drug satisfies any of the
8 criteria described in paragraph (1), the Secretary
9 shall, to the extent practicable, use data that is ag-
10 gregated across dosage forms and strengths of the
11 drug and not based on the specific formulation or
12 package size or package type of the drug.

13 “(3) PUBLICATION.—Not later than the se-
14 lected drug publication date with respect to an ini-
15 tial price applicability year, the Secretary shall pub-
16 lish in the Federal Register a list of negotiation-eli-
17 gible drugs with respect to such selected drug publi-
18 cation date.

19 “(e) QUALIFYING SINGLE SOURCE DRUG.—For pur-
20 poses of this part, the term ‘qualifying single source drug’
21 means any of the following:

22 “(1) DRUG PRODUCTS.—A drug that—

23 “(A) is approved under section 505(c) of
24 the Federal Food, Drug, and Cosmetic Act and

1 continues to be marketed pursuant to such ap-
2 proval; and

3 “(B) is not the listed drug for any drug
4 that is approved and continues to be marketed
5 under section 505(j) of such Act.

6 “(2) BIOLOGICAL PRODUCTS.—A biological
7 product that—

8 “(A) is licensed under section 351(a) of
9 the Public Health Service Act, including any
10 product that has been deemed to be licensed
11 under section 351 of such Act pursuant to sec-
12 tion 7002(e)(4) of the Biologics Price Competi-
13 tion and Innovation Act of 2009, and continues
14 to be marketed under section 351 of such Act;
15 and

16 “(B) is not the reference product for any
17 biological product that is licensed and continues
18 to be marketed under section 351(k) of such
19 Act.

20 “(3) INSULIN PRODUCT.—Notwithstanding
21 paragraphs (1) and (2), any insulin product that is
22 approved under subsection (c) or (j) of section 505
23 of the Federal Food, Drug, and Cosmetic Act or li-
24 censed under subsection (a) or (k) of section 351 of
25 the Public Health Service Act and continues to be

1 marketed under such section 505 or 351, including
2 any insulin product that has been deemed to be li-
3 censed under section 351(a) of the Public Health
4 Service Act pursuant to section 7002(e)(4) of the
5 Biologics Price Competition and Innovation Act of
6 2009 and continues to be marketed pursuant to such
7 licensure.

8 For purposes of applying paragraphs (1) and (2), a drug
9 or biological product that is marketed by the same sponsor
10 or manufacturer (or an affiliate thereof or a cross-licensed
11 producer or distributor) as the listed drug or reference
12 product described in such respective paragraph shall not
13 be taken into consideration.

14 “(f) INFORMATION ON INTERNATIONAL DRUG
15 PRICES.—For purposes of determining which negotiation-
16 eligible drugs to select under subsection (a) and, in the
17 case of such drugs that are selected drugs, to determine
18 the maximum fair price for such a drug and whether such
19 maximum fair price should be renegotiated under section
20 1194, the Secretary shall use data relating to the AIM
21 price with respect to such drug as available or provided
22 to the Secretary and shall on an ongoing basis request
23 from manufacturers of selected drugs information on the
24 AIM price of such a drug.

1 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE
2 DRUGS.—

3 “(1) IN GENERAL.—For purposes of this part,
4 the term ‘new-entrant negotiation-eligible drug’
5 means, with respect to the selected drug publication
6 date with respect to an initial price applicability
7 year, a qualifying single source drug—

8 “(A) that is first approved or licensed, as
9 described in paragraph (1), (2), or (3) of sub-
10 section (e), as applicable, during the year pre-
11 ceding such selected drug publication date; and

12 “(B) that the Secretary determines under
13 paragraph (2) is likely to be included as a nego-
14 tiation-eligible drug with respect to the subse-
15 quent selected drug publication date.

16 “(2) DETERMINATION.—In the case of a quali-
17 fying single source drug that meets the criteria de-
18 scribed in subparagraph (A) of paragraph (1), with
19 respect to an initial price applicability year, if the
20 wholesale acquisition cost at which such drug is first
21 marketed in the United States is equal to or greater
22 than the median household income (as determined
23 according to the most recent data collected by the
24 United States Census Bureau), the Secretary shall
25 determine before the selected drug publication date

1 with respect to the initial price applicability year, if
2 the drug is likely to be included as a negotiation-eli-
3 gible drug with respect to the subsequent selected
4 drug publication date, based on the projected spend-
5 ing under title XVIII or in the United States on
6 such drug. For purposes of this paragraph the term
7 ‘United States’ includes the 50 States, the District
8 of Columbia, and the territories of the United
9 States.

10 “(h) CONFLICT OF INTEREST.—

11 “(1) IN GENERAL.—In the case the Inspector
12 General of the Department of Health and Human
13 Services determines the Secretary has a conflict,
14 with respect to a matter described in paragraph (2),
15 the individual described in paragraph (3) shall carry
16 out the duties of the Secretary under this part, with
17 respect to a negotiation-eligible drug, that would
18 otherwise be such a conflict.

19 “(2) MATTER DESCRIBED.—A matter described
20 in this paragraph is—

21 “(A) a financial interest (as described in
22 section 2635.402 of title 5, Code of Federal
23 Regulations (except for an interest described in
24 subsection (b)(2)(iv) of such section)) on the
25 date of the selected drug publication date, with

1 respect the price applicability year (as applica-
2 ble);

3 “(B) a personal or business relationship
4 (as described in section 2635.502 of such title)
5 on the date of the selected drug publication
6 date, with respect the price applicability year;

7 “(C) employment by a manufacturer of a
8 negotiation-eligible drug during the preceding
9 10-year period beginning on the date of the se-
10 lected drug publication date, with respect to
11 each price applicability year; and

12 “(D) any other matter the General Counsel
13 determines appropriate.

14 “(3) INDIVIDUAL DESCRIBED.—An individual
15 described in this paragraph is—

16 “(A) the highest-ranking officer or em-
17 ployee of the Department of Health and
18 Human Services (as determined by the organi-
19 zational chart of the Department) that does not
20 have a conflict under this subsection; and

21 “(B) is nominated by the President and
22 confirmed by the Senate with respect to the po-
23 sition.

1 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

2 “(a) IN GENERAL.—For purposes of section
3 1191(a)(2), the Secretary shall enter into agreements with
4 manufacturers of selected drugs with respect to a price
5 applicability period, by not later than June 15 following
6 the selected drug publication date with respect to such se-
7 lected drug, under which—

8 “(1) during the voluntary negotiation period for
9 the initial price applicability year for the selected
10 drug, the Secretary and manufacturer, in accordance
11 with section 1194, negotiate to determine (and, by
12 not later than the last date of such period and in ac-
13 cordance with subsection (c), agree to) a maximum
14 fair price for such selected drug of the manufacturer
15 in order to provide access to such price—

16 “(A) to fair price eligible individuals who
17 with respect to such drug are described in sub-
18 paragraph (A) of section 1191(c)(1) and are
19 furnished or dispensed such drug during, sub-
20 ject to subparagraph (2), the price applicability
21 period; and

22 “(B) to hospitals, physicians, and other
23 providers of services and suppliers with respect
24 to fair price eligible individuals who with re-
25 spect to such drug are described in subpara-
26 graph (B) of such section and are furnished or

1 administered such drug during, subject to sub-
2 paragraph (2), the price applicability period;

3 “(2) the Secretary and the manufacturer shall,
4 in accordance with a process and during a period
5 specified by the Secretary pursuant to rulemaking,
6 renegotiate (and, by not later than the last date of
7 such period and in accordance with subsection (c),
8 agree to) the maximum fair price for such drug if
9 the Secretary determines that there is a material
10 change in any of the factors described in section
11 1194(d) relating to the drug, including changes in
12 the AIM price for such drug, in order to provide ac-
13 cess to such maximum fair price (as so renegoti-
14 ated)—

15 “(A) to fair price eligible individuals who
16 with respect to such drug are described in sub-
17 paragraph (A) of section 1191(c)(1) and are
18 furnished or dispensed such drug during any
19 year during the price applicability period (be-
20 ginning after such renegotiation) with respect
21 to such selected drug; and

22 “(B) to hospitals, physicians, and other
23 providers of services and suppliers with respect
24 to fair price eligible individuals who with re-
25 spect to such drug are described in subpara-

1 graph (B) of such section and are furnished or
2 administered such drug during any year de-
3 scribed in subparagraph (A);

4 “(3) the maximum fair price (including as re-
5 negotiated pursuant to paragraph (2)), with respect
6 to such a selected drug, shall be provided to fair
7 price eligible individuals, who with respect to such
8 drug are described in subparagraph (A) of section
9 1191(c)(1), at the pharmacy or by a mail order serv-
10 ice at the point-of-sale of such drug;

11 “(4) the manufacturer, subject to subsection
12 (d), submits to the Secretary, in a form and manner
13 specified by the Secretary—

14 “(A) for the voluntary negotiation period
15 for the price applicability period (and, if appli-
16 cable, before any period of renegotiation speci-
17 fied pursuant to paragraph (2)) with respect to
18 such drug all information that the Secretary re-
19 quires to carry out the negotiation (or renegoti-
20 ation process) under this part, including infor-
21 mation described in section 1192(f) and section
22 1194(d)(1); and

23 “(B) on an ongoing basis, information on
24 changes in prices for such drug that would af-
25 fect the AIM price for such drug or otherwise

1 provide a basis for renegotiation of the max-
2 imum fair price for such drug pursuant to
3 paragraph (2);

4 “(5) the manufacturer agrees that in the case
5 the selected drug of a manufacturer is a drug de-
6 scribed in subsection (c), the manufacturer will, in
7 accordance with such subsection, make any payment
8 required under such subsection with respect to such
9 drug; and

10 “(6) the manufacturer complies with require-
11 ments imposed by the Secretary for purposes of ad-
12 ministering the program, including with respect to
13 the duties described in section 1196.

14 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO
15 LONGER A SELECTED DRUG.—An agreement entered into
16 under this section shall be effective, with respect to a drug,
17 until such drug is no longer considered a selected drug
18 under section 1192(c).

19 “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS
20 WITHOUT AIM PRICE.—

21 “(1) IN GENERAL.—In the case of a selected
22 drug for which there is no AIM price available with
23 respect to the initial price applicability year for such
24 drug and for which an AIM price becomes available
25 beginning with respect to a subsequent plan year

1 during the price applicability period for such drug,
2 if the Secretary determines that the amount de-
3 scribed in paragraph (2)(A) for a unit of such drug
4 is greater than the amount described in paragraph
5 (2)(B) for a unit of such drug, then by not later
6 than one year after the date of such determination,
7 the manufacturer of such selected drug shall pay to
8 the Treasury an amount equal to the product of—

9 “(A) the difference between such amount
10 described in paragraph (2)(A) for a unit of
11 such drug and such amount described in para-
12 graph (2)(B) for a unit of such drug; and

13 “(B) the number of units of such drug sold
14 in the United States, including the 50 States,
15 the District of Columbia, and the territories of
16 the United States, during the period described
17 in paragraph (2)(B).

18 “(2) AMOUNTS DESCRIBED.—

19 “(A) WEIGHTED AVERAGE PRICE BEFORE
20 AIM PRICE AVAILABLE.—For purposes of para-
21 graph (1), the amount described in this sub-
22 paragraph for a selected drug described in such
23 paragraph, is the amount equal to the weighted
24 average manufacturer price (as defined in sec-
25 tion 1927(k)(1)) for such dosage strength and

1 form for the drug during the period beginning
2 with the first plan year for which the drug is
3 included on the list of negotiation-eligible drugs
4 published under section 1192(d) and ending
5 with the last plan year during the price applica-
6 bility period for such drug with respect to which
7 there is no AIM price available for such drug.

8 “(B) AMOUNT MULTIPLIER AFTER AIM
9 PRICE AVAILABLE.—For purposes of paragraph
10 (1), the amount described in this subparagraph
11 for a selected drug described in such paragraph,
12 is the amount equal to 200 percent of the AIM
13 price for such drug with respect to the first
14 plan year during the price applicability period
15 for such drug with respect to which there is an
16 AIM price available for such drug.

17 “(d) CONFIDENTIALITY OF INFORMATION.—Infor-
18 mation submitted to the Secretary under this part by a
19 manufacturer of a selected drug that is proprietary infor-
20 mation of such manufacturer (as determined by the Sec-
21 retary) may be used only by the Secretary or disclosed
22 to and used by the Comptroller General of the United
23 States or the Medicare Payment Advisory Commission for
24 purposes of carrying out this part.

25 “(e) REGULATIONS.—

1 “(1) IN GENERAL.—The Secretary shall, pursu-
2 ant to rulemaking, specify, in accordance with para-
3 graph (2), the information that must be submitted
4 under subsection (a)(4).

5 “(2) INFORMATION SPECIFIED.—Information
6 described in paragraph (1), with respect to a se-
7 lected drug, shall include information on sales of the
8 drug (by the manufacturer of the drug or by another
9 entity under license or other agreement with the
10 manufacturer, with respect to the sales of such drug,
11 regardless of the name under which the drug is sold)
12 in any foreign country that is part of the AIM price.
13 The Secretary shall verify, to the extent practicable,
14 such sales from appropriate officials of the govern-
15 ment of the foreign country involved.

16 “(f) COMPLIANCE WITH REQUIREMENTS FOR AD-
17 MINISTRATION OF PROGRAM.—Each manufacturer with
18 an agreement in effect under this section shall comply with
19 requirements imposed by the Secretary or a third party
20 with a contract under section 1196(c)(1), as applicable,
21 for purposes of administering the program.

22 **“SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.**

23 “(a) IN GENERAL.—For purposes of this part, under
24 an agreement under section 1193 between the Secretary
25 and a manufacturer of a selected drug, with respect to

1 the period for which such agreement is in effect and in
2 accordance with subsections (b) and (c), the Secretary and
3 the manufacturer—

4 “(1) shall during the voluntary negotiation pe-
5 riod with respect to the initial price applicability
6 year for such drug, in accordance with this section,
7 negotiate a maximum fair price for such drug for
8 the purpose described in section 1193(a)(1); and

9 “(2) as applicable pursuant to section
10 1193(a)(2) and in accordance with the process speci-
11 fied pursuant to such section, renegotiate such max-
12 imum fair price for such drug for the purpose de-
13 scribed in such section.

14 “(b) NEGOTIATING METHODOLOGY AND OBJEC-
15 TIVE.—

16 “(1) IN GENERAL.—The Secretary shall develop
17 and use a consistent methodology for negotiations
18 under subsection (a) that, in accordance with para-
19 graph (2) and subject to paragraph (3), achieves the
20 lowest maximum fair price for each selected drug
21 while appropriately rewarding innovation.

22 “(2) PRIORITIZING FACTORS.—In considering
23 the factors described in subsection (d) in negotiating
24 (and, as applicable, renegotiating) the maximum fair
25 price for a selected drug, the Secretary shall, to the

1 extent practicable, consider all of the available fac-
2 tors listed but shall prioritize the following factors:

3 “(A) RESEARCH AND DEVELOPMENT
4 COSTS.—The factor described in paragraph
5 (1)(A) of subsection (d).

6 “(B) MARKET DATA.—The factor de-
7 scribed in paragraph (1)(B) of such subsection.

8 “(C) UNIT COSTS OF PRODUCTION AND
9 DISTRIBUTION.—The factor described in para-
10 graph (1)(C) of such subsection.

11 “(D) COMPARISON TO EXISTING THERA-
12 PEUTIC ALTERNATIVES.—The factor described
13 in paragraph (2)(A) of such subsection.

14 “(3) REQUIREMENT.—

15 “(A) IN GENERAL.—In negotiating the
16 maximum fair price of a selected drug, with re-
17 spect to an initial price applicability year for
18 the selected drug, and, as applicable, in renego-
19 tiating the maximum fair price for such drug,
20 with respect to a subsequent year during the
21 price applicability period for such drug, in the
22 case that the manufacturer of the selected drug
23 offers under the negotiation or renegotiation, as
24 applicable, a price for such drug that is not
25 more than the target price described in sub-

1 paragraph (B) for such drug for the respective
2 year, the Secretary shall agree under such ne-
3 gotiation or renegotiation, respectively, to such
4 offered price as the maximum fair price.

5 “(B) TARGET PRICE.—

6 “(i) IN GENERAL.—Subject to clause
7 (ii), the target price described in this sub-
8 paragraph for a selected drug with respect
9 to a year, is the average price (which shall
10 be the net average price, if practicable, and
11 volume-weighted, if practicable) for a unit
12 of such drug for sales of such drug, as
13 computed (across different dosage forms
14 and strengths of the drug and not based
15 on the specific formulation or package size
16 or package type of the drug) in the appli-
17 cable country described in section
18 1191(c)(3)(B) with respect to such drug
19 that, with respect to such year, has the
20 lowest average price for such drug as com-
21 pared to the average prices (as so com-
22 puted) of such drug with respect to such
23 year in the other applicable countries de-
24 scribed in such section with respect to such
25 drug.

1 “(ii) SELECTED DRUGS WITHOUT AIM
2 PRICE.—In applying this paragraph in the
3 case of negotiating the maximum fair price
4 of a selected drug for which there is no
5 AIM price available with respect to the ini-
6 tial price applicability year for such drug,
7 or, as applicable, renegotiating the max-
8 imum fair price for such drug with respect
9 to a subsequent year during the price ap-
10 plicability period for such drug before the
11 first plan year for which there is an AIM
12 price available for such drug, the target
13 price described in this subparagraph for
14 such drug and respective year is the
15 amount that is 80 percent of the average
16 manufacturer price (as defined in section
17 1927(k)(1)) for such drug and year.

18 “(4) ANNUAL REPORT.—After the completion
19 of each voluntary negotiation period, the Secretary
20 shall submit to Congress a report on the maximum
21 fair prices negotiated (or, as applicable, renegoti-
22 ated) for such period. Such report shall include in-
23 formation on how such prices so negotiated (or re-
24 negotiated) meet the requirements of this part, in-
25 cluding the requirements of this subsection.

1 “(c) LIMITATION.—

2 “(1) IN GENERAL.—Subject to paragraph (2),
3 the maximum fair price negotiated (including as re-
4 negotiated) under this section for a selected drug,
5 with respect to each plan year during a price appli-
6 cability period for such drug, shall not exceed 120
7 percent of the AIM price applicable to such drug
8 with respect to such year.

9 “(2) SELECTED DRUGS WITHOUT AIM PRICE.—

10 In the case of a selected drug for which there is no
11 AIM price available with respect to the initial price
12 applicability year for such drug, for each plan year
13 during the price applicability period before the first
14 plan year for which there is an AIM price available
15 for such drug, the maximum fair price negotiated
16 (including as renegotiated) under this section for the
17 selected drug shall not exceed the amount equal to
18 85 percent of the average manufacturer price for the
19 drug with respect to such year.

20 “(d) CONSIDERATIONS.—For purposes of negotiating
21 and, as applicable, renegotiating (including for purposes
22 of determining whether to renegotiate) the maximum fair
23 price of a selected drug under this part with the manufac-
24 turer of the drug, the Secretary, consistent with sub-
25 section (b)(2), shall take into consideration the factors de-

1 scribed in paragraphs (1), (2), (3), and (5), and may take
2 into consideration the factor described in paragraph (4):

3 “(1) MANUFACTURER-SPECIFIC INFORMA-
4 TION.—The following information, including as sub-
5 mitted by the manufacturer:

6 “(A) Research and development costs of
7 the manufacturer for the drug and the extent to
8 which the manufacturer has recouped research
9 and development costs.

10 “(B) Market data for the drug, including
11 the distribution of sales across different pro-
12 grams and purchasers and projected future rev-
13 enues for the drug.

14 “(C) Unit costs of production and distribu-
15 tion of the drug.

16 “(D) Prior Federal financial support for
17 novel therapeutic discovery and development
18 with respect to the drug.

19 “(E) Data on patents and on existing and
20 pending exclusivity for the drug.

21 “(F) National sales data for the drug.

22 “(G) Information on clinical trials for the
23 drug in the United States or in applicable coun-
24 tries described in section 1191(c)(3)(B).

1 “(2) INFORMATION ON ALTERNATIVE PROD-
2 UCTS.—The following information:

3 “(A) The extent to which the drug rep-
4 resents a therapeutic advance as compared to
5 existing therapeutic alternatives and, to the ex-
6 tent such information is available, the costs of
7 such existing therapeutic alternatives.

8 “(B) Information on approval by the Food
9 and Drug Administration of alternative drug
10 products.

11 “(C) Information on comparative effective-
12 ness analysis for such products, taking into
13 consideration the effects of such products on
14 specific populations, such as individuals with
15 disabilities, the elderly, terminally ill, children,
16 and other patient populations.

17 In considering information described in subpara-
18 graph (C), the Secretary shall not use evidence or
19 findings from comparative clinical effectiveness re-
20 search in a manner that treats extending the life of
21 an elderly, disabled, or terminally ill individual as of
22 lower value than extending the life of an individual
23 who is younger, nondisabled, or not terminally ill.
24 Nothing in the previous sentence shall affect the ap-

1 publication or consideration of an AIM price for a se-
2 lected drug.

3 “(3) FOREIGN SALES INFORMATION.—To the
4 extent available on a timely basis, including as pro-
5 vided by a manufacturer of the selected drug or oth-
6 erwise, information on sales of the selected drug in
7 each of the countries described in section
8 1191(c)(3)(B).

9 “(4) VA DRUG PRICING INFORMATION.—Infor-
10 mation disclosed to the Secretary pursuant to sub-
11 section (f).

12 “(5) ADDITIONAL INFORMATION.—Information
13 submitted to the Secretary, in accordance with a
14 process specified by the Secretary, by other parties
15 that are affected by the establishment of a maximum
16 fair price for the selected drug.

17 “(e) REQUEST FOR INFORMATION.—For purposes of
18 negotiating and, as applicable, renegotiating (including for
19 purposes of determining whether to renegotiate) the max-
20 imum fair price of a selected drug under this part with
21 the manufacturer of the drug, with respect to a price ap-
22 plicability period, and other relevant data for purposes of
23 this section—

24 “(1) the Secretary shall, not later than the se-
25 lected drug publication date with respect to the ini-

1 tial price applicability year of such period, request
2 drug pricing information from the manufacturer of
3 such selected drug, including information described
4 in subsection (d)(1); and

5 “(2) by not later than October 1 following the
6 selected drug publication date, the manufacturer of
7 such selected drug shall submit to the Secretary
8 such requested information in such form and man-
9 ner as the Secretary may require.

10 The Secretary shall request, from the manufacturer or
11 others, such additional information as may be needed to
12 carry out the negotiation and renegotiation process under
13 this section.

14 “(f) DISCLOSURE OF INFORMATION.—For purposes
15 of this part, the Secretary of Veterans Affairs may disclose
16 to the Secretary of Health and Human Services the price
17 of any negotiation-eligible drug that is purchased pursuant
18 to section 8126 of title 38, United States Code.

19 **“SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.**

20 “(a) IN GENERAL.—With respect to an initial price
21 applicability year and selected drug with respect to such
22 year, not later than April 1 of the plan year prior to such
23 initial price applicability year, the Secretary shall publish
24 in the Federal Register the maximum fair price for such

1 drug negotiated under this part with the manufacturer of
2 such drug.

3 “(b) UPDATES.—

4 “(1) SUBSEQUENT YEAR MAXIMUM FAIR
5 PRICES.—For a selected drug, for each plan year
6 subsequent to the initial price applicability year for
7 such drug with respect to which an agreement for
8 such drug is in effect under section 1193, the Sec-
9 retary shall publish in the Federal Register—

10 “(A) subject to subparagraph (B), the
11 amount equal to the maximum fair price pub-
12 lished for such drug for the previous year, in-
13 creased by the annual percentage increase in
14 the consumer price index for all urban con-
15 sumers (all items; U.S. city average) as of Sep-
16 tember of such previous year; or

17 “(B) in the case the maximum fair price
18 for such drug was renegotiated, for the first
19 year for which such price as so renegotiated ap-
20 plies, such renegotiated maximum fair price.

21 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

22 In the case of a selected drug with respect to an ini-
23 tial price applicability year for which the maximum
24 fair price is determined under this part after the
25 date of publication under this section, the Secretary

1 shall publish such maximum fair price in the Fed-
2 eral Register by not later than 30 days after the
3 date such maximum price is so determined.

4 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
5 **VISIONS.**

6 “(a) ADMINISTRATIVE DUTIES.—

7 “(1) IN GENERAL.—For purposes of section
8 1191, the administrative duties described in this sec-
9 tion are the following:

10 “(A) The establishment of procedures (in-
11 cluding through agreements with manufacturers
12 under this part, contracts with prescription
13 drug plans under part D of title XVIII and
14 MA–PD plans under part C of such title, and
15 agreements under section 1197 with group
16 health plans and health insurance issuers of
17 health insurance coverage offered in the indi-
18 vidual or group market) under which the max-
19 imum fair price for a selected drug is provided
20 to fair price eligible individuals, who with re-
21 spect to such drug are described in subpara-
22 graph (A) of section 1191(c)(1), at pharmacies
23 or by mail order service at the point-of-sale of
24 the drug for the applicable price period for such
25 drug and providing that such maximum fair

1 price is used for determining cost-sharing under
2 such plans or coverage for the selected drug.

3 “(B) The establishment of procedures (in-
4 cluding through agreements with manufacturers
5 under this part and contracts with hospitals,
6 physicians, and other providers of services and
7 suppliers and agreements under section 1197
8 with group health plans and health insurance
9 issuers of health insurance coverage offered in
10 the individual or group market) under which, in
11 the case of a selected drug furnished or admin-
12 istered by such a hospital, physician, or other
13 provider of services or supplier to fair price eli-
14 gible individuals (who with respect to such drug
15 are described in subparagraph (B) of section
16 1191(c)(1)), the maximum fair price for the se-
17 lected drug is provided to such hospitals, physi-
18 cians, and other providers of services and sup-
19 pliers (as applicable) with respect to such indi-
20 viduals and providing that such maximum fair
21 price is used for determining cost-sharing under
22 the respective part, plan, or coverage for the se-
23 lected drug.

24 “(C) The establishment of procedures (in-
25 cluding through agreements and contracts de-

scribed in subparagraphs (A) and (B)) to ensure that, not later than 90 days after the dispensing of a selected drug to a fair price eligible individual by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

“(i) the lesser of—

“(I) the wholesale acquisition cost of the drug;

“(II) the national average drug acquisition cost of the drug; and

“(III) any other similar determination of pharmacy acquisition costs of the drug, as determined by the Secretary; and

“(ii) the maximum fair price for the drug.

“(D) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

“(i) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provi-

1 sion of prescription drug coverage on be-
2 half of fair price eligible individuals as the
3 Secretary may specify; and

4 “(ii) any other discounts.

5 “(E) The establishment of procedures to
6 enter into appropriate agreements and protocols
7 for the ongoing computation of AIM prices for
8 selected drugs, including, to the extent possible,
9 to compute the AIM price for selected drugs
10 and including by providing that the manufac-
11 turer of such a selected drug should provide in-
12 formation for such computation not later than
13 3 months after the first date of the voluntary
14 negotiation period for such selected drug.

15 “(F) The establishment of procedures to
16 compute and apply the maximum fair price
17 across different strengths and dosage forms of
18 a selected drug and not based on the specific
19 formulation or package size or package type of
20 the drug.

21 “(G) The establishment of procedures to
22 negotiate and apply the maximum fair price in
23 a manner that does not include any dispensing
24 or similar fee.

1 “(H) The establishment of procedures to
2 carry out the provisions of this part, as applica-
3 ble, with respect to—

4 “(i) fair price eligible individuals who
5 are enrolled under a prescription drug plan
6 under part D of title XVIII or an MA–PD
7 plan under part C of such title;

8 “(ii) fair price eligible individuals who
9 are enrolled under a group health plan or
10 health insurance coverage offered by a
11 health insurance issuer in the individual or
12 group market with respect to which there
13 is an agreement in effect under section
14 1197; and

15 “(iii) fair price eligible individuals who
16 are entitled to benefits under part A of
17 title XVIII or enrolled under part B of
18 such title.

19 “(I) The establishment of a negotiation
20 process and renegotiation process in accordance
21 with section 1194, including a process for ac-
22 quiring information described in subsection (d)
23 of such section and determining amounts de-
24 scribed in subsection (b) of such section.

1 “(J) The provision of a reasonable dispute
2 resolution mechanism to resolve disagreements
3 between manufacturers, fair price eligible indi-
4 viduals, and the third party with a contract
5 under subsection (c)(1).

6 “(2) MONITORING COMPLIANCE.—

7 “(A) IN GENERAL.—The Secretary shall
8 monitor compliance by a manufacturer with the
9 terms of an agreement under section 1193, in-
10 cluding by establishing a mechanism through
11 which violations of such terms may be reported.

12 “(B) NOTIFICATION.—If a third party
13 with a contract under subsection (c)(1) deter-
14 mines that the manufacturer is not in compli-
15 ance with such agreement, the third party shall
16 notify the Secretary of such noncompliance for
17 appropriate enforcement under section 4192 of
18 the Internal Revenue Code of 1986 or section
19 1198, as applicable.

20 “(b) COLLECTION OF DATA.—

21 “(1) FROM PRESCRIPTION DRUG PLANS AND
22 MA–PD PLANS.—The Secretary may collect appro-
23 priate data from prescription drug plans under part
24 D of title XVIII and MA–PD plans under part C of
25 such title in a timeframe that allows for maximum

1 fair prices to be provided under this part for selected
2 drugs.

3 “(2) FROM HEALTH PLANS.—The Secretary
4 may collect appropriate data from group health
5 plans or health insurance issuers offering group or
6 individual health insurance coverage in a timeframe
7 that allows for maximum fair prices to be provided
8 under this part for selected drugs.

9 “(3) COORDINATION OF DATA COLLECTION.—
10 To the extent feasible, as determined by the Sec-
11 retary, the Secretary shall ensure that data collected
12 pursuant to this subsection is coordinated with, and
13 not duplicative of, other Federal data collection ef-
14 forts.

15 “(c) CONTRACT WITH THIRD PARTIES.—

16 “(1) IN GENERAL.—The Secretary may enter
17 into a contract with 1 or more third parties to ad-
18 minister the requirements established by the Sec-
19 retary in order to carry out this part. At a min-
20 imum, the contract with a third party under the pre-
21 ceding sentence shall require that the third party—

22 “(A) receive and transmit information be-
23 tween the Secretary, manufacturers, and other
24 individuals or entities the Secretary determines
25 appropriate;

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

6 “(C) provide adequate and timely informa-
7 tion to manufacturers, consistent with the
8 agreement with the manufacturer under this
9 part, as necessary for the manufacturer to ful-
10 fill its obligations under this part; and

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

16 “(2) PERFORMANCE REQUIREMENTS.—The
17 Secretary shall establish performance requirements
18 for a third party with a contract under paragraph
19 (1) and safeguards to protect the independence and
20 integrity of the activities carried out by the third
21 party under the program under this part.

22 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
23 **HEALTH PLANS.**

24 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-
25 GRAM.—

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 under the program under this part the Secretary
3 shall be treated as having in effect an agreement
4 with a group health plan or health insurance issuer
5 offering group or individual health insurance cov-
6 erage (as such terms are defined in section 2791 of
7 the Public Health Service Act), with respect to a
8 price applicability period and a selected drug with
9 respect to such period—

10 “(A) with respect to such selected drug
11 furnished or dispensed at a pharmacy or by
12 mail order service if coverage is provided under
13 such plan or coverage during such period for
14 such selected drug as so furnished or dispensed;
15 and

16 “(B) with respect to such selected drug
17 furnished or administered by a hospital, physi-
18 cian, or other provider of services or supplier if
19 coverage is provided under such plan or cov-
20 erage during such period for such selected drug
21 as so furnished or administered.

22 “(2) OPTING OUT OF AGREEMENT.—The Sec-
23 retary shall not be treated as having in effect an
24 agreement under the program under this part with
25 a group health plan or health insurance issuer offer-

1 ing group or individual health insurance coverage
2 with respect to a price applicability period and a se-
3 lected drug with respect to such period if such a
4 plan or issuer affirmatively elects, through a process
5 specified by the Secretary, not to participate under
6 the program with respect to such period and drug.

7 “(b) PUBLICATION OF ELECTION.—With respect to
8 each price applicability period and each selected drug with
9 respect to such period, the Secretary and the Secretary
10 of Labor and the Secretary of the Treasury, as applicable,
11 shall make public a list of each group health plan and each
12 health insurance issuer offering group or individual health
13 insurance coverage, with respect to which coverage is pro-
14 vided under such plan or coverage for such drug, that has
15 elected under subsection (a) not to participate under the
16 program with respect to such period and drug.

17 **“SEC. 1198. CIVIL MONETARY PENALTY.**

18 “(a) VIOLATIONS RELATING TO OFFERING OF MAX-
19 IMUM FAIR PRICE.—Any manufacturer of a selected drug
20 that has entered into an agreement under section 1193,
21 with respect to a plan year during the price applicability
22 period for such drug, that does not provide access to a
23 price that is not more than the maximum fair price (or
24 a lesser price) for such drug for such year—

1 “(1) to a fair price eligible individual who with
2 respect to such drug is described in subparagraph
3 (A) of section 1191(c)(1) and who is furnished or
4 dispensed such drug during such year; or

5 “(2) to a hospital, physician, or other provider
6 of services or supplier with respect to fair price eligi-
7 ble individuals who with respect to such drug is de-
8 scribed in subparagraph (B) of such section and is
9 furnished or administered such drug by such hos-
10 pital, physician, or provider or supplier during such
11 year;

12 shall be subject to a civil monetary penalty equal to ten
13 times the amount equal to the difference between the price
14 for such drug made available for such year by such manu-
15 facturer with respect to such individual or hospital, physi-
16 cian, provider, or supplier and the maximum fair price for
17 such drug for such year.

18 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
19 MENT.—Any manufacturer of a selected drug that has en-
20 tered into an agreement under section 1193, with respect
21 to a plan year during the price applicability period for
22 such drug, that is in violation of a requirement imposed
23 pursuant to section 1193(a)(6) shall be subject to a civil
24 monetary penalty of not more than \$1,000,000 for each
25 such violation.

1 “(c) APPLICATION.—The provisions of section 1128A
2 (other than subsections (a) and (b)) shall apply to a civil
3 monetary penalty under this section in the same manner
4 as such provisions apply to a penalty or proceeding under
5 section 1128A(a).

6 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

7 “(a) PAPERWORK REDUCTION ACT.—Chapter 35 of
8 title 44, United States Code, shall not apply to data col-
9 lected under this part.

10 “(b) NATIONAL ACADEMY OF MEDICINE STUDY.—
11 Not later than December 31, 2025, the National Academy
12 of Medicine shall conduct a study, and submit to Congress
13 a report, on recommendations for improvements to the
14 program under this part, including the determination of
15 the limits applied under section 1194(c).

16 “(c) MEDPAC STUDY.—Not later than December 31,
17 2025, the Medicare Payment Advisory Commission shall
18 conduct a study, and submit to Congress a report, on the
19 program under this part with respect to the Medicare pro-
20 gram under title XVIII, including with respect to the ef-
21 fect of the program on individuals entitled to benefits or
22 enrolled under such title.

23 “(d) LIMITATION ON JUDICIAL REVIEW.—The fol-
24 lowing shall not be subject to judicial review:

1 “(1) The selection of drugs for publication
2 under section 1192(a).

3 “(2) The determination of whether a drug is a
4 negotiation-eligible drug under section 1192(d).

5 “(3) The determination of the maximum fair
6 price of a selected drug under section 1194.

7 “(4) The determination of units of a drug for
8 purposes of section 1191(c)(3).

9 “(e) COORDINATION.—In carrying out this part with
10 respect to group health plans or health insurance coverage
11 offered in the group market that are subject to oversight
12 by the Secretary of Labor or the Secretary of the Treas-
13 ury, the Secretary of Health and Human Services shall
14 coordinate with such respective Secretary.

15 “(f) DATA SHARING.—The Secretary shall share with
16 the Secretary of the Treasury such information as is nec-
17 essary to determine the tax imposed by section 4192 of
18 the Internal Revenue Code of 1986.

19 “(g) GAO STUDY.—Not later than December 31,
20 2025, the Comptroller General of the United States shall
21 conduct a study of, and submit to Congress a report on,
22 the implementation of the Fair Price Negotiation Program
23 under this part.”.

24 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
25 CONFORMING AMENDMENTS.—

1 (1) UNDER MEDICARE.—

2 (A) APPLICATION TO PAYMENTS UNDER
3 PART B.—Section 1847A(b)(1)(B) of the Social
4 Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is
5 amended by inserting “or in the case of such a
6 drug or biological that is a selected drug (as de-
7 fined in section 1192(c)), with respect to a
8 price applicability period (as defined in section
9 1191(b)(2)), 106 percent of the maximum fair
10 price (as defined in section 1191(c)(2) applica-
11 ble for such drug and a plan year during such
12 period” after “paragraph (4)”.

13 (B) EXCEPTION TO PART D NON-INTER-
14 FERENCE.—Section 1860D–11(i) of the Social
15 Security Act (42 U.S.C. 1395w–111(i)) is
16 amended by inserting “, except as provided
17 under part E of title XI” after “the Secretary”.

18 (C) APPLICATION AS NEGOTIATED PRICE
19 UNDER PART D.—Section 1860D–2(d)(1) of the
20 Social Security Act (42 U.S.C. 1395w–
21 102(d)(1)) is amended—

22 (i) in subparagraph (B), by inserting
23 “, subject to subparagraph (D),” after
24 “negotiated prices”; and

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

3 “(D) APPLICATION OF MAXIMUM FAIR
4 PRICE FOR SELECTED DRUGS.—In applying this
5 section, in the case of a covered part D drug
6 that is a selected drug (as defined in section
7 1192(c)), with respect to a price applicability
8 period (as defined in section 1191(b)(2)), the
9 negotiated prices used for payment (as de-
10 scribed in this subsection) shall be the max-
11 imum fair price (as defined in section
12 1191(c)(2)) for such drug and for each plan
13 year during such period.”.

14 (D) INFORMATION FROM PRESCRIPTION
15 DRUG PLANS AND MA–PD PLANS REQUIRED.—

16 (i) PRESCRIPTION DRUG PLANS.—Sec-
17 tion 1860D–12(b) of the Social Security
18 Act (42 U.S.C. 1395w–112(b)) is amended
19 by adding at the end the following new
20 paragraph:

21 “(8) PROVISION OF INFORMATION RELATED TO
22 MAXIMUM FAIR PRICES.—Each contract entered into
23 with a PDP sponsor under this part with respect to
24 a prescription drug plan offered by such sponsor
25 shall require the sponsor to provide information to

1 the Secretary as requested by the Secretary in ac-
 2 cordance with section 1196(b).”.

3 (ii) MA–PD PLANS.—Section
 4 1857(f)(3) of the Social Security Act (42
 5 U.S.C. 1395w–27(f)(3)) is amended by
 6 adding at the end the following new sub-
 7 paragraph:

8 “(E) PROVISION OF INFORMATION RE-
 9 LATED TO MAXIMUM FAIR PRICES.—Section
 10 1860D–12(b)(8).”.

11 (2) UNDER GROUP HEALTH PLANS AND
 12 HEALTH INSURANCE COVERAGE.—

13 (A) PHSA.—Part A of title XXVII of the
 14 Public Health Service Act is amended by insert-
 15 ing after section 2729 the following new sec-
 16 tion:

17 **“SEC. 2729A. FAIR PRICE NEGOTIATION PROGRAM AND AP-
 18 PPLICATION OF MAXIMUM FAIR PRICES.**

19 “(a) IN GENERAL.—In the case of a group health
 20 plan or health insurance issuer offering group or indi-
 21 vidual health insurance coverage that is treated under sec-
 22 tion 1197 of the Social Security Act as having in effect
 23 an agreement with the Secretary under the Fair Price Ne-
 24 gotiation Program under part E of title XI of such Act,
 25 with respect to a price applicability period (as defined in

1 section 1191(b) of such Act) and a selected drug (as de-
2 fined in section 1192(c) of such Act) with respect to such
3 period with respect to which coverage is provided under
4 such plan or coverage—

5 “(1) the provisions of such part shall apply—

6 “(A) if coverage of such selected drug is
7 provided under such plan or coverage if the
8 drug is furnished or dispensed at a pharmacy
9 or by a mail order service, to the plans or cov-
10 erage offered by such plan or issuer, and to the
11 individuals enrolled under such plans or cov-
12 erage, during such period, with respect to such
13 selected drug, in the same manner as such pro-
14 visions apply to prescription drug plans and
15 MA–PD plans, and to individuals enrolled
16 under such prescription drug plans and MA–
17 PD plans during such period; and

18 “(B) if coverage of such selected drug is
19 provided under such plan or coverage if the
20 drug is furnished or administered by a hospital,
21 physician, or other provider of services or sup-
22 plier, to the plans or coverage offered by such
23 plan or issuers, to the individuals enrolled
24 under such plans or coverage, and to hospitals,
25 physicians, and other providers of services and

1 suppliers during such period, with respect to
2 such drug in the same manner as such provi-
3 sions apply to the Secretary, to individuals enti-
4 tled to benefits under part A of title XVIII or
5 enrolled under part B of such title, and to hos-
6 pitals, physicians, and other providers and sup-
7 pliers participating under title XVIII during
8 such period;

9 “(2) the plan or issuer shall apply any cost-
10 sharing responsibilities under such plan or coverage,
11 with respect to such selected drug, by substituting
12 an amount not more than the maximum fair price
13 negotiated under such part E of title XI for such
14 drug in lieu of the drug price upon which the cost-
15 sharing would have otherwise applied, and such cost-
16 sharing responsibilities with respect to such selected
17 drug may not exceed such maximum fair price; and

18 “(3) the Secretary shall apply the provisions of
19 such part E to such plan, issuer, and coverage, such
20 individuals so enrolled in such plans and coverage,
21 and such hospitals, physicians, and other providers
22 and suppliers participating in such plans and cov-
23 erage.

24 “(b) NOTIFICATION REGARDING NONPARTICIPATION
25 IN FAIR PRICE NEGOTIATION PROGRAM.—A group health

1 plan or a health insurance issuer offering group or indi-
 2 vidual health insurance coverage shall publicly disclose in
 3 a manner and in accordance with a process specified by
 4 the Secretary any election made under section 1197 of the
 5 Social Security Act by the plan or issuer to not participate
 6 in the Fair Price Negotiation Program under part E of
 7 title XI of such Act with respect to a selected drug (as
 8 defined in section 1192(c) of such Act) for which coverage
 9 is provided under such plan or coverage before the begin-
 10 ning of the plan year for which such election was made.”.

11 (B) ERISA.—

12 (i) IN GENERAL.—Subpart B of part
 13 7 of subtitle B of title I of the Employee
 14 Retirement Income Security Act of 1974
 15 (29 U.S.C. 1181 et. seq.) is amended by
 16 adding at the end the following new sec-
 17 tion:

18 **“SEC. 716. FAIR PRICE NEGOTIATION PROGRAM AND APPLI-**
 19 **CATION OF MAXIMUM FAIR PRICES.**

20 “(a) IN GENERAL.—In the case of a group health
 21 plan or health insurance issuer offering group health in-
 22 surance coverage that is treated under section 1197 of the
 23 Social Security Act as having in effect an agreement with
 24 the Secretary under the Fair Price Negotiation Program
 25 under part E of title XI of such Act, with respect to a

1 price applicability period (as defined in section 1191(b)
2 of such Act) and a selected drug (as defined in section
3 1192(c) of such Act) with respect to such period with re-
4 spect to which coverage is provided under such plan or
5 coverage—

6 “(1) the provisions of such part shall apply, as
7 applicable—

8 “(A) if coverage of such selected drug is
9 provided under such plan or coverage if the
10 drug is furnished or dispensed at a pharmacy
11 or by a mail order service, to the plans or cov-
12 erage offered by such plan or issuer, and to the
13 individuals enrolled under such plans or cov-
14 erage, during such period, with respect to such
15 selected drug, in the same manner as such pro-
16 visions apply to prescription drug plans and
17 MA–PD plans, and to individuals enrolled
18 under such prescription drug plans and MA–
19 PD plans during such period; and

20 “(B) if coverage of such selected drug is
21 provided under such plan or coverage if the
22 drug is furnished or administered by a hospital,
23 physician, or other provider of services or sup-
24 plier, to the plans or coverage offered by such
25 plan or issuers, to the individuals enrolled

1 under such plans or coverage, and to hospitals,
2 physicians, and other providers of services and
3 suppliers during such period, with respect to
4 such drug in the same manner as such provi-
5 sions apply to the Secretary, to individuals enti-
6 tled to benefits under part A of title XVIII or
7 enrolled under part B of such title, and to hos-
8 pitals, physicians, and other providers and sup-
9 pliers participating under title XVIII during
10 such period;

11 “(2) the plan or issuer shall apply any cost-
12 sharing responsibilities under such plan or coverage,
13 with respect to such selected drug, by substituting
14 an amount not more than the maximum fair price
15 negotiated under such part E of title XI for such
16 drug in lieu of the drug price upon which the cost-
17 sharing would have otherwise applied, and such cost-
18 sharing responsibilities with respect to such selected
19 drug may not exceed such maximum fair price; and

20 “(3) the Secretary shall apply the provisions of
21 such part E to such plan, issuer, and coverage, and
22 such individuals so enrolled in such plans.

23 “(b) NOTIFICATION REGARDING NONPARTICIPATION
24 IN FAIR PRICE NEGOTIATION PROGRAM.—A group health
25 plan or a health insurance issuer offering group health in-

1 insurance coverage shall publicly disclose in a manner and
 2 in accordance with a process specified by the Secretary
 3 any election made under section 1197 of the Social Secu-
 4 rity Act by the plan or issuer to not participate in the
 5 Fair Price Negotiation Program under part E of title XI
 6 of such Act with respect to a selected drug (as defined
 7 in section 1192(c) of such Act) for which coverage is pro-
 8 vided under such plan or coverage before the beginning
 9 of the plan year for which such election was made.”.

10 (ii) APPLICATION TO RETIREE AND
 11 CERTAIN SMALL GROUP HEALTH PLANS.—
 12 Section 732(a) of the Employee Retire-
 13 ment Income Security Act of 1974 (29
 14 U.S.C. 1191a(a)) is amended by striking
 15 “section 711” and inserting “sections 711
 16 and 716”.

17 (iii) CLERICAL AMENDMENT.—The
 18 table of sections for subpart B of part 7 of
 19 subtitle B of title I of the Employee Re-
 20 tirement Income Security Act of 1974 is
 21 amended by adding at the end the fol-
 22 lowing:

“Sec. 716. Fair Price Negotiation Program and application of maximum fair
 prices.”.

23 (C) IRC.—

1 (i) IN GENERAL.—Subchapter B of
2 chapter 100 of the Internal Revenue Code
3 of 1986 is amended by adding at the end
4 the following new section:

5 **“SEC. 9816. FAIR PRICE NEGOTIATION PROGRAM AND AP-**
6 **PLICATION OF MAXIMUM FAIR PRICES.**

7 “(a) IN GENERAL.—In the case of a group health
8 plan that is treated under section 1197 of the Social Secu-
9 rity Act as having in effect an agreement with the Sec-
10 retary under the Fair Price Negotiation Program under
11 part E of title XI of such Act, with respect to a price
12 applicability period (as defined in section 1191(b) of such
13 Act) and a selected drug (as defined in section 1192(c)
14 of such Act) with respect to such period with respect to
15 which coverage is provided under such plan—

16 “(1) the provisions of such part shall apply, as
17 applicable—

18 “(A) if coverage of such selected drug is
19 provided under such plan if the drug is fur-
20 nished or dispensed at a pharmacy or by a mail
21 order service, to the plan, and to the individuals
22 enrolled under such plan during such period,
23 with respect to such selected drug, in the same
24 manner as such provisions apply to prescription
25 drug plans and MA–PD plans, and to individ-

1 uals enrolled under such prescription drug
2 plans and MA–PD plans during such period;
3 and

4 “(B) if coverage of such selected drug is
5 provided under such plan if the drug is fur-
6 nished or administered by a hospital, physician,
7 or other provider of services or supplier, to the
8 plan, to the individuals enrolled under such
9 plan, and to hospitals, physicians, and other
10 providers of services and suppliers during such
11 period, with respect to such drug in the same
12 manner as such provisions apply to the Sec-
13 retary, to individuals entitled to benefits under
14 part A of title XVIII or enrolled under part B
15 of such title, and to hospitals, physicians, and
16 other providers and suppliers participating
17 under title XVIII during such period;

18 “(2) the plan shall apply any cost-sharing re-
19 sponsibilities under such plan, with respect to such
20 selected drug, by substituting an amount not more
21 than the maximum fair price negotiated under such
22 part E of title XI for such drug in lieu of the drug
23 price upon which the cost-sharing would have other-
24 wise applied, and such cost-sharing responsibilities

1 with respect to such selected drug may not exceed
2 such maximum fair price; and

3 “(3) the Secretary shall apply the provisions of
4 such part E to such plan and such individuals so en-
5 rolled in such plan.

6 “(b) NOTIFICATION REGARDING NONPARTICIPATION
7 IN FAIR PRICE NEGOTIATION PROGRAM.—A group health
8 plan shall publicly disclose in a manner and in accordance
9 with a process specified by the Secretary any election
10 made under section 1197 of the Social Security Act by
11 the plan to not participate in the Fair Price Negotiation
12 Program under part E of title XI of such Act with respect
13 to a selected drug (as defined in section 1192(c) of such
14 Act) for which coverage is provided under such plan before
15 the beginning of the plan year for which such election was
16 made.”.

17 (ii) APPLICATION TO RETIREE AND
18 CERTAIN SMALL GROUP HEALTH PLANS.—
19 Section 9831(a)(2) of the Internal Revenue
20 Code of 1986 is amended by inserting
21 “other than with respect to section 9816,”
22 before “any group health plan”.

23 (iii) CLERICAL AMENDMENT.—The
24 table of sections for subchapter B of chap-

1 ter 100 of such Code is amended by add-
 2 ing at the end the following new item:

“Sec. 9816. Fair Price Negotiation Program and application of maximum fair
 prices.”.

3 (3) FAIR PRICE NEGOTIATION PROGRAM PRICES
 4 INCLUDED IN BEST PRICE AND AMP.—Section 1927
 5 of the Social Security Act (42 U.S.C. 1396r–8) is
 6 amended—

7 (A) in subsection (c)(1)(C)(ii)—

8 (i) in subclause (III), by striking at
 9 the end “; and”;

10 (ii) in subclause (IV), by striking at
 11 the end the period and inserting “; and”;
 12 and

13 (iii) by adding at the end the fol-
 14 lowing new subclause:

15 “(V) in the case of a rebate pe-
 16 riod and a covered outpatient drug
 17 that is a selected drug (as defined in
 18 section 1192(c)) during such rebate
 19 period, shall be inclusive of the price
 20 for such drug made available from the
 21 manufacturer during the rebate period
 22 by reason of application of part E of
 23 title XI to any wholesaler, retailer,
 24 provider, health maintenance organi-

1 zation, nonprofit entity, or govern-
2 mental entity within the United
3 States.”; and

4 (B) in subsection (k)(1)(B), by adding at
5 the end the following new clause:

6 “(iii) CLARIFICATION.—Notwith-
7 standing clause (i), in the case of a rebate
8 period and a covered outpatient drug that
9 is a selected drug (as defined in section
10 1192(c)) during such rebate period, any
11 reduction in price paid during the rebate
12 period to the manufacturer for the drug by
13 a wholesaler or retail community pharmacy
14 described in subparagraph (A) by reason of
15 application of part E of title XI shall be
16 included in the average manufacturer price
17 for the covered outpatient drug.”.

18 (4) FEHBP.—Section 8902 of title 5, United
19 States Code, is amended by adding at the end the
20 following:

21 “(p) A contract may not be made or a plan approved
22 under this chapter with any carrier that has affirmatively
23 elected, pursuant to section 1197 of the Social Security
24 Act, not to participate in the Fair Price Negotiation Pro-
25 gram established under section 1191 of such Act for any

1 selected drug (as that term is defined in section 1192(c)
2 of such Act).”.

3 (5) OPTION OF SECRETARY OF VETERANS AF-
4 FAIRS TO PURCHASE COVERED DRUGS AT MAXIMUM
5 FAIR PRICES.—Section 8126 of title 38, United
6 States Code, is amended—

7 (A) in subsection (a)(2), by inserting “,
8 subject to subsection (j),” after “may not ex-
9 ceed”;

10 (B) in subsection (d), in the matter pre-
11 ceding paragraph (1), by inserting “, subject to
12 subsection (j)” after “for the procurement of
13 the drug”; and

14 (C) by adding at the end the following new
15 subsection:

16 “(j)(1) In the case of a covered drug that is a selected
17 drug, for any year during the price applicability period for
18 such drug, if the Secretary determines that the maximum
19 fair price of such drug for such year is less than the price
20 for such drug otherwise in effect pursuant to this section
21 (including after application of any reduction under sub-
22 section (a)(2) and any discount under subsection (c)), at
23 the option of the Secretary, in lieu of the maximum price
24 (determined after application of the reduction under sub-
25 section (a)(2) and any discount under subsection (c), as

1 applicable) that would be permitted to be charged during
2 such year for such drug pursuant to this section without
3 application of this subsection, the maximum price per-
4 mitted to be charged during such year for such drug pur-
5 suant to this section shall be such maximum fair price for
6 such drug and year.

7 “(2) For purposes of this subsection:

8 “(A) The term ‘maximum fair price’ means,
9 with respect to a selected drug and year during the
10 price applicability period for such drug, the max-
11 imum fair price (as defined in section 1191(c)(2) of
12 the Social Security Act) for such drug and year.

13 “(B) The term ‘negotiation eligible drug’ has
14 the meaning given such term in section 1192(d)(1)
15 of the Social Security Act.

16 “(C) The term ‘price applicability period’ has,
17 with respect to a selected drug, the meaning given
18 such term in section 1191(b)(2) of such Act.

19 “(D) The term ‘selected drug’ means, with re-
20 spect to a year, a drug that is a selected drug under
21 section 1192(c) of such Act for such year.”.

1 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**
2 **IMPOSED DURING NONCOMPLIANCE PERI-**
3 **ODS.**

4 (a) IN GENERAL.—Subchapter E of chapter 32 of the
5 Internal Revenue Code of 1986 is amended by adding at
6 the end the following new section:

7 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
8 **PERIODS.**

9 “(a) IN GENERAL.—There is hereby imposed on the
10 sale by the manufacturer, producer, or importer of any
11 selected drug during a day described in subsection (b) a
12 tax in an amount such that the applicable percentage is
13 equal to the ratio of—

14 “(1) such tax, divided by

15 “(2) the sum of such tax and the price for
16 which so sold.

17 “(b) NONCOMPLIANCE PERIODS.—A day is described
18 in this subsection with respect to a selected drug if it is
19 a day during one of the following periods:

20 “(1) The period beginning on the June 16th
21 immediately following the selected drug publication
22 date and ending on the first date during which the
23 manufacturer of the drug has in place an agreement
24 described in subsection (a) of section 1193 of the
25 Social Security Act with respect to such drug.

1 “(2) The period beginning on the April 1st im-
2 mediately following the June 16th described in para-
3 graph (1) and ending on the first date during which
4 the manufacturer of the drug has agreed to a max-
5 imum fair price under such agreement.

6 “(3) In the case of a selected drug with respect
7 to which the Secretary of Health and Human Serv-
8 ices has specified a renegotiation period under such
9 agreement, the period beginning on the first date
10 after the last date of such renegotiation period and
11 ending on the first date during which the manufac-
12 turer of the drug has agreed to a renegotiated max-
13 imum fair price under such agreement.

14 “(4) With respect to information that is re-
15 quired to be submitted to the Secretary of Health
16 and Human Services under such agreement, the pe-
17 riod beginning on the date on which such Secretary
18 certifies that such information is overdue and ending
19 on the date that such information is so submitted.

20 “(5) In the case of a selected drug with respect
21 to which a payment is due under subsection (c) of
22 such section 1193, the period beginning on the date
23 on which the Secretary of Health and Human Serv-
24 ices certifies that such payment is overdue and end-
25 ing on the date that such payment is made in full.

1 “(c) APPLICABLE PERCENTAGE.—For purposes of
2 this section, the term ‘applicable percentage’ means—

3 “(1) in the case of sales of a selected drug dur-
4 ing the first 90 days described in subsection (b) with
5 respect to such drug, 65 percent,

6 “(2) in the case of sales of such drug during
7 the 91st day through the 180th day described in
8 subsection (b) with respect to such drug, 75 percent,

9 “(3) in the case of sales of such drug during
10 the 181st day through the 270th day described in
11 subsection (b) with respect to such drug, 85 percent,
12 and

13 “(4) in the case of sales of such drug during
14 any subsequent day, 95 percent.

15 “(d) SELECTED DRUG.—For purposes of this sec-
16 tion—

17 “(1) IN GENERAL.—The term ‘selected drug’
18 means any selected drug (within the meaning of sec-
19 tion 1192 of the Social Security Act) which is manu-
20 factured or produced in the United States or entered
21 into the United States for consumption, use, or
22 warehousing.

23 “(2) UNITED STATES.—The term ‘United
24 States’ has the meaning given such term by section
25 4612(a)(4).

1 “(3) COORDINATION WITH RULES FOR POSSES-
2 SIONS OF THE UNITED STATES.—Rules similar to
3 the rules of paragraphs (2) and (4) of section
4 4132(c) shall apply for purposes of this section.

5 “(e) OTHER DEFINITIONS.—For purposes of this
6 section, the terms ‘selected drug publication date’ and
7 ‘maximum fair price’ have the meaning given such terms
8 in section 1191 of the Social Security Act.

9 “(f) ANTI-ABUSE RULE.—In the case of a sale which
10 was timed for the purpose of avoiding the tax imposed by
11 this section, the Secretary may treat such sale as occur-
12 ring during a day described in subsection (b).”.

13 (b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—
14 Section 275 of the Internal Revenue Code of 1986 is
15 amended by adding “or by section 4192” before the period
16 at the end of subsection (a)(6).

17 (c) CONFORMING AMENDMENTS.—

18 (1) Section 4221(a) of the Internal Revenue
19 Code of 1986 is amended by inserting “or 4192”
20 after “section 4191”.

21 (2) Section 6416(b)(2) of such Code is amend-
22 ed by inserting “or 4192” after “section 4191”.

23 (d) CLERICAL AMENDMENTS.—

24 (1) The heading of subchapter E of chapter 32
25 of the Internal Revenue Code of 1986 is amended by

1 striking “**Medical Devices**” and inserting
 2 “**Other Medical Products**”.

3 (2) The table of subchapters for chapter 32 of
 4 such Code is amended by striking the item relating
 5 to subchapter E and inserting the following new
 6 item:

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

7 (3) The table of sections for subchapter E of
 8 chapter 32 of such Code is amended by adding at
 9 the end the following new item:

“Sec. 4192. Selected drugs during noncompliance periods.”.

10 (e) **EFFECTIVE DATE.**—The amendments made by
 11 this section shall apply to sales after the date of the enact-
 12 ment of this Act.

13 **SEC. 103. FAIR PRICE NEGOTIATION IMPLEMENTATION**
 14 **FUND.**

15 (a) **IN GENERAL.**—There is hereby established a Fair
 16 Price Negotiation Implementation Fund (referred to in
 17 this section as the “Fund”). The Secretary of Health and
 18 Human Services may obligate and expend amounts in the
 19 Fund to carry out this title and titles II and III (and the
 20 amendments made by such titles).

21 (b) **FUNDING.**—There is authorized to be appro-
 22 priated, and there is hereby appropriated, out of any mon-
 23 ies in the Treasury not otherwise appropriated, to the

1 Fund \$3,000,000,000, to remain available until expended,
2 of which—

3 (1) \$600,000,000 shall become available on the
4 date of the enactment of this Act;

5 (2) \$600,000,000 shall become available on Oc-
6 tober 1, 2020;

7 (3) \$600,000,000 shall become available on Oc-
8 tober 1, 2021;

9 (4) \$600,000,000 shall become available on Oc-
10 tober 1, 2022; and

11 (5) \$600,000,000 shall become available on Oc-
12 tober 1, 2023.

13 (c) SUPPLEMENT NOT SUPPLANT.—Any amounts
14 appropriated pursuant to this section shall be in addition
15 to any other amounts otherwise appropriated pursuant to
16 any other provision of law.

17 **TITLE II—MEDICARE PARTS B**
18 **AND D PRESCRIPTION DRUG**
19 **INFLATION REBATES**

20 **SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.**

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

1 “(x) REBATE BY MANUFACTURERS FOR SINGLE
2 SOURCE DRUGS WITH PRICES INCREASING FASTER
3 THAN INFLATION.—

4 “(1) REQUIREMENTS.—

5 “(A) SECRETARIAL PROVISION OF INFOR-
6 MATION.—Not later than 6 months after the
7 end of each calendar quarter beginning on or
8 after July 1, 2021, the Secretary shall, for each
9 part B rebatable drug, report to each manufac-
10 turer of such part B rebatable drug the fol-
11 lowing for such calendar quarter:

12 “(i) Information on the total number
13 of units of the billing and payment code
14 described in subparagraph (A)(i) of para-
15 graph (3) with respect to such drug and
16 calendar quarter.

17 “(ii) Information on the amount (if
18 any) of the excess average sales price in-
19 crease described in subparagraph (A)(ii) of
20 such paragraph for such drug and calendar
21 quarter.

22 “(iii) The rebate amount specified
23 under such paragraph for such part B
24 rebatable drug and calendar quarter.

“(B) MANUFACTURER REQUIREMENT.—

For each calendar quarter beginning on or after July 1, 2021, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

“(2) PART B REBATABLE DRUG DEFINED.—

“(A) IN GENERAL.—In this subsection, the term ‘part B rebatable drug’ means a single source drug or biological (as defined in subparagraph (D) of section 1847A(c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such section), paid for under this part, except such term shall not include such a drug or biological—

“(i) if the average total allowed charges for a year per individual that uses such a drug or biological, as determined by the Secretary, are less than, subject to subparagraph (B), \$100; or

1 “(ii) that is a vaccine described in
2 subparagraph (A) or (B) of section
3 1861(s)(10).

4 “(B) INCREASE.—The dollar amount ap-
5 plied under subparagraph (A)(i)—

6 “(i) for 2022, shall be the dollar
7 amount specified under such subparagraph
8 for 2021, increased by the percentage in-
9 crease in the consumer price index for all
10 urban consumers (United States city aver-
11 age) for the 12 month period ending with
12 June of the previous year; and

13 “(ii) for a subsequent year, shall be
14 the dollar amount specified in this clause
15 (or clause (i)) for the previous year, in-
16 creased by the percentage increase in the
17 consumer price index for all urban con-
18 sumers (United States city average) for
19 the 12 month period ending with June of
20 the previous year.

21 Any dollar amount specified under this sub-
22 paragraph that is not a multiple of \$10 shall be
23 rounded to the nearest multiple of \$10.

24 “(3) REBATE AMOUNT.—

1 “(A) IN GENERAL.—For purposes of para-
2 graph (1), the amount specified in this para-
3 graph for a part B rebatable drug assigned to
4 a billing and payment code for a calendar quar-
5 ter is, subject to paragraph (4), the amount
6 equal to the product of—

7 “(i) subject to subparagraphs (B) and
8 (G), the total number of units of the bill-
9 ing and payment code for such part B
10 rebatable drug furnished under this part
11 during the calendar quarter; and

12 “(ii) the amount (if any) by which—

13 “(I) the payment amount under
14 subparagraph (B) or (C) of section
15 1847A(b)(1), as applicable, for such
16 part B rebatable drug during the cal-
17 endar quarter; exceeds

18 “(II) the inflation-adjusted pay-
19 ment amount determined under sub-
20 paragraph (C) for such part B
21 rebatable drug during the calendar
22 quarter.

23 “(B) EXCLUDED UNITS.—For purposes of
24 subparagraph (A)(i), the total number of units
25 of the billing and payment code for each part

1 B rebatable drug furnished during a calendar
2 quarter shall not include—

3 “(i) units packaged into the payment
4 for a procedure or service under section
5 1833(t) or under section 1833(i) (instead
6 of separately payable under such respective
7 section);

8 “(ii) units included under the single
9 payment system for renal dialysis services
10 under section 1881(b)(14); or

11 “(iii) units of a part B rebatable drug
12 of a manufacturer furnished to an indi-
13 vidual, if such manufacturer, with respect
14 to the furnishing of such units of such
15 drug, provides for discounts under section
16 340B of the Public Health Service Act or
17 for rebates under section 1927.

18 “(C) DETERMINATION OF INFLATION-AD-
19 JUSTED PAYMENT AMOUNT.—The inflation-ad-
20 justed payment amount determined under this
21 subparagraph for a part B rebatable drug for
22 a calendar quarter is—

23 “(i) the payment amount for the bill-
24 ing and payment code for such drug in the

1 payment amount benchmark quarter (as
2 defined in subparagraph (D)); increased by

3 “(ii) the percentage by which the re-
4 bate period CPI–U (as defined in subpara-
5 graph (F)) for the calendar quarter ex-
6 ceeds the benchmark period CPI–U (as de-
7 fined in subparagraph (E)).

8 “(D) PAYMENT AMOUNT BENCHMARK
9 QUARTER.—The term ‘payment amount bench-
10 mark quarter’ means the calendar quarter be-
11 ginning January 1, 2016.

12 “(E) BENCHMARK PERIOD CPI–U.—The
13 term ‘benchmark period CPI–U’ means the con-
14 sumer price index for all urban consumers
15 (United States city average) for July 2015.

16 “(F) REBATE PERIOD CPI–U.—The term
17 ‘rebate period CPI–U’ means, with respect to a
18 calendar quarter described in subparagraph
19 (C), the greater of the benchmark period CPI–
20 U and the consumer price index for all urban
21 consumers (United States city average) for the
22 first month of the calendar quarter that is two
23 calendar quarters prior to such described cal-
24 endar quarter.

25 “(G) COUNTING UNITS.—

1 “(i) CUT-OFF PERIOD TO COUNT
2 UNITS.—For purposes of subparagraph
3 (A)(i), subject to clause (ii), to count the
4 total number of billing units for a part B
5 rebtable drug for a quarter, the Secretary
6 may use a cut-off period in order to ex-
7 clude from such total number of billing
8 units for such quarter claims for services
9 furnished during such quarter that were
10 not processed at an appropriate time prior
11 to the end of the cut-off period.

12 “(ii) COUNTING UNITS FOR CLAIMS
13 PROCESSED AFTER CUT-OFF PERIOD.—If
14 the Secretary uses a cut-off period pursu-
15 ant to clause (i), in the case of units of a
16 part B rebtable drug furnished during a
17 quarter but pursuant to application of such
18 cut-off period excluded for purposes of sub-
19 paragraph (A)(i) from the total number of
20 billing units for the drug for such quarter,
21 the Secretary shall count such units of
22 such drug so furnished in the total number
23 of billing units for such drug for a subse-
24 quent quarter, as the Secretary determines
25 appropriate.

1 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
2 AND EXEMPTION.—

3 “(A) SUBSEQUENTLY APPROVED DRUGS.—
4 Subject to subparagraph (B), in the case of a
5 part B rebatable drug first approved or licensed
6 by the Food and Drug Administration after
7 July 1, 2015, clause (i) of paragraph (3)(C)
8 shall be applied as if the term ‘payment amount
9 benchmark quarter’ were defined under para-
10 graph (3)(D) as the third full calendar quarter
11 after the day on which the drug was first mar-
12 keted and clause (ii) of paragraph (3)(C) shall
13 be applied as if the term ‘benchmark period
14 CPI-U’ were defined under paragraph (3)(E)
15 as if the reference to ‘July 2015’ under such
16 paragraph were a reference to ‘the first month
17 of the first full calendar quarter after the day
18 on which the drug was first marketed’.

19 “(B) TIMELINE FOR PROVISION OF RE-
20 BATES FOR SUBSEQUENTLY APPROVED
21 DRUGS.—In the case of a part B rebatable drug
22 first approved or licensed by the Food and
23 Drug Administration after July 1, 2015, para-
24 graph (1)(B) shall be applied as if the reference
25 to ‘July 1, 2021’ under such paragraph were a

1 reference to the later of the 6th full calendar
2 quarter after the day on which the drug was
3 first marketed or July 1, 2021.

4 “(C) EXEMPTION FOR SHORTAGES.—The
5 Secretary may reduce or waive the rebate
6 amount under paragraph (1)(B) with respect to
7 a part B rebatable drug that is described as
8 currently in shortage on the shortage list in ef-
9 fect under section 506E of the Federal Food,
10 Drug, and Cosmetic Act or in the case of other
11 exigent circumstances, as determined by the
12 Secretary.

13 “(D) SELECTED DRUGS.—In the case of a
14 part B rebatable drug that is a selected drug
15 (as defined in section 1192(c)) for a price appli-
16 cability period (as defined in section
17 1191(b)(2))—

18 “(i) for calendar quarters during such
19 period for which a maximum fair price (as
20 defined in section 1191(c)(2)) for such
21 drug has been determined and is applied
22 under part E of title XI, the rebate
23 amount under paragraph (1)(B) shall be
24 waived; and

1 “(ii) in the case such drug is deter-
2 mined (pursuant to such section 1192(c))
3 to no longer be a selected drug, for each
4 applicable year beginning after the price
5 applicability period with respect to such
6 drug, clause (i) of paragraph (3)(C) shall
7 be applied as if the term ‘payment amount
8 benchmark quarter’ were defined under
9 paragraph (3)(D) as the calendar quarter
10 beginning January 1 of the last year be-
11 ginning during such price applicability pe-
12 riod with respect to such selected drug and
13 clause (ii) of paragraph (3)(C) shall be ap-
14 plied as if the term ‘benchmark period
15 CPI-U’ were defined under paragraph
16 (3)(E) as if the reference to ‘July 2015’
17 under such paragraph were a reference to
18 the July of the year preceding such last
19 year.

20 “(5) APPLICATION TO BENEFICIARY COINSUR-
21 ANCE.—In the case of a part B rebatable drug, if
22 the payment amount for a quarter exceeds the infla-
23 tion adjusted payment for such quarter—

24 “(A) in computing the amount of any coin-
25 surance applicable under this title to an indi-

vidual with respect to such drug, the computation of such coinsurance shall be based on the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

“(B) the amount of such coinsurance is equal to 20 percent of such inflation-adjusted payment amount so determined.

“(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

“(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the

1 same manner as such provisions apply to a penalty
2 or proceeding under section 1128A(a).

3 “(8) STUDY AND REPORT.—

4 “(A) STUDY.—The Secretary shall conduct
5 a study of the feasibility of and operational
6 issues involved with the following:

7 “(i) Including multiple source drugs
8 (as defined in section 1847A(c)(6)(C)) in
9 the rebate system under this subsection.

10 “(ii) Including drugs and biologicals
11 paid for under MA plans under part C in
12 the rebate system under this subsection.

13 “(iii) Including drugs excluded under
14 paragraph (2)(A) and units of the billing
15 and payment code of the drugs excluded
16 under paragraph (3)(B) in the rebate sys-
17 tem under this subsection.

18 “(B) REPORT.—Not later than 3 years
19 after the date of the enactment of this sub-
20 section, the Secretary shall submit to Congress
21 a report on the study conducted under subpara-
22 graph (A).

23 “(9) APPLICATION TO MULTIPLE SOURCE
24 DRUGS.—The Secretary may, based on the report
25 submitted under paragraph (8) and pursuant to

1 rulemaking, apply the provisions of this subsection
 2 to multiple source drugs (as defined in section
 3 1847A(c)(6)(C)), including, for purposes of deter-
 4 mining the rebate amount under paragraph (3), by
 5 calculating manufacturer-specific average sales
 6 prices for the benchmark period and the rebate pe-
 7 riod.”.

8 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
 9 1833 of the Social Security Act (42 U.S.C. 1395l) is
 10 amended—

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) in subparagraph (S), by striking
 14 “with respect to” and inserting “subject to
 15 subparagraph (DD), with respect to”;

16 (ii) by striking “and (CC)” and in-
 17 serting “(CC)”; and

18 (iii) by inserting before the semicolon
 19 at the end the following: “, and (DD) with
 20 respect to a part B rebatable drug (as de-
 21 fined in paragraph (2) of section 1834(x))
 22 for which the payment amount for a cal-
 23 endar quarter under paragraph
 24 (3)(A)(ii)(I) of such section for such quar-
 25 ter exceeds the inflation-adjusted payment

1 under paragraph (3)(A)(ii)(II) of such sec-
2 tion for such quarter, the amounts paid
3 shall be the difference between (i) the pay-
4 ment amount under paragraph
5 (3)(A)(ii)(I) of such section for such drug,
6 and (ii) 20 percent of the inflation-ad-
7 justed payment amount under paragraph
8 (3)(A)(ii)(II) of such section for such
9 drug”;

10 (B) by adding at the end of the flush left
11 matter following paragraph (9), the following:

12 “For purposes of applying paragraph (1)(DD), sub-
13 sections (i)(9) and (t)(8)(F), and section 1834(x)(5), the
14 Secretary shall make such estimates and use such data
15 as the Secretary determines appropriate, and notwith-
16 standing any other provision of law, may do so by program
17 instruction or otherwise.”;

18 (2) in subsection (i), by adding at the end the
19 following new paragraph:

20 “(9) In the case of a part B rebatable drug (as de-
21 fined in paragraph (2) of section 1834(x)) for which pay-
22 ment under this subsection is not packaged into a payment
23 for a covered OPD service (as defined in subsection
24 (t)(1)(B)) (or group of services) furnished on or after July
25 1, 2021, under the system under this subsection, in lieu

1 of calculation of coinsurance and the amount of payment
2 otherwise applicable under this subsection, the provisions
3 of section 1834(x)(5), paragraph (1)(DD) of subsection
4 (a), and the flush left matter following paragraph (9) of
5 subsection (a), shall, as determined appropriate by the
6 Secretary, apply under this subsection in the same manner
7 as such provisions of section 1834(x)(5) and subsection
8 (a) apply under such section and subsection.”; and

9 (3) in subsection (t)(8), by adding at the end
10 the following new subparagraph:

11 “(F) PART B REBATABLE DRUGS.—In the
12 case of a part B rebatable drug (as defined in
13 paragraph (2) of section 1834(x)) for which
14 payment under this part is not packaged into a
15 payment for a service furnished on or after July
16 1, 2021, under the system under this sub-
17 section, in lieu of calculation of coinsurance and
18 the amount of payment otherwise applicable
19 under this subsection, the provisions of section
20 1834(x)(5), paragraph (1)(DD) of subsection
21 (a), and the flush left matter following para-
22 graph (9) of subsection (a), shall, as determined
23 appropriate by the Secretary, apply under this
24 subsection in the same manner as such provi-

1 sions of section 1834(x)(5) and subsection (a)
2 apply under such section and subsection.”.

3 (c) CONFORMING AMENDMENTS.—

4 (1) TO PART B ASP CALCULATION.—Section
5 1847A(c)(3) of the Social Security Act (42 U.S.C.
6 1395w–3a(c)(3)) is amended by inserting “or section
7 1834(x)” after “section 1927”.

8 (2) EXCLUDING PARTS B DRUG INFLATION RE-
9 BATE FROM BEST PRICE.—Section
10 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
11 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-
12 serting “or section 1834(x)” after “this section”.

13 (3) COORDINATION WITH MEDICAID REBATE IN-
14 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
15 of the Social Security Act (42 U.S.C. 1396r–
16 8(b)(3)(D)(i)) is amended by striking “or to carry
17 out section 1847B” and inserting “to carry out sec-
18 tion 1847B or section 1834(x)”.

19 **SEC. 202. MEDICARE PART D REBATE BY MANUFACTURERS.**

20 (a) IN GENERAL.—Part D of title XVIII of the Social
21 Security Act is amended by inserting after section 1860D–
22 14A (42 U.S.C. 1395w–114a) the following new section:

1 **“SEC. 1860D-14B. MANUFACTURER REBATE FOR CERTAIN**
2 **DRUGS WITH PRICES INCREASING FASTER**
3 **THAN INFLATION.**

4 “(a) IN GENERAL.—

5 “(1) IN GENERAL.—Subject to the provisions of
6 this section, in order for coverage to be available
7 under this part for a part D rebatable drug (as de-
8 fined in subsection (h)(1)) of a manufacturer (as de-
9 fined in section 1927(k)(5)) dispensed during an ap-
10 plicable year, the manufacturer must have entered
11 into and have in effect an agreement described in
12 subsection (b).

13 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT
14 COVERED UNDER AGREEMENTS.—Paragraph (1)
15 shall not apply to the dispensing of a covered part
16 D drug if—

17 “(A) the Secretary has made a determina-
18 tion that the availability of the drug is essential
19 to the health of beneficiaries under this part; or

20 “(B) the Secretary determines that in the
21 period beginning on January 1, 2022, and end-
22 ing on December 31, 2022, there were extenu-
23 ating circumstances.

24 “(3) APPLICABLE YEAR.—For purposes of this
25 section the term ‘applicable year’ means a year be-
26 ginning with 2022.

1 “(b) AGREEMENTS.—

2 “(1) TERMS OF AGREEMENT.—An agreement
3 described in this subsection, with respect to a manu-
4 facturer of a part D rebatable drug, is an agreement
5 under which the following shall apply:

6 “(A) SECRETARIAL PROVISION OF INFOR-
7 MATION.—Not later than 9 months after the
8 end of each applicable year with respect to
9 which the agreement is in effect, the Secretary,
10 for each part D rebatable drug of the manufac-
11 turer, shall report to the manufacturer the fol-
12 lowing for such year:

13 “(i) Information on the total number
14 of units (as defined in subsection (h)(2))
15 for each dosage form and strength with re-
16 spect to such part D rebatable drug and
17 year.

18 “(ii) Information on the amount (if
19 any) of the excess average manufacturer
20 price increase described in subsection
21 (c)(1)(B) for each dosage form and
22 strength with respect to such drug and
23 year.

24 “(iii) The rebate amount specified
25 under subsection (c) for each dosage form

1 and strength with respect to such drug and
2 year.

3 “(B) MANUFACTURER REQUIREMENTS.—

4 For each applicable year with respect to which
5 the agreement is in effect, the manufacturer of
6 the part D rebatable drug, for each dosage
7 form and strength with respect to such drug,
8 not later than 30 days after the date of receipt
9 from the Secretary of the information described
10 in subparagraph (A) for such year, shall pro-
11 vide to the Secretary a rebate that is equal to
12 the amount specified in subsection (c) for such
13 dosage form and strength with respect to such
14 drug for such year.

15 “(2) LENGTH OF AGREEMENT.—

16 “(A) IN GENERAL.—An agreement under
17 this section, with respect to a part D rebatable
18 drug, shall be effective for an initial period of
19 not less than one year and shall be automati-
20 cally renewed for a period of not less than one
21 year unless terminated under subparagraph
22 (B).

23 “(B) TERMINATION.—

24 “(i) BY SECRETARY.—The Secretary
25 may provide for termination of an agree-

1 ment under this section for violation of the
2 requirements of the agreement or other
3 good cause shown. Such termination shall
4 not be effective earlier than 30 days after
5 the date of notice of such termination. The
6 Secretary shall provide, upon request, a
7 manufacturer with a hearing concerning
8 such a termination, but such hearing shall
9 not delay the effective date of the termi-
10 nation.

11 “(ii) BY A MANUFACTURER.—A man-
12 ufacturer may terminate an agreement
13 under this section for any reason. Any
14 such termination shall be effective, with re-
15 spect to a plan year—

16 “(I) if the termination occurs be-
17 fore January 30 of the plan year, as
18 of the day after the end of the plan
19 year; and

20 “(II) if the termination occurs on
21 or after January 30 of the plan year,
22 as of the day after the end of the suc-
23 ceeding plan year.

24 “(C) EFFECTIVENESS OF TERMINATION.—

25 Any termination under this paragraph shall not

1 affect rebates due under the agreement under
 2 this section before the effective date of its ter-
 3 mination.

4 “(D) DELAY BEFORE REENTRY.—In the
 5 case of any agreement under this section with
 6 a manufacturer that is terminated in a plan
 7 year, the Secretary may not enter into another
 8 such agreement with the manufacturer (or a
 9 successor manufacturer) before the subsequent
 10 plan year, unless the Secretary finds good cause
 11 for an earlier reinstatement of such an agree-
 12 ment.

13 “(c) REBATE AMOUNT.—

14 “(1) IN GENERAL.—For purposes of this sec-
 15 tion, the amount specified in this subsection for a
 16 dosage form and strength with respect to a part D
 17 rebtable drug and applicable year is, subject to sub-
 18 paragraphs (B) and (C) of paragraph (5), the
 19 amount equal to the product of—

20 “(A) the total number of units of such dos-
 21 age form and strength with respect to such part
 22 D rebtable drug and year; and

23 “(B) the amount (if any) by which—

24 “(i) the annual manufacturer price
 25 (as determined in paragraph (2)) paid for

1 such dosage form and strength with re-
2 spect to such part D rebatable drug for the
3 year; exceeds

4 “(ii) the inflation-adjusted payment
5 amount determined under paragraph (3)
6 for such dosage form and strength with re-
7 spect to such part D rebatable drug for the
8 year.

9 “(2) DETERMINATION OF ANNUAL MANUFAC-
10 TURER PRICE.—The annual manufacturer price de-
11 termined under this paragraph for a dosage form
12 and strength, with respect to a part D rebatable
13 drug and an applicable year, is the sum of the prod-
14 ucts of—

15 “(A) the average manufacturer price (as
16 defined in subsection (h)(6)) of such dosage
17 form and strength, as calculated for a unit of
18 such drug, with respect to each of the calendar
19 quarters of such year; and

20 “(B) the ratio of—

21 “(i) the total number of units of such
22 dosage form and strength dispensed during
23 each such calendar quarter of such year; to

1 “(ii) the total number of units of such
 2 dosage form and strength dispensed during
 3 such year.

4 “(3) DETERMINATION OF INFLATION-ADJUSTED
 5 PAYMENT AMOUNT.—The inflation-adjusted payment
 6 amount determined under this paragraph for a dos-
 7 age form and strength with respect to a part D
 8 rebatable drug for an applicable year, subject to sub-
 9 paragraphs (A) and (D) of paragraph (5), is—

10 “(A) the benchmark year manufacturer
 11 price determined under paragraph (4) for such
 12 dosage form and strength with respect to such
 13 drug and an applicable year; increased by

14 “(B) the percentage by which the applica-
 15 ble year CPI–U (as defined in subsection
 16 (h)(5)) for the applicable year exceeds the
 17 benchmark period CPI–U (as defined in sub-
 18 section (h)(4)).

19 “(4) DETERMINATION OF BENCHMARK YEAR
 20 MANUFACTURER PRICE.—The benchmark year man-
 21 ufacturer price determined under this paragraph for
 22 a dosage form and strength, with respect to a part
 23 D rebatable drug and an applicable year, is the sum
 24 of the products of—

“(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark year (as defined in subsection (h)(3)); and

“(B) the ratio of—

“(i) the total number of units of such dosage form and strength dispensed during each such calendar quarter of such payment amount benchmark year; to

“(ii) the total number of units of such dosage form and strength dispensed during such payment amount benchmark year.

“(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

“(A) SUBSEQUENTLY APPROVED DRUGS.—

In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after January 1, 2016, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term ‘payment amount benchmark year’ were defined under subsection (h)(3) as the first calendar year beginning after the day on which the drug was first marketed

1 by any manufacturer and subparagraph (B) of
2 paragraph (3) shall be applied as if the term
3 ‘benchmark period CPI-U’ were defined under
4 subsection (h)(4) as if the reference to ‘January
5 2016’ under such subsection were a reference to
6 ‘January of the first year beginning after the
7 date on which the drug was first marketed by
8 any manufacturer’.

9 “(B) EXEMPTION FOR SHORTAGES.—The
10 Secretary may reduce or waive the rebate under
11 paragraph (1) with respect to a part D
12 rebatable drug that is described as currently in
13 shortage on the shortage list in effect under
14 section 506E of the Federal Food, Drug, and
15 Cosmetic Act or in the case of other exigent cir-
16 cumstances, as determined by the Secretary.

17 “(C) TREATMENT OF NEW FORMULA-
18 TIONS.—

19 “(i) IN GENERAL.—In the case of a
20 part D rebatable drug that is a line exten-
21 sion of a part D rebatable drug that is an
22 oral solid dosage form, the Secretary shall
23 establish a formula for determining the
24 amount specified in this subsection with
25 respect to such part D rebatable drug and

1 an applicable year with consideration of
2 the original part D rebatable drug.

3 “(ii) LINE EXTENSION DEFINED.—In
4 this subparagraph, the term ‘line exten-
5 sion’ means, with respect to a part D
6 rebatable drug, a new formulation of the
7 drug (as determined by the Secretary),
8 such as an extended release formulation,
9 but does not include an abuse-deterrent
10 formulation of the drug (as determined by
11 the Secretary), regardless of whether such
12 abuse-deterrent formulation is an extended
13 release formulation.

14 “(D) SELECTED DRUGS.—In the case of a
15 part D rebatable drug that is a selected drug
16 (as defined in section 1192(c)) for a price appli-
17 cability period (as defined in section
18 1191(b)(2))—

19 “(i) for plan years during such period
20 for which a maximum fair price (as defined
21 in section 1191(c)(2)) for such drug has
22 been determined and is applied under part
23 E of title XI, the rebate under subsection
24 (b)(1)(B) shall be waived; and

1 “(ii) in the case such drug is deter-
2 mined (pursuant to such section 1192(c))
3 to no longer be a selected drug, for each
4 applicable year beginning after the price
5 applicability period with respect to such
6 drug, subparagraphs (A) and (B) of para-
7 graph (4) shall be applied as if the term
8 ‘payment amount benchmark year’ were
9 defined under subsection (h)(3) as the last
10 year beginning during such price applica-
11 bility period with respect to such selected
12 drug and subparagraph (B) of paragraph
13 (3) shall be applied as if the term ‘bench-
14 mark period CPI-U’ were defined under
15 subsection (h)(4) as if the reference to
16 ‘January 2016’ under such subsection were
17 a reference to January of the last year be-
18 ginning during such price applicability pe-
19 riod with respect to such drug.

20 “(d) REBATE DEPOSITS.—Amounts paid as rebates
21 under subsection (c) shall be deposited into the Medicare
22 Prescription Drug Account in the Federal Supplementary
23 Medical Insurance Trust Fund established under section
24 1841.

1 “(e) INFORMATION.—For purposes of carrying out
2 this section, the Secretary shall use information submitted
3 by manufacturers under section 1927(b)(3).

4 “(f) CIVIL MONEY PENALTY.—In the case of a man-
5 ufacturer of a part D rebatable drug with an agreement
6 in effect under this section who has failed to comply with
7 the terms of the agreement under subsection (b)(1)(B)
8 with respect to such drug for an applicable year, the Sec-
9 retary may impose a civil money penalty on such manufac-
10 turer in an amount equal to 125 percent of the amount
11 specified in subsection (c) for such drug for such year.
12 The provisions of section 1128A (other than subsections
13 (a) (with respect to amounts of penalties or additional as-
14 sessments) and (b)) shall apply to a civil money penalty
15 under this subsection in the same manner as such provi-
16 sions apply to a penalty or proceeding under section
17 1128A(a).

18 “(g) JUDICIAL REVIEW.—There shall be no judicial
19 review of the following:

20 “(1) The determination of units under this sec-
21 tion.

22 “(2) The determination of whether a drug is a
23 part D rebatable drug under this section.

24 “(3) The calculation of the rebate amount
25 under this section.

1 “(h) DEFINITIONS.—In this section:

2 “(1) PART D REBATABLE DRUG DEFINED.—

3 “(A) IN GENERAL.—The term ‘part D
4 rebatable drug’ means a drug or biological that
5 would (without application of this section) be a
6 covered part D drug, except such term shall,
7 with respect to an applicable year, not include
8 such a drug or biological if the average annual
9 total cost under this part for such year per in-
10 dividual who uses such a drug or biological, as
11 determined by the Secretary, is less than, sub-
12 ject to subparagraph (B), \$100, as determined
13 by the Secretary using the most recent data
14 available or, if data is not available, as esti-
15 mated by the Secretary.

16 “(B) INCREASE.—The dollar amount ap-
17 plied under subparagraph (A)—

18 “(i) for 2023, shall be the dollar
19 amount specified under such subparagraph
20 for 2022, increased by the percentage in-
21 crease in the consumer price index for all
22 urban consumers (United States city aver-
23 age) for the 12-month period beginning
24 with January of 2022; and

1 “(ii) for a subsequent year, shall be
2 the dollar amount specified in this sub-
3 paragraph for the previous year, increased
4 by the percentage increase in the consumer
5 price index for all urban consumers
6 (United States city average) for the 12-
7 month period beginning with January of
8 the previous year.

9 Any dollar amount specified under this sub-
10 paragraph that is not a multiple of \$10 shall be
11 rounded to the nearest multiple of \$10.

12 “(2) UNIT DEFINED.—The term ‘unit’ means,
13 with respect to a part D rebatable drug, the lowest
14 identifiable quantity (such as a capsule or tablet,
15 milligram of molecules, or grams) of the part D
16 rebatable drug that is dispensed to individuals under
17 this part.

18 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—
19 The term ‘payment amount benchmark year’ means
20 the year beginning January 1, 2016.

21 “(4) BENCHMARK PERIOD CPI–U.—The term
22 ‘benchmark period CPI–U’ means the consumer
23 price index for all urban consumers (United States
24 city average) for January 2016.

1 “(5) APPLICABLE YEAR CPI-U.—The term ‘ap-
 2 plicable year CPI-U’ means, with respect to an ap-
 3 plicable year, the consumer price index for all urban
 4 consumers (United States city average) for January
 5 of such year.

6 “(6) AVERAGE MANUFACTURER PRICE.—The
 7 term ‘average manufacturer price’ has the meaning,
 8 with respect to a part D rebatable drug of a manu-
 9 facturer, given such term in section 1927(k)(1), with
 10 respect to a covered outpatient drug of a manufac-
 11 turer for a rebate period under section 1927.”.

12 (b) CONFORMING AMENDMENTS.—

13 (1) TO PART B ASP CALCULATION.—Section
 14 1847A(c)(3) of the Social Security Act (42 U.S.C.
 15 1395w–3a(c)(3)), as amended by section 201(c)(1),
 16 is further amended by striking “section 1927 or sec-
 17 tion 1834(x)” and inserting “section 1927, section
 18 1834(x), or section 1860D–14B”.

19 (2) EXCLUDING PART D DRUG INFLATION RE-
 20 BATE FROM BEST PRICE.—Section
 21 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
 22 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
 23 tion 201(c)(2), is further amended by striking “or
 24 section 1834(x)” and inserting “, section 1834(x), or
 25 section 1860D–14B”.

1 (3) COORDINATION WITH MEDICAID REBATE IN-
2 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
3 of the Social Security Act (42 U.S.C. 1396r-
4 8(b)(3)(D)(i)), as amended by section 201(c)(3), is
5 further amended by striking “or section 1834(x)”
6 and inserting “, section 1834(x), or section 1860D-
7 14B”.

8 **SEC. 203. PROVISION REGARDING INFLATION REBATES**
9 **FOR GROUP HEALTH PLANS AND GROUP**
10 **HEALTH INSURANCE COVERAGE.**

11 (a) IN GENERAL.—Not later than December 31,
12 2021, the Secretary of Labor, in consultation with the
13 Secretary of Health and Human Services and the Sec-
14 retary of the Treasury, shall submit to Congress a report
15 on—

16 (1) potential models for an agreement process
17 with manufacturers of prescription drugs under
18 which such manufacturers provide for inflation re-
19 bates with respect to such drugs that are furnished
20 or dispensed to participants and beneficiaries of
21 group health plans and health insurance coverage of-
22 fered in the group market in a manner similar to
23 how manufacturers provide for rebates under section
24 1834(x) of the Social Security Act, as added by sec-
25 tion 201, and section 1860D–14B of such Act, as

1 added by section 202, with respect to prescription
2 drugs that are furnished or dispensed under part B
3 of title XVIII of such Act and part D of such title,
4 respectively; and

5 (2) potential models for enforcement mecha-
6 nisms with respect to such an agreement process
7 that ensure that such inflation rebates are propor-
8 tionally distributed, with respect to costs, to group
9 health plans and health insurance issuers offering
10 health insurance coverage in the group market, to
11 participants and beneficiaries of such plans and cov-
12 erage, or to both.

13 (b) REGULATIONS.—Not later than December 31,
14 2022, the Secretary of Labor shall, in consultation with
15 the Secretary of Health and Human Services and the Sec-
16 retary of the Treasury, promulgate regulations to imple-
17 ment a model described in subsection (a)(1) and a model
18 described in subsection (a)(2), if the Secretary determines
19 that—

20 (1) the prices of a sufficient number (as deter-
21 mined by the Secretary) of drugs described in sub-
22 section (a)(1) have increased over a period of time
23 (as determined by the Secretary) at a percentage
24 that exceeds the percentage by which the consumer

1 price index for all urban consumers (United States
2 city average) has increased over such period; and

3 (2) such model described in subsection (a)(1)
4 and such model described in subsection (a)(2) are
5 feasible.

6 **SEC. 204. ANNUAL REPORT ON DRUG COSTS IN GROUP**
7 **HEALTH PLANS AND GROUP HEALTH INSUR-**
8 **ANCE COVERAGE.**

9 (a) INITIAL REPORT.—Not later than December 31,
10 2021, the Secretary of Labor shall, in consultation with
11 the Secretary of Health and Human Services and the Sec-
12 retary of the Treasury, submit to Congress a report, with
13 respect to a period (as determined by the Secretary of
14 Labor), on—

15 (1) whether the prices of prescription drugs
16 that are furnished or dispensed to participants and
17 beneficiaries of group health plans and health insur-
18 ance coverage offered in the group market during
19 such period have increased at a percentage that ex-
20 ceeds the percentage by which the consumer price
21 index for all urban consumers (United States city
22 average) increased for such period; and

23 (2) whether there are mechanisms by which
24 manufacturers of prescription drugs have attempted
25 to recover rebate payments required of such manu-

1 facturers under section 1834(x) of the Social Secu-
2 rity Act, as added by section 201, and section
3 1860D–14B of such Act, as added by section 202,
4 with respect to prescription drugs that are furnished
5 or dispensed under part B of title XVIII of such Act
6 and part D of such title, respectively, through in-
7 creased prices charged with respect to drugs that are
8 furnished or dispensed to participants and bene-
9 ficiaries of group health plans and health insurance
10 coverage offered in the group market during such
11 period.

12 (b) ANNUAL REPORT.—Not later than December 31
13 of each year following 2021, the Secretary of Labor shall,
14 in consultation with the Secretary of Health and Human
15 Services and the Secretary of the Treasury, submit to
16 Congress a report updating the information and analysis
17 included in the report required under subsection (a), re-
18 flecting, in part, new price and cost information and data
19 for the 12-month period after the period on which the
20 prior year’s report was based.

21 **SEC. 205. COLLECTION OF DATA.**

22 (a) MANUFACTURERS OF PRESCRIPTION DRUGS.—
23 Manufacturers of prescription drugs shall submit to the
24 Secretary of Health and Human Services, Secretary of
25 Labor, and the Secretary of the Treasury appropriate data

1 as necessary for the Secretaries to obtain information
 2 needed to provide the reports under sections 203 and 204.

3 (b) GROUP HEALTH PLANS AND HEALTH INSUR-
 4 ANCE ISSUERS OFFERING HEALTH INSURANCE COV-
 5 ERAGE IN THE GROUP MARKET.—Group health plans and
 6 health insurance issuers offering health insurance cov-
 7 erage in the group market shall submit to the Secretary
 8 of Health and Human Services, Secretary of Labor, and
 9 the Secretary of the Treasury appropriate data as nec-
 10 essary for the Secretaries to obtain information needed to
 11 provide the reports under sections 203 and 204.

12 **TITLE III—PART D IMPROVE-**
 13 **MENTS AND MAXIMUM OUT-**
 14 **OF-POCKET CAP FOR MEDI-**
 15 **CARE BENEFICIARIES**

16 **SEC. 301. MEDICARE PART D BENEFIT REDESIGN.**

17 (a) BENEFIT STRUCTURE REDESIGN.—Section
 18 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
 19 102(b)) is amended—

20 (1) in paragraph (2)—

21 (A) in subparagraph (A), in the matter
 22 preceding clause (i), by inserting “for a year
 23 preceding 2022 and for costs above the annual
 24 deductible specified in paragraph (1) and up to
 25 the annual out-of-pocket threshold specified in

paragraph (4)(B) for 2022 and each subsequent year” after “paragraph (3)”;

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting “for a year preceding 2022,” after “paragraph (4),”; and

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

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2022,” after “paragraph (4),”; and

(II) in subclause (I)(bb), by striking “a year after 2018” and inserting “each of years 2018 through 2021”; and

(ii) in clause (ii)(V), by striking “2019 and each subsequent year” and inserting “each of years 2019 through 2021”;

(2) in paragraph (3)(A)—

1 (A) in the matter preceding clause (i), by
2 inserting “for a year preceding 2022,” after
3 “and (4),”; and

4 (B) in clause (ii), by striking “for a subse-
5 quent year” and inserting “for each of years
6 2007 through 2021”; and

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

10 (I) by redesignating subclauses
11 (I) and (II) as items (aa) and (bb),
12 respectively, and moving the margin
13 of each such redesignated item 2 ems
14 to the right;

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

19 “(I) for a year preceding 2022,
20 the greater of—”;

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

1 (IV) by adding at the end the fol-
2 lowing:

3 “(II) for 2022 and each suc-
4 ceeding year, \$0.”; and

5 (ii) in clause (ii), by striking “clause
6 (i)(I)” and inserting “clause (i)(I)(aa)”;

7 (B) in subparagraph (B)—

8 (i) in clause (i)—

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

11 (II) in subclause (VI)—

12 (aa) by striking “for a sub-
13 sequent year” and inserting “for
14 2021”; and

15 (bb) by striking the period
16 at the end and inserting a semi-
17 colon; and

18 (III) by adding at the end the
19 following new subclauses:

20 “(VII) for 2022, is equal to
21 \$2,000; or

22 “(VIII) for a subsequent year, is
23 equal to the amount specified in this
24 subparagraph for the previous year,
25 increased by the annual percentage in-

1 crease described in paragraph (6) for
2 the year involved.”; and

3 (ii) in clause (ii), by striking “clause
4 (i)(II)” and inserting “clause (i)”;

5 (C) in subparagraph (C)(i), by striking
6 “and for amounts” and inserting “and, for a
7 year preceding 2022, for amounts”; and

8 (D) in subparagraph (E), by striking “In
9 applying” and inserting “For each of years
10 2011 through 2021, in applying”.

11 (b) DECREASING REINSURANCE PAYMENT
12 AMOUNT.—Section 1860D–15(b)(1) of the Social Security
13 Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting
14 after “80 percent” the following: “(or, with respect to a
15 coverage year after 2021, 20 percent)”.

16 (c) MANUFACTURER DISCOUNT PROGRAM.—

17 (1) IN GENERAL.—Part D of title XVIII of the
18 Social Security Act (42 U.S.C. 1395w–101 et seq.),
19 as amended by section 202, is further amended by
20 inserting after section 1860D–14B the following new
21 section:

22 **“SEC. 1860D–14C. MANUFACTURER DISCOUNT PROGRAM.**

23 “(a) ESTABLISHMENT.—The Secretary shall estab-
24 lish a manufacturer discount program (in this section re-
25 ferred to as the ‘program’). Under the program, the Sec-

1 retary shall enter into agreements described in subsection
2 (b) with manufacturers and provide for the performance
3 of the duties described in subsection (c). The Secretary
4 shall establish a model agreement for use under the pro-
5 gram by not later than January 1, 2021, in consultation
6 with manufacturers, and allow for comment on such model
7 agreement.

8 “(b) TERMS OF AGREEMENT.—

9 “(1) IN GENERAL.—

10 “(A) AGREEMENT.—An agreement under
11 this section shall require the manufacturer to
12 provide applicable beneficiaries access to dis-
13 counted prices for applicable drugs of the man-
14 ufacturer that are dispensed on or after Janu-
15 ary 1, 2022.

16 “(B) PROVISION OF DISCOUNTED PRICES
17 AT THE POINT-OF-SALE.—The discounted prices
18 described in subparagraph (A) shall be provided
19 to the applicable beneficiary at the pharmacy or
20 by the mail order service at the point-of-sale of
21 an applicable drug.

22 “(C) TIMING OF AGREEMENT.—

23 “(i) SPECIAL RULE FOR 2022.—In
24 order for an agreement with a manufac-
25 turer to be in effect under this section with

1 respect to the period beginning on January
2 1, 2022, and ending on December 31,
3 2022, the manufacturer shall enter into
4 such agreement not later than 30 days
5 after the date of the establishment of a
6 model agreement under subsection (a).

7 “(ii) 2023 AND SUBSEQUENT
8 YEARS.—In order for an agreement with a
9 manufacturer to be in effect under this
10 section with respect to plan year 2023 or
11 a subsequent plan year, the manufacturer
12 shall enter into such agreement (or such
13 agreement shall be renewed under para-
14 graph (4)(A)) not later than January 30 of
15 the preceding year.

16 “(2) PROVISION OF APPROPRIATE DATA.—Each
17 manufacturer with an agreement in effect under this
18 section shall collect and have available appropriate
19 data, as determined by the Secretary, to ensure that
20 it can demonstrate to the Secretary compliance with
21 the requirements under the program.

22 “(3) COMPLIANCE WITH REQUIREMENTS FOR
23 ADMINISTRATION OF PROGRAM.—Each manufac-
24 turer with an agreement in effect under this section
25 shall comply with requirements imposed by the Sec-

1 retary or a third party with a contract under sub-
2 section (d)(3), as applicable, for purposes of admin-
3 istering the program, including any determination
4 under subparagraph (A) of subsection (c)(1) or pro-
5 cedures established under such subsection (c)(1).

6 “(4) LENGTH OF AGREEMENT.—

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

13 “(B) TERMINATION.—

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

1 termination with sufficient time for such
2 effective date to be repealed if the Sec-
3 retary determines appropriate.

4 “(ii) BY A MANUFACTURER.—A man-
5 ufacturer may terminate an agreement
6 under this section for any reason. Any
7 such termination shall be effective, with re-
8 spect to a plan year—

9 “(I) if the termination occurs be-
10 fore January 30 of a plan year, as of
11 the day after the end of the plan year;
12 and

13 “(II) if the termination occurs on
14 or after January 30 of a plan year, as
15 of the day after the end of the suc-
16 ceeding plan year.

17 “(iii) EFFECTIVENESS OF TERMI-
18 NATION.—Any termination under this sub-
19 paragraph shall not affect discounts for
20 applicable drugs of the manufacturer that
21 are due under the agreement before the ef-
22 fective date of its termination.

23 “(iv) NOTICE TO THIRD PARTY.—The
24 Secretary shall provide notice of such ter-
25 mination to a third party with a contract

1 under subsection (d)(3) within not less
2 than 30 days before the effective date of
3 such termination.

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

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

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

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

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

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

1 “(ii) the discounted price of the appli-
2 cable drug;

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

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

17 “(2) MONITORING COMPLIANCE.—

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

21 “(B) NOTIFICATION.—If a third party
22 with a contract under subsection (d)(3) deter-
23 mines that the manufacturer is not in compli-
24 ance with such agreement, the third party shall

1 notify the Secretary of such noncompliance for
2 appropriate enforcement under subsection (e).

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

9 “(d) ADMINISTRATION.—

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

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

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

1 “(A) receive and transmit information be-
2 tween the Secretary, manufacturers, and other
3 individuals or entities the Secretary determines
4 appropriate;

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

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

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

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

1 “(5) IMPLEMENTATION.—Notwithstanding any
2 other provision of law, the Secretary may implement
3 the program under this section by program instruc-
4 tion or otherwise.

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

8 “(e) ENFORCEMENT.—

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

12 “(2) CIVIL MONEY PENALTY.—

13 “(A) IN GENERAL.—The Secretary may
14 impose a civil money penalty on a manufacturer
15 that fails to provide applicable beneficiaries dis-
16 counts for applicable drugs of the manufacturer
17 in accordance with such agreement for each
18 such failure in an amount the Secretary deter-
19 mines is equal to the sum of—

20 “(i) the amount that the manufac-
21 turer would have paid with respect to such
22 discounts under the agreement, which will
23 then be used to pay the discounts which
24 the manufacturer had failed to provide;
25 and

1 “(ii) 25 percent of such amount.

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

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

15 “(g) DEFINITIONS.—In this section:

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

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

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

23 “(C) has incurred costs, as determined in
24 accordance with section 1860D–2(b)(4)(C), for
25 covered part D drugs in the year that exceed

1 the annual deductible with respect to such indi-
2 vidual for such year, as specified in section
3 1860D–2(b)(1), section 1860D–14(a)(1)(B), or
4 section 1860D–14(a)(2)(B), as applicable.

5 “(2) APPLICABLE DRUG.—The term ‘applicable
6 drug’, with respect to an applicable beneficiary—

7 “(A) means a covered part D drug—

8 “(i) approved under a new drug appli-
9 cation under section 505(c) of the Federal
10 Food, Drug, and Cosmetic Act or, in the
11 case of a biologic product, licensed under
12 section 351 of the Public Health Service
13 Act; and

14 “(ii)(I) if the PDP sponsor of the pre-
15 scription drug plan or the MA organization
16 offering the MA–PD plan uses a for-
17 mulary, which is on the formulary of the
18 prescription drug plan or MA–PD plan
19 that the applicable beneficiary is enrolled
20 in;

21 “(II) if the PDP sponsor of the pre-
22 scription drug plan or the MA organization
23 offering the MA–PD plan does not use a
24 formulary, for which benefits are available
25 under the prescription drug plan or MA–

1 PD plan that the applicable beneficiary is
2 enrolled in; or

3 “(III) is provided through an excep-
4 tion or appeal; and

5 “(B) does not include a selected drug (as
6 defined in section 1192(c)) during a price appli-
7 cability period (as defined in section
8 1191(b)(2)) with respect to such drug.

9 “(3) APPLICABLE NUMBER OF CALENDAR
10 DAYS.—The term ‘applicable number of calendar
11 days’ means—

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

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

16 “(4) DISCOUNTED PRICE.—

17 “(A) IN GENERAL.—The term ‘discounted
18 price’ means, with respect to an applicable drug
19 of a manufacturer dispensed during a year to
20 an applicable beneficiary—

21 “(i) who has not incurred costs, as de-
22 termined in accordance with section
23 1860D–2(b)(4)(C), for covered part D
24 drugs in the year that are equal to or ex-
25 ceed the annual out-of-pocket threshold

1 specified in section 1860D–2(b)(4)(B)(i)
2 for the year, 90 percent of the negotiated
3 price of such drug; and

4 “(ii) who has incurred such costs, as
5 so determined, in the year that are equal
6 to or exceed such threshold for the year,
7 70 percent of the negotiated price of such
8 drug.

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

13 “(C) SPECIAL CASE FOR CERTAIN
14 CLAIMS.—

15 “(i) CLAIMS SPANNING DEDUCT-
16 IBLE.—In the case where the entire
17 amount of the negotiated price of an indi-
18 vidual claim for an applicable drug with re-
19 spect to an applicable beneficiary does not
20 fall above the annual deductible specified
21 in section 1860D–2(b)(1) for the year, the
22 manufacturer of the applicable drug shall
23 provide the discounted price under this
24 section on only the portion of the nego-

1 tiated price of the applicable drug that
2 falls above such annual deductible.

3 “(ii) CLAIMS SPANNING OUT-OF-POCK-
4 ET THRESHOLD.—In the case where the
5 entire amount of the negotiated price of an
6 individual claim for an applicable drug
7 with respect to an applicable beneficiary
8 does not fall entirely below or entirely
9 above the annual out-of-pocket threshold
10 specified in section 1860D–2(b)(4)(B)(i)
11 for the year, the manufacturer of the ap-
12 plicable drug shall provide the discounted
13 price—

14 “(I) in accordance with subpara-
15 graph (A)(i) on the portion of the ne-
16 gotiated price of the applicable drug
17 that falls below such threshold; and

18 “(II) in accordance with subpara-
19 graph (A)(ii) on the portion of such
20 price of such drug that falls at or
21 above such threshold.

22 “(5) MANUFACTURER.—The term ‘manufac-
23 turer’ means any entity which is engaged in the pro-
24 duction, preparation, propagation, compounding,
25 conversion, or processing of prescription drug prod-

1 ucts, either directly or indirectly by extraction from
2 substances of natural origin, or independently by
3 means of chemical synthesis, or by a combination of
4 extraction and chemical synthesis. Such term does
5 not include a wholesale distributor of drugs or a re-
6 tail pharmacy licensed under State law.

7 “(6) NEGOTIATED PRICE.—The term ‘nego-
8 tiated price’ has the meaning given such term in sec-
9 tion 423.100 of title 42, Code of Federal Regula-
10 tions (or any successor regulation), except that, with
11 respect to an applicable drug, such negotiated price
12 shall not include any dispensing fee for the applica-
13 ble drug.

14 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
15 PLAN.—The term ‘qualified retiree prescription drug
16 plan’ has the meaning given such term in section
17 1860D–22(a)(2).”.

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

22 (A) in subsection (a), in the first sentence,
23 by striking “The Secretary” and inserting
24 “Subject to subsection (h), the Secretary”; and

1 (B) by adding at the end the following new
2 subsection:

3 “(h) SUNSET OF PROGRAM.—

4 “(1) IN GENERAL.—The program shall not
5 apply with respect to applicable drugs dispensed on
6 or after January 1, 2022, and, subject to paragraph
7 (2), agreements under this section shall be termi-
8 nated as of such date.

9 “(2) CONTINUED APPLICATION FOR APPLICA-
10 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
11 provisions of this section (including all responsibil-
12 ities and duties) shall continue to apply after Janu-
13 ary 1, 2022, with respect to applicable drugs dis-
14 pensed prior to such date.”.

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

19 (A) in subsection (b)(2)(C)(iii)—

20 (i) by striking “assumptions regarding
21 the reinsurance” and inserting “assump-
22 tions regarding—

23 “(I) the reinsurance”; and

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

1 “(II) for 2022 and each subse-
 2 quent year, the manufacturer dis-
 3 counts provided under section 1860D–
 4 14C subtracted from the actuarial
 5 value to produce such bid; and”; and
 6 (B) in subsection (c)(1)(C)—

7 (i) by striking “an actuarial valuation
 8 of the reinsurance” and inserting “an ac-
 9 tuarial valuation of—

10 “(i) the reinsurance”;

11 (ii) in clause (i), as inserted by clause
 12 (i) of this subparagraph, by adding “and”
 13 at the end; and

14 (iii) by adding at the end the fol-
 15 lowing:

16 “(ii) for 2022 and each subsequent
 17 year, the manufacturer discounts provided
 18 under section 1860D–14C;”.

19 (d) CONFORMING AMENDMENTS.—

20 (1) Section 1860D–2 of the Social Security Act
 21 (42 U.S.C. 1395w–102) is amended—

22 (A) in subsection (a)(2)(A)(i)(I), by strik-
 23 ing “, or an increase in the initial” and insert-
 24 ing “or, for a year preceding 2022, an increase
 25 in the initial”;

1 (B) in subsection (c)(1)(C)—

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

5 (ii) by inserting “for a year preceding
6 2022 or the annual out-of-pocket threshold
7 specified in subsection (b)(4)(B) for the
8 year for 2022 and each subsequent year”
9 after “subsection (b)(3) for the year” each
10 place it appears; and

11 (C) in subsection (d)(1)(A), by striking “or
12 an initial” and inserting “or, for a year pre-
13 ceding 2022, an initial”.

14 (2) Section 1860D–4(a)(4)(B)(i) of the Social
15 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
16 amended by striking “the initial” and inserting “for
17 a year preceding 2022, the initial”.

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

20 (A) in paragraph (1)—

21 (i) in subparagraph (C), by striking
22 “The continuation” and inserting “For a
23 year preceding 2022, the continuation”;

1 (ii) in subparagraph (D)(iii), by strik-
 2 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
 3 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

4 (iii) in subparagraph (E), by striking
 5 “The elimination” and inserting “For a
 6 year preceding 2022, the elimination”; and
 7 (B) in paragraph (2)—

8 (i) in subparagraph (C), by striking
 9 “The continuation” and inserting “For a
 10 year preceding 2022, the continuation”;
 11 and

12 (ii) in subparagraph (E), by striking
 13 “1860D–2(b)(4)(A)(i)(I)” and inserting
 14 “1860D–2(b)(4)(A)(i)(I)(aa)”.

15 (4) Section 1860D–21(d)(7) of the Social Secu-
 16 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended
 17 by striking “section 1860D–2(b)(4)(B)(i)” and in-
 18 serting “section 1860D–2(b)(4)(C)(i)”.

19 (5) Section 1860D–22(a)(2)(A) of the Social
 20 Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is
 21 amended—

22 (A) by striking “the value of any discount”
 23 and inserting the following: “the value of—

24 “(i) for years prior to 2022, any dis-
 25 count”;

1 (B) in clause (i), as inserted by subpara-
2 graph (A) of this paragraph, by striking the pe-
3 riod at the end and inserting “; and”; and

4 (C) by adding at the end the following new
5 clause:

6 “(ii) for 2022 and each subsequent
7 year, any discount provided pursuant to
8 section 1860D–14C.”.

9 (6) Section 1860D–41(a)(6) of the Social Secu-
10 rity Act (42 U.S.C. 1395w–151(a)(6)) is amended—

11 (A) by inserting “for a year before 2022”
12 after “1860D–2(b)(3)”; and

13 (B) by inserting “for such year” before the
14 period.

15 (7) Section 1860D–43 of the Social Security
16 Act (42 U.S.C. 1395w–153) is amended—

17 (A) in subsection (a)—

18 (i) by striking paragraph (1) and in-
19 serting the following:

20 “(1) participate in—

21 “(A) for 2011 through 2021, the Medicare
22 coverage gap discount program under section
23 1860D–14A; and

1 “(B) for 2022 and each subsequent year,
2 the manufacturer discount program under sec-
3 tion 1860D–14C.”;

4 (ii) by striking paragraph (2) and in-
5 serting the following:

6 “(2) have entered into and have in effect—

7 “(A) for 2011 through 2021, an agreement
8 described in subsection (b) of section 1860D–
9 14A with the Secretary; and

10 “(B) for 2022 and each subsequent year,
11 an agreement described in subsection (b) of sec-
12 tion 1860D–14C with the Secretary; and”;

13 (iii) by striking paragraph (3) and in-
14 serting the following:

15 “(3) have entered into and have in effect, under
16 terms and conditions specified by the Secretary—

17 “(A) for 2011 through 2021, a contract
18 with a third party that the Secretary has en-
19 tered into a contract with under subsection
20 (d)(3) of section 1860D–14A; and

21 “(B) for 2022 and each subsequent year,
22 a contract with a third party that the Secretary
23 has entered into a contract with under sub-
24 section (d)(3) of section 1860D–14C.”; and

1 (B) by striking subsection (b) and insert-
2 ing the following:

3 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),
4 and (3)(A) of subsection (a) shall apply to covered part
5 D drugs dispensed under this part on or after January
6 1, 2011, and before January 1, 2022, and paragraphs
7 (1)(B), (2)(B), and (3)(B) of such subsection shall apply
8 to covered part D drugs dispensed under this part on or
9 after January 1, 2022.”.

10 (8) Section 1927 of the Social Security Act (42
11 U.S.C. 1396r–8) is amended—

12 (A) in subsection (c)(1)(C)(i)(VI), by in-
13 serting before the period at the end the fol-
14 lowing: “or under the manufacturer discount
15 program under section 1860D–14C”; and

16 (B) in subsection (k)(1)(B)(i)(V), by in-
17 serting before the period at the end the fol-
18 lowing: “or under section 1860D–14C”.

19 (e) EFFECTIVE DATE.—The amendments made by
20 this section shall apply with respect to plan year 2022 and
21 subsequent plan years.

1 **SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
 2 **TION DRUGS PLANS AND MA-PD PLANS**
 3 **UNDER MEDICARE PROGRAM TO SPREAD**
 4 **OUT COST-SHARING UNDER CERTAIN CIR-**
 5 **CUMSTANCES.**

6 Section 1860D–2(b)(2) of the Social Security Act (42
 7 U.S.C. 1395w–102(b)(2)), as amended by section 301, is
 8 further amended—

9 (1) in subparagraph (A), by striking “Subject
 10 to subparagraphs (C) and (D)” and inserting “Sub-
 11 ject to subparagraphs (C), (D), and (E)”; and

12 (2) by adding at the end the following new sub-
 13 paragraph:

14 “(E) ENROLLEE OPTION REGARDING
 15 SPREADING COST-SHARING.—The Secretary
 16 shall establish by regulation a process under
 17 which, with respect to plan year 2022 and sub-
 18 sequent plan years, a prescription drug plan or
 19 an MA–PD plan shall, in the case of a part D
 20 eligible individual enrolled with such plan for
 21 such plan year who is not a subsidy eligible in-
 22 dividual (as defined in section 1860D–14(a)(3))
 23 and with respect to whom the plan projects that
 24 the dispensing of the first fill of a covered part
 25 D drug to such individual will result in the indi-
 26 vidual incurring costs that are equal to or above

the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the co-insurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.”.

SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) by redesignating the paragraph (6), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), as paragraph (7); and

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

“(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

“(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under sub-

paragraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

“(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

“(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2021, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).”.

TITLE IV—DRUG PRICE TRANSPARENCY

SEC. 401. DRUG PRICE TRANSPARENCY.

Part A of title XI of the Social Security Act is amended by adding at the end the following new sections:

“SEC. 1150C. REPORTING ON DRUG PRICES.

“(a) DEFINITIONS.—In this section:

1 “(1) MANUFACTURER.—The term ‘manufac-
2 turer’ means the person—

3 “(A) that holds the application for a drug
4 approved under section 505 of the Federal
5 Food, Drug, and Cosmetic Act or licensed
6 under section 351 of the Public Health Service
7 Act; or

8 “(B) who is responsible for setting the
9 wholesale acquisition cost for the drug.

10 “(2) QUALIFYING DRUG.—The term ‘qualifying
11 drug’ means any drug that is approved under sub-
12 section (c) or (j) of section 505 of the Federal Food,
13 Drug, and Cosmetic Act or licensed under subsection
14 (a) or (k) of section 351 of the Public Health Serv-
15 ice Act—

16 “(A) that has a wholesale acquisition cost
17 of \$100 or more, adjusted for inflation occur-
18 ring after the date of enactment of this section,
19 for a month’s supply or a typical course of
20 treatment that lasts less than a month, and
21 is—

22 “(i) subject to section 503(b)(1) of
23 the Federal Food, Drug, and Cosmetic
24 Act; and

25 “(ii) not a preventative vaccine; and

1 “(B) for which, during the previous cal-
2 endar year, at least 1 dollar of the total amount
3 of sales were for individuals enrolled under the
4 Medicare program under title XVIII or under a
5 State Medicaid plan under title XIX or under
6 a waiver of such plan.

7 “(3) WHOLESALE ACQUISITION COST.—The
8 term ‘wholesale acquisition cost’ has the meaning
9 given that term in section 1847A(c)(6)(B).

10 “(b) REPORT.—

11 “(1) REPORT REQUIRED.—The manufacturer of
12 a qualifying drug shall submit a report to the Sec-
13 retary if, with respect to the qualifying drug—

14 “(A) there is an increase in the price of
15 the qualifying drug that results in an increase
16 in the wholesale acquisition cost of that drug
17 that is equal to—

18 “(i) 10 percent or more within a 12-
19 month period beginning on or after Janu-
20 ary 1, 2019; or

21 “(ii) 25 percent or more within a 36-
22 month period beginning on or after Janu-
23 ary 1, 2019;

24 “(B) the estimated price of the qualifying
25 drug or spending per individual or per user of

1 such drug (as estimated by the Secretary) for
2 the applicable year (or per course of treatment
3 in such applicable year as determined by the
4 Secretary) is at least \$26,000 beginning on or
5 after January 1, 2021; or

6 “(C) there was an increase in the price of
7 the qualifying drug that resulted in an increase
8 in the wholesale acquisition cost of that drug
9 that is equal to—

10 “(i) 10 percent or more within a 12-
11 month period that begins and ends during
12 the 5-year period preceding January 1,
13 2021; or

14 “(ii) 25 percent or more within a 36-
15 month period that begins and ends during
16 the 5-year period preceding January 1,
17 2021.

18 “(2) REPORT DEADLINE.—Each report de-
19 scribed in paragraph (1) shall be submitted to the
20 Secretary—

21 “(A) in the case of a report with respect
22 to an increase in the price of a qualifying drug
23 that occurs during the period beginning on Jan-
24 uary 1, 2019, and ending on the day that is 60
25 days after the date of the enactment of this sec-

1 tion, not later than 90 days after such date of
2 enactment;

3 “(B) in the case of a report with respect
4 to an increase in the price of a qualifying drug
5 that occurs after the period described in sub-
6 paragraph (A), not later than 30 days prior to
7 the planned effective date of such price increase
8 for such qualifying drug;

9 “(C) in the case of a report with respect
10 to a qualifying drug that meets the criteria
11 under paragraph (1)(B), not later than 30 days
12 after such drug meets such criteria; and

13 “(D) in the case of a report with respect
14 to an increase in the price of a qualifying drug
15 that occurs during a 12-month or 36-month pe-
16 riod described in paragraph (1)(C), not later
17 than April 1, 2021.

18 “(c) CONTENTS.—A report under subsection (b), con-
19 sistent with the standard for disclosures described in sec-
20 tion 213.3(d) of title 12, Code of Federal Regulations (as
21 in effect on the date of enactment of this section), shall,
22 at a minimum, include—

23 “(1) with respect to the qualifying drug—

24 “(A) the percentage by which the manufac-
25 turer will raise the wholesale acquisition cost of

1 the drug within the 12-month period or 36-
2 month period as described in subsection
3 (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or
4 (b)(1)(C)(ii), as applicable, and the effective
5 date of such price increase or the cost associ-
6 ated with a qualifying drug if such drug meets
7 the criteria under subsection (b)(1)(B) and the
8 effective date at which such drug meets such
9 criteria;

10 “(B) an explanation for, and description
11 of, each price increase for such drug that will
12 occur during the 12-month period or the 36-
13 month period described in subsection
14 (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or
15 (b)(1)(C)(ii), as applicable;

16 “(C) an explanation for, and description
17 of, the cost associated with a qualifying drug if
18 such drug meets the criteria under subsection
19 (b)(1)(B), as applicable;

20 “(D) if known and different from the man-
21 ufacturer of the qualifying drug, the identity
22 of—

23 “(i) the sponsor or sponsors of any in-
24 vestigational new drug applications under
25 section 505(i) of the Federal Food, Drug,

1 and Cosmetic Act for clinical investigations
2 with respect to such drug, for which the
3 full reports are submitted as part of the
4 application—

5 “(I) for approval of the drug
6 under section 505 of such Act; or

7 “(II) for licensure of the drug
8 under section 351 of the Public Health
9 Service Act; and

10 “(ii) the sponsor of an application for
11 the drug approved under such section 505
12 of the Federal Food, Drug, and Cosmetic
13 Act or licensed under section 351 of the
14 Public Health Service Act;

15 “(E) a description of the history of the
16 manufacturer’s price increases for the drug
17 since the approval of the application for the
18 drug under section 505 of the Federal Food,
19 Drug, and Cosmetic Act or the issuance of the
20 license for the drug under section 351 of the
21 Public Health Service Act, or since the manu-
22 facturer acquired such approved application or
23 license, if applicable;

24 “(F) the current wholesale acquisition cost
25 of the drug;

1 “(G) the total expenditures of the manu-
2 facturer on—

3 “(i) materials and manufacturing for
4 such drug;

5 “(ii) acquiring patents and licensing
6 for such drug; and

7 “(iii) purchasing or acquiring such
8 drug from another manufacturer, if appli-
9 cable;

10 “(H) the percentage of total expenditures
11 of the manufacturer on research and develop-
12 ment for such drug that was derived from Fed-
13 eral funds;

14 “(I) the total expenditures of the manufac-
15 turer on research and development for such
16 drug that is necessary to demonstrate that it
17 meets applicable statutory standards for ap-
18 proval under section 505 of the Federal Food,
19 Drug, and Cosmetic Act or licensure under sec-
20 tion 351 of the Public Health Service Act, as
21 applicable;

22 “(J) the total expenditures of the manufac-
23 turer on pursuing new or expanded indications
24 or dosage changes for such drug under section
25 505 of the Federal Food, Drug, and Cosmetic

1 Act or section 351 of the Public Health Service
2 Act;

3 “(K) the total expenditures of the manu-
4 facturer on carrying out postmarket require-
5 ments related to such drug, including under
6 section 505(o)(3) of the Federal Food, Drug,
7 and Cosmetic Act;

8 “(L) the total revenue and the net profit
9 generated from the qualifying drug for each cal-
10 endar year since the approval of the application
11 for the drug under section 505 of the Federal
12 Food, Drug, and Cosmetic Act or the issuance
13 of the license for the drug under section 351 of
14 the Public Health Service Act, or since the
15 manufacturer acquired such approved applica-
16 tion or license; and

17 “(M) the total costs associated with mar-
18 keting and advertising for the qualifying drug;
19 “(2) with respect to the manufacturer—

20 “(A) the total revenue and the net profit
21 of the manufacturer for each of the 12-month
22 period described in subsection (b)(1)(A)(i) or
23 (b)(1)(C)(i) or the 36-month period described in
24 subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as ap-
25 plicable;

1 “(B) all stock-based performance metrics
2 used by the manufacturer to determine execu-
3 tive compensation for each of the 12-month pe-
4 riods described in subsection (b)(1)(A)(i) or
5 (b)(1)(C)(i) or the 36-month periods described
6 in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as
7 applicable; and

8 “(C) any additional information the manu-
9 facturer chooses to provide related to drug pric-
10 ing decisions, such as total expenditures on—

11 “(i) drug research and development;

12 or

13 “(ii) clinical trials, including on drugs
14 that failed to receive approval by the Food
15 and Drug Administration; and

16 “(3) such other related information as the Sec-
17 retary considers appropriate and as specified by the
18 Secretary.

19 “(d) INFORMATION PROVIDED.—The manufacturer
20 of a qualifying drug that is required to submit a report
21 under subsection (b), shall ensure that such report and
22 any explanation for, and description of, each price increase
23 described in subsection (c)(1) shall be truthful, not mis-
24 leading, and accurate.

1 “(e) CIVIL MONETARY PENALTY.—Any manufac-
2 turer of a qualifying drug that fails to submit a report
3 for the drug as required by this section, following notifica-
4 tion by the Secretary to the manufacturer that the manu-
5 facturer is not in compliance with this section, shall be
6 subject to a civil monetary penalty of \$75,000 for each
7 day on which the violation continues.

8 “(f) FALSE INFORMATION.—Any manufacturer that
9 submits a report for a drug as required by this section
10 that knowingly provides false information in such report
11 is subject to a civil monetary penalty in an amount not
12 to exceed \$100,000 for each item of false information.

13 “(g) PUBLIC POSTING.—

14 “(1) IN GENERAL.—Subject to paragraph (4),
15 the Secretary shall post each report submitted under
16 subsection (b) on the public website of the Depart-
17 ment of Health and Human Services the day the
18 price increase of a qualifying drug is scheduled to go
19 into effect.

20 “(2) FORMAT.—In developing the format in
21 which reports will be publicly posted under para-
22 graph (1), the Secretary shall consult with stake-
23 holders, including beneficiary groups, and shall seek
24 feedback from consumer advocates and readability
25 experts on the format and presentation of the con-

1 tent of such reports to ensure that such reports
2 are—

3 “(A) user-friendly to the public; and

4 “(B) written in plain language that con-
5 sumers can readily understand.

6 “(3) LIST.—In addition to the reports sub-
7 mitted under subsection (b), the Secretary shall also
8 post a list of each qualifying drug with respect to
9 which the manufacturer was required to submit such
10 a report in the preceding year and whether such
11 manufacturer was required to submit such report
12 based on a qualifying price increase or whether such
13 drug meets the criteria under subsection (b)(1)(B).

14 “(4) PROTECTED INFORMATION.—In carrying
15 out this section, the Secretary shall enforce applica-
16 ble law concerning the protection of confidential
17 commercial information and trade secrets.

18 **“SEC. 1150D. ANNUAL REPORT TO CONGRESS.**

19 “(a) IN GENERAL.—Subject to subsection (b), the
20 Secretary shall submit to the Committees on Energy and
21 Commerce and Ways and Means of the House of Rep-
22 resentatives and the Committees on Health, Education,
23 Labor, and Pensions and Finance of the Senate, and post
24 on the public website of the Department of Health and
25 Human Services in a way that is user-friendly to the pub-

1 lie and written in plain language that consumers can read-
2 ily understand, an annual report—

3 “(1) summarizing the information reported pur-
4 suant to section 1150C;

5 “(2) including copies of the reports and sup-
6 porting detailed economic analyses submitted pursu-
7 ant to such section;

8 “(3) detailing the costs and expenditures in-
9 curred by the Department of Health and Human
10 Services in carrying out section 1150C; and

11 “(4) explaining how the Department of Health
12 and Human Services is improving consumer and
13 provider information about drug value and drug
14 price transparency.

15 “(b) PROTECTED INFORMATION.—In carrying out
16 this section, the Secretary shall enforce applicable law con-
17 cerning the protection of confidential commercial informa-
18 tion and trade secrets.”.

1 **TITLE V—PROGRAM IMPROVE-**
2 **MENTS FOR MEDICARE LOW-**
3 **INCOME BENEFICIARIES**

4 **SEC. 501. DISSEMINATION TO MEDICARE PART D SUBSIDY**
5 **ELIGIBLE INDIVIDUALS OF INFORMATION**
6 **COMPARING PREMIUMS OF CERTAIN PRE-**
7 **SCRIPTION DRUG PLANS.**

8 Section 1860D–1(c)(3) of the Social Security Act (42
9 U.S.C. 1395w–101(c)(3)) is amended by adding at the end
10 the following new subparagraph:

11 “(C) INFORMATION ON PREMIUMS FOR
12 SUBSIDY ELIGIBLE INDIVIDUALS.—

13 “(i) IN GENERAL.—For plan year
14 2022 and each subsequent plan year, the
15 Secretary shall disseminate to each subsidy
16 eligible individual (as defined in section
17 1860D–14(a)(3)) information under this
18 paragraph comparing premiums that would
19 apply to such individual for prescription
20 drug coverage under LIS benchmark plans,
21 including, in the case of an individual en-
22 rolled in a prescription drug plan under
23 this part, information that compares the
24 premium that would apply if such indi-
25 vidual were to remain enrolled in such plan

1 to premiums that would apply if the indi-
 2 vidual were to enroll in other LIS bench-
 3 mark plans.

4 “(ii) LIS BENCHMARK PLAN.—For
 5 purposes of clause (i), the term ‘LIS
 6 benchmark plan’ means, with respect to an
 7 individual, a prescription drug plan under
 8 this part that is offered in the region in
 9 which the individual resides and—

10 “(I) that provides for a premium
 11 that is not more than the low-income
 12 benchmark premium amount (as de-
 13 fined in section 1860D–14(b)(2)) for
 14 such region; or

15 “(II) with respect to which the
 16 premium would be waived as de mini-
 17 mis pursuant to section 1860D–
 18 14(a)(5) for such individual.”.

19 **SEC. 502. PROVIDING FOR INTELLIGENT ASSIGNMENT OF**
 20 **CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS**
 21 **AUTO-ENROLLED UNDER MEDICARE PRE-**
 22 **SCRIPTION DRUG PLANS AND MA-PD PLANS.**

23 (a) IN GENERAL.—Section 1860D–1(b)(1) of the So-
 24 cial Security Act (42 U.S.C. 1395w–101(b)(1)) is amend-
 25 ed—

1 (1) in subparagraph (C)—

2 (A) by inserting after “PDP region” the
3 following: “or through use of an intelligent as-
4 signment process that is designed to maximize
5 the access of such individual to necessary pre-
6 scription drugs while minimizing costs to such
7 individual and to the program under this part
8 to the greatest extent possible. In the case the
9 Secretary enrolls such individuals through use
10 of an intelligent assignment process, such proc-
11 ess shall take into account the extent to which
12 prescription drugs necessary for the individual
13 are covered in the case of a PDP sponsor of a
14 prescription drug plan that uses a formulary,
15 the use of prior authorization or other restric-
16 tions on access to coverage of such prescription
17 drugs by such a sponsor, and the overall quality
18 of a prescription drug plan as measured by
19 quality ratings established by the Secretary”;
20 and

21 (B) by striking “Nothing in the previous
22 sentence” and inserting “Nothing in this sub-
23 paragraph”; and

24 (2) in subparagraph (D)—

1 (A) by inserting after “PDP region” the
2 following: “or through use of an intelligent as-
3 signment process that is designed to maximize
4 the access of such individual to necessary pre-
5 scription drugs while minimizing costs to such
6 individual and to the program under this part
7 to the greatest extent possible. In the case the
8 Secretary enrolls such individuals through use
9 of an intelligent assignment process, such proc-
10 ess shall take into account the extent to which
11 prescription drugs necessary for the individual
12 are covered in the case of a PDP sponsor of a
13 prescription drug plan that uses a formulary,
14 the use of prior authorization or other restric-
15 tions on access to coverage of such prescription
16 drugs by such a sponsor, and the overall quality
17 of a prescription drug plan as measured by
18 quality ratings established by the Secretary”;
19 and

20 (B) by striking “Nothing in the previous
21 sentence” and inserting “Nothing in this sub-
22 paragraph”.

23 (b) EFFECTIVE DATE.—The amendments made by
24 subsection (a) shall apply with respect to plan years begin-
25 ning with plan year 2022.

1 **SEC. 503. EXPANDING ELIGIBILITY FOR LOW-INCOME SUB-**
2 **SIDIES UNDER PART D OF THE MEDICARE**
3 **PROGRAM.**

4 Section 1860D–14(a) of the Social Security Act (42
5 U.S.C. 1395w–114(a)), as amended by section 301(d), is
6 further amended—

7 (1) in the subsection heading, by striking “IN-
8 DIVIDUALS” and all that follows through “LINE”
9 and inserting “CERTAIN INDIVIDUALS”;

10 (2) in paragraph (1)—

11 (A) by striking the paragraph heading and
12 inserting “INDIVIDUALS WITH CERTAIN LOW IN-
13 COMES”; and

14 (B) in the matter preceding subparagraph
15 (A), by inserting “(or, with respect to a plan
16 year beginning on or after January 1, 2022,
17 150 percent)” after “135 percent”; and

18 (3) in paragraph (2)—

19 (A) by striking the paragraph heading and
20 inserting “OTHER LOW-INCOME INDIVIDUALS”;
21 and

22 (B) in the matter preceding subparagraph
23 (A), by striking “In the case of a subsidy” and
24 inserting “With respect to a plan year begin-
25 ning before January 1, 2022, in the case of a
26 subsidy”.

1 **SEC. 504. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-**
 2 **COME TERRITORIAL RESIDENTS FOR PRE-**
 3 **MIUM AND COST-SHARING SUBSIDIES UNDER**
 4 **THE MEDICARE PROGRAM; SUNSET OF EN-**
 5 **HANCED ALLOTMENT PROGRAM.**

6 (a) AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-
 7 COME TERRITORIAL RESIDENTS FOR PREMIUM AND
 8 COST-SHARING SUBSIDIES UNDER THE MEDICARE PRO-
 9 GRAM.—

10 (1) IN GENERAL.—Section 1860D–14(a)(3) of
 11 the Social Security Act (42 U.S.C. 1395w–
 12 114(a)(3)) is amended—

13 (A) in subparagraph (B)(v)—

14 (i) in subclause (I), by striking “and”
 15 at the end;

16 (ii) in subclause (II), by striking the
 17 period and inserting “; and”; and

18 (iii) by inserting after subclause (II)
 19 the following new subclause:

20 “(III) with respect to plan years
 21 beginning on or after January 1,
 22 2024, shall provide that any part D
 23 eligible individual who is enrolled for
 24 medical assistance under the State
 25 Medicaid plan of a territory (as de-
 26 fined in section 1935(f)) under title

1 XIX (or a waiver of such a plan) shall
2 be treated as a subsidy eligible indi-
3 vidual described in paragraph (1).”;
4 and

5 (B) in subparagraph (F), by adding at the
6 end the following new sentence: “The previous
7 sentence shall not apply with respect to eligi-
8 bility determinations for premium and cost-
9 sharing subsidies under this section made on or
10 after January 1, 2024.”.

11 (2) CONFORMING AMENDMENT.—Section
12 1860D–31(j)(2)(D) of the Social Security Act (42
13 U.S.C. 1395w–141(j)(2)(D)) is amended by adding
14 at the end the following new sentence: “The previous
15 sentence shall not apply with respect to amounts
16 made available to a State under this paragraph on
17 or after January 1, 2024.”.

18 (b) SUNSET OF ENHANCED ALLOTMENT PRO-
19 GRAM.—

20 (1) IN GENERAL.—Section 1935(e) of the So-
21 cial Security Act (42 U.S.C. 1396u–5(e)) is amend-
22 ed—

23 (A) in paragraph (1)(A), by inserting after
24 “such State” the following: “before January 1,
25 2021”; and

1 (B) in paragraph (3)—

2 (i) in subparagraph (A), in the matter
3 preceding clause (i), by inserting after “a
4 year” the following: “(before 2024)”; and

5 (ii) in subparagraph (B)(iii), by strik-
6 ing “a subsequent year” and inserting
7 “each of fiscal years 2008 through 2023”.

8 (2) TERRITORY DEFINED.—Section 1935 of the
9 Social Security Act (42 U.S.C. 1396u–5) is amended
10 by adding at the end the following new subsection:

11 “(f) TERRITORY DEFINED.—In this section, the term
12 ‘territory’ means Puerto Rico, the Virgin Islands, Guam,
13 the Northern Mariana Islands, and American Samoa.”.

14 **SEC. 505. AUTOMATIC QUALIFICATION OF CERTAIN MED-**
15 **ICAID BENEFICIARIES FOR PREMIUM AND**
16 **COST-SHARING SUBSIDIES UNDER PART D OF**
17 **THE MEDICARE PROGRAM.**

18 Clause (v) of section 1860D–14(a)(3)(B) of the So-
19 cial Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as
20 amended by section 504, is further amended—

21 (1) in subclause (II), by striking “and” at the
22 end;

23 (2) in subclause (III), by striking the period
24 and inserting “; and”; and

1 (3) by inserting after subclause (III) the fol-
2 lowing new subclause:

3 “(IV) with respect to plan years
4 beginning on or after January 1,
5 2024, shall, notwithstanding the pre-
6 ceding clauses of this subparagraph,
7 provide that any part D eligible indi-
8 vidual not described in subclause (I),
9 (II), or (III) who is enrolled, as of the
10 day before the date on which such in-
11 dividual attains the age of 65, for
12 medical assistance under a State plan
13 under title XIX (or a waiver of such
14 plan) pursuant to clause (i)(VIII) or
15 (ii)(XX) of section 1902(a)(10)(A),
16 and who has income below 200 per-
17 cent of the poverty line applicable to
18 a family of the size involved, shall be
19 treated as a subsidy eligible individual
20 described in paragraph (1) for a lim-
21 ited period of time, as specified by the
22 Secretary.”.

1 **SEC. 506. PROVIDING FOR CERTAIN RULES REGARDING**
2 **THE TREATMENT OF ELIGIBLE RETIREMENT**
3 **PLANS IN DETERMINING THE ELIGIBILITY OF**
4 **INDIVIDUALS FOR PREMIUM AND COST-**
5 **SHARING SUBSIDIES UNDER PART D OF THE**
6 **MEDICARE PROGRAM.**

7 Section 1860D–14(a)(3)(C)(i) of the Social Security
8 Act (42 U.S.C. 1395w–114(a)(3)(C)(i)) is amended, by
9 striking “except that support and maintenance furnished
10 in kind shall not be counted as income; and” and inserting
11 “except that—

12 “(I) support and maintenance
13 furnished in kind shall not be counted
14 as income; and

15 “(II) for plan years beginning on
16 or after January 1, 2024, any dis-
17 tribution or withdrawal from an eligi-
18 ble retirement plan (as defined in sub-
19 paragraph (B) of section 402(c)(8) of
20 the Internal Revenue Code of 1986,
21 but excluding any defined benefit plan
22 described in clause (iv) or (v) of such
23 subparagraph and any qualified trust
24 (as defined in subparagraph (A) of
25 such section) which is part of such a

1 defined benefit plan) shall be counted
2 as income; and”.

3 **SEC. 507. REDUCING COST-SHARING AND OTHER PROGRAM**
4 **IMPROVEMENTS FOR LOW-INCOME BENE-**
5 **FICIARIES.**

6 (a) INCREASE IN INCOME ELIGIBILITY TO 150 PER-
7 CENT OF FPL FOR QUALIFIED MEDICARE BENE-
8 FICIARIES.—

9 (1) IN GENERAL.—Section 1905(p)(2)(A) of the
10 Social Security Act (42 U.S.C. 1396d(p)(2)(A)) is
11 amended by striking “shall be at least the percent
12 provided under subparagraph (B) (but not more
13 than 100 percent) of the official poverty line” and
14 all that follows through the period at the end and
15 inserting the following: “shall be—

16 “(i) before January 1, 2022, at least
17 the percent provided under subparagraph
18 (B) (but not more than 100 percent) of
19 the official poverty line (as defined by the
20 Office of Management and Budget, and re-
21 vised annually in accordance with section
22 673(2) of the Omnibus Budget Reconcili-
23 ation Act of 1981) applicable to a family
24 of the size involved; and

1 “(ii) on or after January 1, 2022,
2 equal to 150 percent of the official poverty
3 line (as so defined and revised) applicable
4 to a family of the size involved.”.

5 (2) NOT COUNTING IN-KIND SUPPORT AND
6 MAINTENANCE AS INCOME.—Section 1905(p)(2)(D)
7 of the Social Security Act (42 U.S.C.
8 1396d(p)(2)(D)) is amended by adding at the end
9 the following new clause:

10 “(iii) In determining income under
11 this subsection, support and maintenance
12 furnished in kind, as described in section
13 1612(a)(2)(A), shall not be counted as in-
14 come.”.

15 (3) CONFORMING AMENDMENTS.—

16 (A) Section 1902(a)(10)(E) of the Social
17 Security Act (42 U.S.C. 1396a(a)(10)(E)) is
18 amended—

19 (i) in clause (iii), by striking “for
20 making medical” and inserting “before
21 January 1, 2022, for making medical”;
22 and

23 (ii) in clause (iv), by striking “subject
24 to sections” and inserting “before January
25 1, 2022, subject to sections”.

1 (B) Section 1933 of the Social Security
2 Act (42 U.S.C. 1396u–3) is amended—

3 (i) in subsection (a), by striking “A
4 State plan” and inserting “Subject to sub-
5 section (h), a State plan”; and

6 (ii) by adding at the end the following
7 new subsection:

8 “(h) SUNSET.—The provisions of this section shall
9 have no force or effect after December 31, 2021.”.

10 (b) 100 PERCENT FMAP.—Section 1905 of the So-
11 cial Security Act (42 U.S.C. 1396d) is amended by adding
12 at the end the following new subsection:

13 “(gg) INCREASED FMAP FOR EXPANDED MEDICARE
14 COST-SHARING POPULATIONS.—

15 “(1) IN GENERAL.—Notwithstanding subsection
16 (b), with respect to expenditures described in para-
17 graph (2) the Federal medical assistance percentage
18 shall be equal to 100 percent.

19 “(2) EXPENDITURES DESCRIBED.—The expend-
20 itures described in this paragraph are expenditures
21 made on or after January 1, 2022, for medical as-
22 sistance for medicare cost-sharing provided to any
23 individual under clause (i) or (ii) of section
24 1902(a)(10)(E) who would not have been eligible for
25 medicare cost-sharing under any such clause under

1 the income or resource eligibility standards in effect
 2 on October 1, 2018.”.

3 **TITLE VI—PROVIDING FOR DEN-**
 4 **TAL, VISION, AND HEARING**
 5 **COVERAGE UNDER THE MEDI-**
 6 **CARE PROGRAM**

7 **SEC. 601. DENTAL AND ORAL HEALTH CARE.**

8 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-
 9 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

10 (1) in subparagraph (GG), by striking “and”
 11 after the semicolon at the end;

12 (2) in subparagraph (HH), by striking the pe-
 13 riod at the end and adding “; and”; and

14 (3) by adding at the end the following new sub-
 15 paragraph:

16 “(II) dental and oral health services (as defined
 17 in subsection (kkk));”.

18 (b) DENTAL AND ORAL HEALTH SERVICES DE-
 19 FINED.—Section 1861 of the Social Security Act (42
 20 U.S.C. 1395x) is amended by adding at the end the fol-
 21 lowing new subsection:

22 “(kkk) DENTAL AND ORAL HEALTH SERVICES.—

23 “(1) IN GENERAL.—The term ‘dental and oral
 24 health services’ means items and services (other
 25 than such items and services for which payment may

1 be made under part A as inpatient hospital services)
 2 that are furnished during 2025 or a subsequent
 3 year, for which coverage was not provided under
 4 part B as of the date of the enactment of this sub-
 5 section, and that are—

6 “(A) the preventive and screening services
 7 described in paragraph (2) furnished by a doc-
 8 tor of dental surgery or of dental medicine (as
 9 described in subsection (r)(2)) or an oral health
 10 professional (as defined in paragraph (4)); or

11 “(B) the basic treatments specified for
 12 such year by the Secretary pursuant to para-
 13 graph (3)(A) and the major treatments speci-
 14 fied for such year by the Secretary pursuant to
 15 paragraph (3)(B) furnished by such a doctor or
 16 such a professional.

17 “(2) PREVENTIVE AND SCREENING SERV-
 18 ICES.—The preventive and screening services de-
 19 scribed in this paragraph are the following:

20 “(A) Oral exams.

21 “(B) Dental cleanings.

22 “(C) Dental x-rays performed in the office
 23 of a doctor or professional described in para-
 24 graph (1)(A).

25 “(D) Fluoride treatments.

1 “(3) BASIC AND MAJOR TREATMENTS.—For
2 2025 and each subsequent year, the Secretary shall
3 specify—

4 “(A) basic treatments (which may include
5 basic tooth restorations, basic periodontic serv-
6 ices, tooth extractions, and oral disease man-
7 agement services); and

8 “(B) major treatments (which may include
9 major tooth restorations, major periodontic
10 services, bridges, crowns, and root canals);
11 that shall be included as dental and oral health serv-
12 ices for such year.

13 “(4) ORAL HEALTH PROFESSIONAL.—The term
14 ‘oral health professional’ means, with respect to den-
15 tal and oral health services, a health professional
16 who is licensed to furnish such services, acting with-
17 in the scope of such license, by the State in which
18 such services are furnished.”.

19 (c) PAYMENT; COINSURANCE; AND LIMITATIONS.—

20 (1) IN GENERAL.—Section 1833(a)(1) of the
21 Social Security Act (42 U.S.C. 1395l(a)(1)) is
22 amended—

23 (A) in subparagraph (N), by inserting
24 “and dental and oral health services (as defined

1 in section 1861(kkk))” after “section
2 1861(hhh)(1))”;

3 (B) by striking “and” before “(CC)”; and

4 (C) by inserting before the semicolon at
5 the end the following: “, and (DD) with respect
6 to dental and oral health services (as defined in
7 section 1861(kkk)), the amount paid shall be
8 the payment amount specified under section
9 1834(x)”.

10 (2) PAYMENT AND LIMITS SPECIFIED.—Section
11 1834 of the Social Security Act (42 U.S.C. 1395m)
12 is amended by adding at the end the following new
13 subsection:

14 “(x) PAYMENT AND LIMITS FOR DENTAL AND ORAL
15 HEALTH SERVICES.—

16 “(1) IN GENERAL.—The payment amount
17 under this part for dental and oral health services
18 (as defined in section 1861(kkk)) shall be, subject to
19 paragraph (3), the applicable percent (specified in
20 paragraph (2)) of the lesser of the actual charge for
21 the services or the amount determined under the
22 payment basis determined under section 1848. In
23 determining such amounts determined under such
24 payment basis, the Secretary shall consider payment
25 rates paid to dentists for comparable services under

1 State plans under title XIX, under the TRICARE
2 program under chapter 55 of title 10 of the United
3 States Code, and by other health care payers, such
4 as Medicare Advantage plans under part C.

5 “(2) APPLICABLE PERCENT.—For purposes of
6 paragraph (1), the applicable percent specified in
7 this paragraph is, with respect to dental and oral
8 health services (as defined in section 1861(kkk)) fur-
9 nished in a year—

10 “(A) that are preventive and screening
11 services described in paragraph (2) or basic
12 treatments specified for such year pursuant to
13 paragraph (3)(A) of such section, 80 percent;
14 and

15 “(B) that are major treatments specified
16 for such year pursuant to paragraph (3)(B) of
17 such section—

18 “(i) in the case such services are fur-
19 nished during 2025, 10 percent;

20 “(ii) in the case such services are fur-
21 nished during 2026 or a subsequent year
22 before 2029, the applicable percent speci-
23 fied under this subparagraph for the pre-
24 vious year, increased by 10 percentage
25 points; and

1 “(iii) in the case such services are fur-
2 nished during 2029 or a subsequent year,
3 50 percent.

4 “(3) LIMITATIONS.—With respect to dental and
5 oral health services that are—

6 “(A) preventive and screening oral exams,
7 payment may be made under this part for not
8 more than two such exams during a 12-month
9 period;

10 “(B) dental cleanings, payment may be
11 made under this part for not more than two
12 such cleanings during a 12-month period; and

13 “(C) not described in subparagraph (A) or
14 (B), payment may be made under this part only
15 at such frequencies and under such cir-
16 cumstances determined appropriate by the Sec-
17 retary.”.

18 (d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—

19 (1) IN GENERAL.—Section 1848(j)(3) of the
20 Social Security Act (42 U.S.C. 1395w-4(j)(3)) is
21 amended by inserting “(2)(II),” before “(3)”.

22 (2) EXCLUSION FROM MIPS.—Section
23 1848(q)(1)(C)(ii) of the Social Security Act (42
24 U.S.C. 1395w-4(q)(1)(C)(ii)) is amended—

1 (A) in subclause (II), by striking “or” at
2 the end;

3 (B) in subclause (III), by striking the pe-
4 riod at the end and inserting “; or”; and

5 (C) by adding at the end the following new
6 subclause:

7 “(IV) with respect to 2025 and
8 each subsequent year, is a doctor of
9 dental surgery or of dental medicine
10 (as described in section 1861(r)(2)) or
11 is an oral health professional (as de-
12 fined in section 1861(kkk)(4)).”.

13 (3) INCLUSION OF ORAL HEALTH PROFES-
14 SIONALS AS CERTAIN PRACTITIONERS.—Section
15 1842(b)(18)(C) of the Social Security Act (42
16 U.S.C. 1395u(b)(18)(C)) is amended by adding at
17 the end the following new clause:

18 “(vii) With respect to 2025 and each subse-
19 quent year, an oral health professional (as defined in
20 section 1861(kkk)(4)).”.

21 (e) DENTURES.—

22 (1) IN GENERAL.—Section 1861(s)(8) of the
23 Social Security Act (42 U.S.C. 1395x(s)(8)) is
24 amended—

25 (A) by striking “(other than dental)”; and

1 (B) by inserting “and excluding dental, ex-
2 cept for a full or partial set of dentures fur-
3 nished on or after January 1, 2025” after “co-
4 lostomy care”.

5 (2) SPECIAL PAYMENT RULES.—

6 (A) LIMITATIONS.—Section 1834(h) of the
7 Social Security Act (42 U.S.C. 1395m(h)) is
8 amended by adding at the end the following
9 new paragraph:

10 “(6) SPECIAL PAYMENT RULE FOR DEN-
11 TURES.—Payment may be made under this part
12 with respect to an individual for dentures—

13 “(A) not more than once during any 5-year
14 period (except in the case that a doctor or pro-
15 fessional described in section 1861(kkk)(1)(A)
16 determines such dentures do not fit the indi-
17 vidual); and

18 “(B) only to the extent that such dentures
19 are furnished pursuant to a written order of
20 such a doctor or professional.”.

21 (B) APPLICATION OF COMPETITIVE ACQUI-
22 SITION.—

23 (i) IN GENERAL.—Section
24 1834(h)(1)(H) of the Social Security Act
25 (42 U.S.C. 1395m(h)(1)(H)) is amended—

1 (I) in the subparagraph heading,
2 by inserting “, DENTURES” after
3 “ORTHOTICS”;

4 (II) by inserting “, of dentures
5 described in paragraph (2)(D) of such
6 section,” after “2011,”; and

7 (III) in clause (i), by inserting “,
8 such dentures” after “orthotics”.

9 (ii) CONFORMING AMENDMENT.—Sec-
10 tion 1847(a)(2) of the Social Security Act
11 (42 U.S.C. 1395w–3(a)(2)) is amended by
12 adding at the end the following new sub-
13 paragraph:

14 “(D) DENTURES.—Dentures described in
15 section 1861(s)(8) for which payment would
16 otherwise be made under section 1834(h).”.

17 (iii) EXEMPTION OF CERTAIN ITEMS
18 FROM COMPETITIVE ACQUISITION.—Sec-
19 tion 1847(a)(7) of the Social Security Act
20 (42 U.S.C. 1395w–3(a)(7)) is amended by
21 adding at the end the following new sub-
22 paragraph:

23 “(C) CERTAIN DENTURES.—Those items
24 and services described in paragraph (2)(D) if
25 furnished by a physician or other practitioner

1 (as defined by the Secretary) to the physician's
2 or practitioner's own patients as part of the
3 physician's or practitioner's professional serv-
4 ice.".

5 (f) EXCLUSION MODIFICATIONS.—Section 1862(a) of
6 the Social Security Act (42 U.S.C. 1395y(a)) is amend-
7 ed—

8 (1) in paragraph (1)—

9 (A) in subparagraph (O), by striking
10 “and” at the end;

11 (B) in subparagraph (P), by striking the
12 semicolon at the end and inserting “, and”; and

13 (C) by adding at the end the following new
14 subparagraph:

15 “(Q) in the case of dental and oral health serv-
16 ices (as defined in section 1861(kkk)) that are pre-
17 ventive and screening services described in para-
18 graph (2) of such section, which are furnished more
19 frequently than provided under section 1834(x)(3)
20 and under circumstances other than circumstances
21 determined appropriate under such section;” and

22 (2) in paragraph (12), by inserting before the
23 semicolon at the end the following: “and except that
24 payment may be made under part B for dental and

1 oral health services that are covered under section
2 1861(s)(2)(II)’’.

3 (g) CERTAIN NON-APPLICATION.—

4 (1) IN GENERAL.—Paragraphs (1) and (4) of
5 section 1839(a) of the Social Security Act (42
6 U.S.C. 1395r(a)) are amended by adding at the end
7 of each such paragraphs the following: “In applying
8 this paragraph there shall not be taken into account
9 benefits and administrative costs attributable to the
10 amendments made by section 601 (other than sub-
11 section (g)) of the Elijah E. Cummings Lower Drug
12 Costs Now Act and the Government contribution
13 under section 1844(a)(4)’’.

14 (2) PAYMENT.—Section 1844(a) of such Act
15 (42 U.S.C. 1395w(a)) is amended—

16 (A) in paragraph (3), by striking the pe-
17 riod at the end and inserting “; plus”; and

18 (B) by adding at the end the following new
19 paragraph:

20 “(4) a Government contribution equal to the
21 amount that is estimated to be payable for benefits
22 and related administrative costs incurred that are
23 attributable to the amendments made by section 601
24 (other than subsection (g)) of the Elijah E. Cum-
25 mings Lower Drug Costs Now Act.’’.

1 (h) IMPLEMENTATION FUNDING.—

2 (1) IN GENERAL.—The Secretary of Health and
3 Human Services (in this subsection referred to as
4 the “Secretary”) shall provide for the transfer from
5 the Federal Supplementary Medical Insurance Trust
6 Fund under section 1841 of the Social Security Act
7 (42 U.S.C. 1395t) to the Centers for Medicare &
8 Medicaid Services Program Management Account
9 of—

10 (A) \$20,000,000 for each of fiscal years
11 2020 through 2025 for purposes of imple-
12 menting the amendments made by this section;
13 and

14 (B) such sums as determined appropriate
15 by the Secretary for each subsequent fiscal year
16 for purposes of administering the provisions of
17 such amendments.

18 (2) AVAILABILITY AND ADDITIONAL USE OF
19 FUNDS.—Funds transferred pursuant to paragraph
20 (1) shall remain available until expended and may be
21 used, in addition to the purpose specified in para-
22 graph (1)(A), to implement the amendments made
23 by sections 602 and 603.

1 **SEC. 602. PROVIDING COVERAGE FOR HEARING CARE**
2 **UNDER THE MEDICARE PROGRAM.**

3 (a) PROVISION OF AURAL REHABILITATION AND
4 TREATMENT SERVICES BY QUALIFIED AUDIOLOGISTS.—
5 Section 1861(l)(3) of the Social Security Act (42 U.S.C.
6 1395x(l)(3)) is amended by inserting “(and, beginning
7 January 1, 2023, such aural rehabilitation and treatment
8 services)” after “assessment services”.

9 (b) COVERAGE OF HEARING AIDS.—

10 (1) INCLUSION OF HEARING AIDS AS PROS-
11 THETIC DEVICES.—Section 1861(s)(8) of the Social
12 Security Act (42 U.S.C. 1395x(s)(8)) is amended by
13 inserting “, and including hearing aids furnished on
14 or after January 1, 2023, to individuals diagnosed
15 with profound or severe hearing loss” before the
16 semicolon at the end.

17 (2) PAYMENT LIMITATIONS FOR HEARING
18 AIDS.—Section 1834(h) of the Social Security Act
19 (42 U.S.C. 1395m(h)), as amended by section
20 601(e)(2)(A), is further amended by adding at the
21 end the following new paragraph:

22 “(7) LIMITATIONS FOR HEARING AIDS.—Pay-
23 ment may be made under this part with respect to
24 an individual, with respect to hearing aids furnished
25 on or after January 1, 2023—

1 “(A) not more than once during a 5-year
2 period;

3 “(B) only for types of such hearing aids
4 that are not over-the-counter hearing aids (as
5 defined in section 520(q)(1) of the Federal
6 Food, Drug, and Cosmetic Act) and that are
7 determined appropriate by the Secretary; and

8 “(C) only if furnished pursuant to a writ-
9 ten order of a physician or qualified audiologist
10 (as defined in section 1861(ll)(4)(B)).”.

11 (3) APPLICATION OF COMPETITIVE ACQUISI-
12 TION.—

13 (A) IN GENERAL.—Section 1834(h)(1)(H)
14 of the Social Security Act (42 U.S.C.
15 1395m(h)(1)(H)), as amended by section
16 601(e)(2)(B)(i), is further amended—

17 (i) in the header, by inserting “,
18 HEARING AIDS” after “DENTURES”;

19 (ii) by inserting “, of hearing aids de-
20 scribed in paragraph (2)(E) of such sec-
21 tion,” after “paragraph (2)(D) of such sec-
22 tion”; and

23 (iii) in clause (i), by inserting “, such
24 hearing aids” after “such dentures”.

25 (B) CONFORMING AMENDMENT.—

1 (i) IN GENERAL.—Section 1847(a)(2)
2 of the Social Security Act (42 U.S.C.
3 1395w–3(a)(2)), as amended by section
4 601(e)(2)(B)(ii), is further amended by
5 adding at the end the following new sub-
6 paragraph:

7 “(E) HEARING AIDS.—Hearing aids de-
8 scribed in section 1861(s)(8) for which payment
9 would otherwise be made under section
10 1834(h).”.

11 (ii) EXEMPTION OF CERTAIN ITEMS
12 FROM COMPETITIVE ACQUISITION.—Sec-
13 tion 1847(a)(7) of the Social Security Act
14 (42 U.S.C. 1395w–3(a)(7)), as amended
15 by section 601(e)(2)(B)(iii), is further
16 amended by adding at the end the fol-
17 lowing new subparagraph:

18 “(D) CERTAIN HEARING AIDS.—Those
19 items and services described in paragraph
20 (2)(E) if furnished by a physician or other
21 practitioner (as defined by the Secretary) to the
22 physician’s or practitioner’s own patients as
23 part of the physician’s or practitioner’s profes-
24 sional service.”.

(c) EXCLUSION MODIFICATION.—Section 1862(a)(7) of the Social Security Act (42 U.S.C. 1395y(a)(7)) is amended by inserting “(except such hearing aids or examinations therefor as described in and otherwise allowed under section 1861(s)(8))” after “hearing aids or examinations therefor”.

(1) IN GENERAL.—The last sentence of section 1839(a)(1) of the Social Security Act (42 U.S.C. 1395r(a)(1)), as added by section 601(g)(1), is amended by striking “section 601 (other than subsection (g))” and inserting “sections 601 (other than subsection (g)), 602 (other than subsection (d))”.

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1 by section 601(g)(2), is amended by striking “sec-
2 tion 601 (other than subsection (g))” and inserting
3 “sections 601 (other than subsection (g)), 602
4 (other than subsection (d))”.

5 (e) REPORT; REGULATIONS.—

6 (1) REPORT.—Not later than the date that is
7 3 years after the date of the enactment of this Act,
8 the Inspector General of the Department of Health
9 and Human Services shall conduct a study to assess
10 (and submit to the Secretary of Health and Human
11 Services a report on) any program integrity or over-
12 utilization risks with respect to allowing qualified
13 audiologists (as defined in paragraph (4)(B) of
14 1861(l) of the Social Security Act (42 U.S.C.
15 1395x(l))) to furnish audiology services (as defined
16 in paragraph (3) of such section) to individuals enti-
17 tled to benefits under part A of title XVIII of such
18 Act (42 U.S.C. 1395c et seq.) and enrolled for bene-
19 fits under part B of such title (42 U.S.C. 1395j et
20 seq.) without such individuals being referred by a
21 physician (as defined in section 1861(r) of such Act
22 (42 U.S.C. 1395x(r))) or practitioner (as described
23 in section 602.32 of title 42, Code of Federal Regu-
24 lations) to such qualified audiologists. In conducting
25 such study, the Inspector General may take into ac-

1 count experiences with audiologists furnishing audi-
2 ology services to enrollees in other Federal pro-
3 grams, including in a health benefit plan under
4 chapter 89 of title 5, United States Code or in
5 health care benefits under the TRICARE program
6 under chapter 55 of title 10 of the United States
7 Code or under chapter 17 of title 38 of such Code.

8 (2) REGULATIONS.—The Secretary of Health
9 and Human Services may promulgate regulations to
10 allow qualified audiologists (as so defined) to furnish
11 audiology services (as so defined) without a referral
12 from a physician or practitioner, consistent with the
13 findings submitted to the Secretary pursuant to
14 paragraph (1)(B).

15 (f) IMPLEMENTATION FUNDING.—

16 (1) IN GENERAL.—The Secretary of Health and
17 Human Services (in this subsection referred to as
18 the “Secretary”) shall provide for the transfer from
19 the Federal Supplementary Medical Insurance Trust
20 Fund under section 1841 of the Social Security Act
21 (42 U.S.C. 1395t) to the Centers for Medicare &
22 Medicaid Services Program Management Account
23 of—

24 (A) \$20,000,000 for each of fiscal years

25 2020 through 2024 for purposes of imple-

1 menting the amendments made by this section;
2 and

3 (B) such sums as determined appropriate
4 by the Secretary for each subsequent fiscal year
5 for purposes of administering the provisions of
6 such amendments.

7 (2) AVAILABILITY AND ADDITIONAL USE OF
8 FUNDS.—Funds transferred pursuant to paragraph
9 (1) shall remain available until expended and may be
10 used, in addition to the purpose specified in para-
11 graph (1)(A), to implement the amendments made
12 by sections 601 and 603.

13 **SEC. 603. PROVIDING COVERAGE FOR VISION CARE UNDER**
14 **THE MEDICARE PROGRAM.**

15 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-
16 curity Act (42 U.S.C. 1395x(s)(2)), as amended by section
17 601(a), is further amended—

18 (1) in subparagraph (HH), by striking “and”
19 after the semicolon at the end;

20 (2) in subparagraph (II), by striking the period
21 at the end and adding “; and”; and

22 (3) by adding at the end the following new sub-
23 paragraph:

24 “(JJ) vision services (as defined in subsection
25 (III));”.

1 (b) VISION SERVICES DEFINED.—Section 1861 of
2 the Social Security Act (42 U.S.C. 1395x), as amended
3 by section 601(b), is further amended by adding at the
4 end the following new subsection:

5 “(III) VISION SERVICES.—The term ‘vision services’
6 means—

7 “(1) routine eye examinations to determine the
8 refractive state of the eyes, including procedures per-
9 formed during the course of such examination; and

10 “(2) contact lens fitting services;
11 furnished on or after January 1, 2023, by or under the
12 direct supervision of an optometrist or ophthalmologist
13 who is legally authorized to furnish such examinations,
14 procedures, or fitting services (as applicable) under State
15 law (or the State regulatory mechanism provided by State
16 law) of the State in which the examinations, procedures,
17 or fitting services are furnished.”.

18 (c) PAYMENT LIMITATIONS.—Section 1834 of the
19 Social Security Act (42 U.S.C. 1395m), as amended by
20 section 601(c)(2), is further amended by adding at the end
21 the following new subsection:

22 “(y) LIMITATION FOR VISION SERVICES.—With re-
23 spect to vision services (as defined in section 1861(III))
24 and an individual, payment may be made under this part
25 for only 1 routine eye examination described in paragraph

1 (1) of such section and 1 contact lens fitting service de-
2 scribed in paragraph (2) of such section during a 2-year
3 period.”.

4 (d) PAYMENT UNDER PHYSICIAN FEE SCHEDULE.—
5 Section 1848(j)(3) of the Social Security Act (42 U.S.C.
6 1395w-4(j)(3)), as amended by section 601(d)(1), is fur-
7 ther amended by inserting “(2)(JJ),” before “(3)”.

8 (e) COVERAGE OF CONVENTIONAL EYEGLASSES AND
9 CONTACT LENSES.—Section 1861(s)(8) of the Social Se-
10 curity Act (42 U.S.C. 1395x(s)(8)), as amended by section
11 602(b)(1), is further amended by striking “, and including
12 one pair of conventional eyeglasses or contact lenses fur-
13 nished subsequent to each cataract surgery with insertion
14 of an intraocular lens” and inserting “, including one pair
15 of conventional eyeglasses or contact lenses furnished sub-
16 sequent to each cataract surgery with insertion of an
17 intraocular lens, if furnished before January 1, 2023, in-
18 cluding conventional eyeglasses or contact lenses, whether
19 or not furnished subsequent to such a surgery, if furnished
20 on or after January 1, 2024”.

21 (f) SPECIAL PAYMENT RULES FOR EYEGLASSES AND
22 CONTACT LENSES.—

23 (1) LIMITATIONS.—Section 1834(h) of the So-
24 cial Security Act (42 U.S.C. 1395m(h)), as amended
25 by section 601(e)(2)(A) and section 602(b)(2), is

1 further amended by adding at the end the following
2 new paragraph:

3 “(8) PAYMENT LIMITATIONS FOR EYEGLASSES
4 AND CONTACT LENSES.—

5 “(A) IN GENERAL.—With respect to eye-
6 glasses and contact lenses furnished to an indi-
7 vidual on or after January 1, 2023, subject to
8 subparagraph (B), payment may be made under
9 this part only—

10 “(i) during a 2-year period, for either
11 1 pair of eyeglasses (including lenses and
12 frames) or not more than a 2-year supply
13 of contact lenses that is provided in not
14 more than 180-day increments;

15 “(ii) with respect to amounts attrib-
16 utable to the lenses and frames of such a
17 pair of eyeglasses or amounts attributable
18 to such a 2-year supply of contact lenses,
19 in an amount not greater than—

20 “(I) for a pair of eyeglasses fur-
21 nished in, or a 2-year supply of con-
22 tact lenses beginning in, 2023—

23 “(aa) \$85 for the lenses of
24 such pair of eyeglasses and \$85

1 for the frames of such pair of
2 eyeglasses; or

3 “(bb) \$85 for such 2-year
4 supply of contact lenses; and

5 “(II) for the lenses and frames of
6 a pair of eyeglasses furnished in, or a
7 2-year supply of contact lenses begin-
8 ning in, a subsequent year, the dollar
9 amounts specified under this subpara-
10 graph for the previous year, increased
11 by the percentage change in the con-
12 sumer price index for all urban con-
13 sumers (United States city average)
14 for the 12-month period ending with
15 June of the previous year;

16 “(iii) for types of eyeglass lenses, and
17 for types of contact lenses, as determined
18 appropriate by the Secretary;

19 “(iv) if furnished pursuant to a writ-
20 ten order of a physician described in sec-
21 tion 1861(l); and

22 “(v) if during the 2-year period de-
23 scribed in clause (i), the individual did not
24 already receive (as described in subpara-
25 graph (B)) one pair of conventional eye-

1 glasses or contact lenses subsequent to a
2 cataract surgery with insertion of an intra-
3 ocular lens furnished during such period.

4 “(B) EXCEPTION.—With respect to a 2-
5 year period described in subparagraph (A)(i), in
6 the case of an individual who receives cataract
7 surgery with insertion of an intraocular lens,
8 notwithstanding subparagraph (A), payment
9 may be made under this part for one pair of
10 conventional eyeglasses or contact lenses fur-
11 nished subsequent to such cataract surgery dur-
12 ing such period.”.

13 (2) APPLICATION OF COMPETITIVE ACQUISI-
14 TION.—

15 (A) IN GENERAL.—Section 1834(h)(1)(H)
16 of the Social Security Act (42 U.S.C.
17 1395m(h)(1)(H)), as amended by section
18 601(e)(2)(B)(i) and section 602(b)(3)(A), is
19 further amended—

20 (i) in the header by inserting “, EYE-
21 GLASSES, AND CONTACT LENSES” after
22 “HEARING AIDS”;

23 (ii) by inserting “and of eyeglasses
24 and contact lenses described in paragraph

1 (2)(F) of such section,” after “paragraph
2 (2)(E) of such section,”; and

3 (iii) in clause (i), by inserting “, or
4 such eyeglasses and contact lenses” after
5 “such hearing aids”.

6 (B) CONFORMING AMENDMENT.—

7 (i) IN GENERAL.—Section 1847(a)(2)
8 of the Social Security Act (42 U.S.C.
9 1395w–3(a)(2)), as amended by section
10 601(e)(2)(B)(ii) and section
11 602(b)(3)(B)(i), is further amended by
12 adding at the end the following new sub-
13 paragraph:

14 “(F) EYEGLASSES AND CONTACT
15 LENSES.—Eyeglasses and contact lenses de-
16 scribed in section 1861(s)(8) for which payment
17 would otherwise be made under section
18 1834(h).”.

19 (ii) EXEMPTION OF CERTAIN ITEMS
20 FROM COMPETITIVE ACQUISITION.—Sec-
21 tion 1847(a)(7) of the Social Security Act
22 (42 U.S.C. 1395w–3(a)(7)), as amended
23 by section 601(e)(2)(B)(iii) and section
24 602(b)(3)(B)(ii), is further amended by

1 adding at the end the following new sub-
2 paragraph:

3 “(E) CERTAIN EYEGLASSES AND CONTACT
4 LENSES.—Those items and services described in
5 paragraph (2)(F) if furnished by a physician or
6 other practitioner (as defined by the Secretary)
7 to the physician’s or practitioner’s own patients
8 as part of the physician’s or practitioner’s pro-
9 fessional service.”.

10 (g) EXCLUSION MODIFICATIONS.—Section 1862(a)
11 of the Social Security Act (42 U.S.C. 1395y(a)), as
12 amended by section 601(f), is further amended—

13 (1) in paragraph (1)—

14 (A) in subparagraph (P), by striking
15 “and” at the end;

16 (B) in subparagraph (Q), by striking the
17 semicolon at the end and inserting “, and”; and

18 (C) by adding at the end the following new
19 subparagraph:

20 “(R) in the case of vision services (as defined
21 in section 1861(l)) that are routine eye examina-
22 tions and contact lens fitting services (as described
23 in paragraph (1) or (2), respectively, of such sec-
24 tion), which are furnished more frequently than once
25 during a 2-year period;” and

1 (2) in paragraph (7)—

2 (A) by inserting “(other than such an ex-
3 amination that is a vision service that is cov-
4 ered under section 1861(s)(2)(JJ))” after “eye
5 examinations”; and

6 (B) by inserting “(other than such a proce-
7 dure that is a vision service that is covered
8 under section 1861(s)(2)(JJ))” after “refractive
9 state of the eyes”.

10 (h) CERTAIN NON-APPLICATION.—

11 (1) IN GENERAL.—The last sentence of section
12 1839(a)(1) of the Social Security Act (42 U.S.C.
13 1395r(a)(1)), as added by section 601(g)(1) and
14 amended by section 602(d)(1), is further amended
15 by inserting “, and 603 (other than subsection (h))”
16 after “602 (other than subsection (d))”.

17 (2) PAYMENT.—Paragraph (4) of section
18 1844(a) of such Act (42 U.S.C. 1395w(a)), as added
19 by section 601(g)(2) and amended by section
20 602(d)(2), is further amended by inserting “, and
21 603 (other than subsection (h))” after “602 (other
22 than subsection (d))”.

23 (i) IMPLEMENTATION FUNDING.—

24 (1) IN GENERAL.—The Secretary of Health and
25 Human Services (in this subsection referred to as

1 the “Secretary”) shall provide for the transfer from
2 the Federal Supplementary Medical Insurance Trust
3 Fund under section 1841 of the Social Security Act
4 (42 U.S.C. 1395t) to the Centers for Medicare &
5 Medicaid Services Program Management Account
6 of—

7 (A) \$20,000,000 for each of fiscal years
8 2020 through 2024 for purposes of imple-
9 menting the amendments made by this section;
10 and

11 (B) such sums as determined appropriate
12 by the Secretary for each subsequent fiscal year
13 for purposes of administering the provisions of
14 such amendments.

15 (2) AVAILABILITY AND ADDITIONAL USE OF
16 FUNDS.—Funds transferred pursuant to paragraph
17 (1) shall remain available until expended and may be
18 used, in addition to the purpose specified in para-
19 graph (1)(A), to implement the amendments made
20 by sections 601 and 602.

1 **TITLE VII—NIH, FDA, AND**
2 **OPIOIDS FUNDING**
3 **Subtitle A—Biomedical Innovation**
4 **Expansion**

5 **SEC. 701. NIH INNOVATION INITIATIVES.**

6 (a) NIH INNOVATION ACCOUNT.—

7 (1) IN GENERAL.—Section 1001(b) of the 21st
8 Century Cures Act (Public Law 114–255) is amend-
9 ed by adding at the end the following:

10 “(5) SUPPLEMENTAL FUNDING AND ADDI-
11 TIONAL ACTIVITIES.—

12 “(A) IN GENERAL.—In addition to the
13 funds made available under paragraph (2),
14 there are authorized to be appropriated, and
15 are hereby appropriated, to the Account, out of
16 any monies in the Treasury not otherwise ap-
17 propriated, to be available until expended with-
18 out further appropriation, the following:

19 “(i) For fiscal year 2021,
20 \$255,400,000.

21 “(ii) For fiscal year 2022,
22 \$260,400,000.

23 “(iii) For fiscal year 2023,
24 \$163,400,000.

1 “(iv) For fiscal year 2024,
2 \$547,000,000.

3 “(v) For fiscal year 2025,
4 \$848,000,000.

5 “(vi) For fiscal year 2026,
6 \$842,400,000.

7 “(vii) For fiscal year 2027,
8 \$1,089,600,000.

9 “(viii) For fiscal year 2028,
10 \$1,115,600,000.

11 “(ix) For fiscal year 2029,
12 \$1,170,600,000.

13 “(x) For fiscal year 2030,
14 \$1,207,600,000.

15 “(B) SUPPLEMENTAL FUNDING FOR CER-
16 TAIN PROJECTS.—Of the total amounts made
17 available under subparagraph (A) for each of
18 fiscal years 2021 through 2030, a total amount
19 not to exceed the following shall be made avail-
20 able for the following categories of NIH Innova-
21 tion Projects:

22 “(i) For projects described in para-
23 graph (4)(A), an amount not to exceed a
24 total of \$2,070,600,000 as follows:

1 “(I) For each of fiscal years
2 2021 and 2022, \$50,000,000.

3 “(II) For fiscal year 2024,
4 \$100,000,000.

5 “(III) For each of fiscal years
6 2025 and 2026, \$300,000,000.

7 “(IV) For each of fiscal years
8 2027 through 2029, \$317,000,000.

9 “(V) For fiscal year 2030,
10 \$319,600,000.

11 “(ii) For projects described in para-
12 graph (4)(B), an amount not to exceed a
13 total of \$2,041,900,000 as follows:

14 “(I) For each of fiscal years
15 2021 and 2022, \$50,000,000.

16 “(II) For fiscal year 2024,
17 \$128,000,000.

18 “(III) For fiscal year 2025,
19 \$209,000,000.

20 “(IV) For fiscal year 2026,
21 \$100,000,000.

22 “(V) For fiscal year 2027,
23 \$325,000,000.

24 “(VI) For fiscal year 2028,
25 \$350,000,000.

1 “(VII) For fiscal year 2029,
2 \$400,000,000.

3 “(VIII) For fiscal year 2030,
4 \$429,900,000.

5 “(iii) For projects described in para-
6 graph (4)(C), an amount not to exceed a
7 total of \$1,558,400,000 as follows:

8 “(I) For each of fiscal years
9 2024 and 2025, \$151,200,000.

10 “(II) For each of fiscal years
11 2026 through 2030, \$251,200,000.

12 “(iv) For projects described in para-
13 graph (4)(D), an amount not to exceed
14 \$15,400,000 for each of fiscal years 2021
15 through 2030.

16 “(C) ADDITIONAL NIH INNOVATION
17 PROJECTS.—In addition to funding NIH Inno-
18 vation Projects pursuant to subparagraph (B),
19 of the total amounts made available under sub-
20 paragraph (A), a total amount not to exceed
21 the following shall be made available for the fol-
22 lowing categories of NIH Innovation Projects:

23 “(i) To support research related to
24 combating antimicrobial resistance and an-
25 tibiotic resistant bacteria, including re-

1 search into new treatments, diagnostics,
2 and vaccines, research, in consultation with
3 the Centers for Disease Control and Pre-
4 vention, into stewardship, and the develop-
5 ment of strategies, in coordination with the
6 Biomedical Advanced Research and Devel-
7 opment Authority under section 319L of
8 the Public Health Service Act, to support
9 commercialization of new antibiotics, not
10 to exceed a total of 1,144,500,000, as fol-
11 lows:

12 “(I) For each of fiscal years
13 2021 through 2024, \$100,000,000.

14 “(II) For each of fiscal years
15 2025 and 2026, \$120,000,000.

16 “(III) For each of fiscal years
17 2027 through 2029, \$125,000,000.

18 “(IV) For fiscal year 2030,
19 \$129,500,000.

20 “(ii) To support research and re-
21 search activities related to rare diseases or
22 conditions, including studies or analyses
23 that help to better understand the natural
24 history of a rare disease or condition and
25 translational studies related to rare dis-

eases or conditions, not to exceed a total of
\$530,600,000, as follows:

“(I) For fiscal year 2021,
\$40,000,000.

“(II) For fiscal year 2022,
\$45,000,000.

“(III) For fiscal year 2023,
\$48,000,000.

“(IV) For each of fiscal years
2024 and 2025, \$52,400,000.

“(V) For fiscal year 2026,
\$55,800,000.

“(VI) For fiscal year 2027,
\$56,000,000.

“(VII) For fiscal year 2028,
\$57,000,000.

“(VIII) For each of fiscal years
2029 and 2030, \$62,000,000.”.

(2) CONFORMING AMENDMENTS.—Section 1001
of the 21st Century Cures Act (Public Law 114–
255) is amended—

(A) in subsection (a), by striking “sub-
section (b)(4)” and inserting “subsections
(b)(4) and (b)(5)”;

1 (B) in subsection (b)(1), by striking “para-
2 graph (4)” and inserting “paragraphs (4) and
3 (5)”; and

4 (C) in subsection (c)(2)(A)(ii), by inserting
5 “or pursuant to subsection (b)(5)” after “sub-
6 section (b)(3)”; and

7 (D) in subsection (d), by inserting “or pur-
8 suant to subsection (b)(5)” after “subsection
9 (b)(3)”.

10 (b) WORKPLAN.—Section 1001(c)(1) of the 21st
11 Century Cures Act (Public Law 114–255) is amended by
12 adding at the end the following:

13 “(D) UPDATES.—The Director of NIH
14 shall , after seeking recommendations in accord-
15 ance with the process described in subpara-
16 graph (C), update the work plan submitted
17 under this subsection for each of fiscal years
18 2021 through 2030 to reflect the amendments
19 made to this section by the Elijah E. Cum-
20 mings Lower Drug Costs Now Act.”.

21 (c) ANNUAL REPORTS.—Section 1001(c)(2)(A) of the
22 21st Century Cures Act (Public Law 114–255) is amend-
23 ed by striking “2027” and inserting “2030”.

24 (d) SUNSET.—Section 1001(e) of the 21st Century
25 Cures Act (Public Law 114–255) is amended by striking

1 “September 30, 2026” and inserting “September 30,
2 2030”.

3 **SEC. 702. NIH CLINICAL TRIAL.**

4 Part A of title IV of the Public Health Service Act
5 (42 U.S.C. 281 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 404O. CLINICAL TRIAL ACCELERATION PILOT INITIA-
8 TIVE.**

9 “(a) ESTABLISHMENT OF PILOT PROGRAM.—The
10 Secretary, acting through the Director of the National In-
11 stitutes of Health, shall, not later than 2 years after the
12 date of enactment of this Act, establish and implement
13 a pilot program to award multi-year contracts to eligible
14 entities to support phase II clinical trials and phase III
15 clinical trials—

16 “(1) to promote innovation in treatments and
17 technologies supporting the advanced research and
18 development and production of high need cures; and

19 “(2) to provide support for the development of
20 medical products and therapies.

21 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
22 assistance under the pilot program established under sub-
23 section (a), an entity shall—

1 “(1) be seeking to market a medical product or
2 therapy that is the subject of clinical trial or trials
3 to be supported using such assistance;

4 “(2) be a public or private entity, which may
5 include a private or public research institution, a
6 contract research organization, an institution of
7 higher education (as defined in section 101 of the
8 Higher Education Act of 1965 (20 U.S.C. 1001)), a
9 medical center, a biotechnology company, or an aca-
10 demic research institution; and

11 “(3) comply with requirements of the Federal
12 Food, Drug, and Cosmetic Act or section 351 of this
13 Act at all stages of development, manufacturing, re-
14 view, approval, and safety surveillance of a medical
15 product.

16 “(c) DUTIES.—The Secretary, acting through the Di-
17 rector of National Institutes of Health, shall—

18 “(1) in establishing the pilot program under
19 subsection (a), consult with—

20 “(A) the Director of the National Center
21 for Advancing Translational Sciences and the
22 other national research institutes in considering
23 their requests for new or expanded clinical trial
24 support efforts; and

1 “(B) the Commissioner of Food and Drugs
2 and any other head of a Federal agency as the
3 Secretary determines to be appropriate to en-
4 sure coordination and efficiently advance clin-
5 ical trial activities;

6 “(2) in implementing the pilot program under
7 subsection (a), consider consulting with patients and
8 patient advocates; and

9 “(3) in awarding contracts under the pilot pro-
10 gram under subsection (a), consider—

11 “(A) the expected health impacts of the
12 clinical trial or trials to be supported under the
13 contract; and

14 “(B) the degree to which the medical prod-
15 uct or therapy that is the subject of such clin-
16 ical trial or trials is a high need cure.

17 “(d) EXCLUSION.—A contract may not be awarded
18 under the pilot program under subsection (a) if the drug
19 that is the subject of the clinical trial or trials to be sup-
20 ported under the contract is a drug designated under sec-
21 tion 526 of the Federal Food, Drug, and Cosmetic Act
22 as a drug for a rare disease or condition.

23 “(e) NIH CLINICAL TRIAL ACCELERATOR AC-
24 COUNT.—

1 “(1) ESTABLISHMENT.—There is established in
2 the Treasury an account, to be known as the ‘NIH
3 Clinical Trial Accelerator Account’ (referred to in
4 this section as the ‘Account’), for purposes of car-
5 rying out this section.

6 “(2) TRANSFER OF DIRECT SPENDING SAV-
7 INGS.—There shall be transferred to the Account
8 from the general fund of the Treasury,
9 \$680,000,000 for each of fiscal years 2021 through
10 2025, to be available until expended without further
11 appropriation.

12 “(3) WORK PLAN.—Not later than 180 days
13 after the date of enactment of this Act, the Sec-
14 retary shall submit to the Committee on Energy and
15 Commerce of the House of Representatives and the
16 Committee on Health, Education, Labor and Pen-
17 sions of the Senate a work plan that includes the
18 proposed implementation of this section and the pro-
19 posed allocation of funds in the Account.

20 “(f) REPORTS TO CONGRESS.—Not later than Octo-
21 ber 1 of each fiscal year, the Secretary shall submit to
22 the Committee on Energy and Commerce of the House
23 of Representatives and the Committee on Health, Edu-
24 cation, Labor and Pensions of the Senate a report on—

25 “(1) the implementation of this section;

1 “(2) any available results on phase II clinical
2 trials and phase III clinical trials supported under
3 this section during such fiscal year; and

4 “(3) the extent to which Federal funds are obli-
5 gated to support such clinical trials, including the
6 specific amount of such support and awards pursu-
7 ant to an allocation from the Account under sub-
8 section (e).

9 “(g) DEFINITIONS.—In this section:

10 “(1) PHASE II CLINICAL TRIAL.—The term
11 ‘phase II clinical trial’ means a phase II clinical in-
12 vestigation, as described in section 312.21 of title
13 21, Code of Federal Regulations (or any successor
14 regulations).

15 “(2) PHASE III CLINICAL TRIALS.—The term
16 ‘phase III clinical trial’ means a phase III clinical
17 investigation, as described in section 312.21 of title
18 21, Code of Federal Regulations (or any successor
19 regulations).

20 “(3) HIGH NEED CURE.—The term ‘high need
21 cure’ has the meaning given such term in section
22 480(a)(3).”.

1 **SEC. 703. INNOVATION NETWORK.**

2 Part A of title IV of the Public Health Service Act
3 (42 U.S.C. 281 et seq.), as amended by section 702, is
4 further amended by adding at the end the following:

5 **“SEC. 404P. INNOVATION NETWORK.**

6 “(a) FUNDS.—The Director of NIH shall award
7 grants or contracts to eligible entities to develop, expand,
8 and enhance the commercialization of biomedical products.

9 “(b) ELIGIBLE ENTITY.—In this section, the term
10 ‘eligible entity’ means an entity receiving funding under—

11 “(1) the Small Business Innovation Research
12 program of the National Institutes of Health; or

13 “(2) the Small Business Technology Transfer
14 program of the National Institutes of Health.

15 “(c) USE OF FUNDS.—An eligible entity shall use the
16 funds received through such grant or contract to sup-
17 port—

18 “(1) the Commercialization Readiness Pilot
19 program of the National Institutes of Health;

20 “(2) the Innovation Corps program of the Na-
21 tional Institutes of Health;

22 “(3) the Commercialization Accelerator pro-
23 gram of the National Institutes of Health;

24 “(4) the Commercialization Assistance program
25 of the National Institutes of Health; and

1 “(5) such other programs and activities as the
2 Director of NIH determines to be appropriate, to
3 support the commercialization stage of research,
4 later stage research and development, technology
5 transfer, and commercialization technical assistance.

6 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
7 are authorized to be appropriated to carry out this section
8 \$100,000,000 for each of fiscal years 2021 through 2025,
9 to be available until expended.”.

10 **Subtitle B—Investing in Safety and** 11 **Innovation**

12 **SEC. 711. FOOD AND DRUG ADMINISTRATION.**

13 (a) FDA INNOVATION ACCOUNT.—

14 (1) IN GENERAL.—Section 1002(b) of the 21st
15 Century Cures Act (Public Law 114–255) is amend-
16 ed—

17 (A) in paragraph (1), by striking “para-
18 graph (4)” and inserting “paragraphs (4) and
19 (5)”; and

20 (B) by adding at the end the following new
21 paragraph:

22 “(5) SUPPLEMENTAL FUNDING AND ADDI-
23 TIONAL ACTIVITIES.—

24 “(A) IN GENERAL.—In addition to the
25 funds made available under paragraph (2),

1 there are authorized to be appropriated, and
2 are hereby appropriated, to the Account, out of
3 any monies in the Treasury not otherwise ap-
4 propriated, to be available until expended with-
5 out further appropriation, the following:

6 “(i) For fiscal year 2020,
7 \$417,500,000.

8 “(ii) For each of fiscal years 2021
9 and 2022, \$157,500,000.

10 “(iii) For each of fiscal years 2023
11 through 2025, \$152,500,000.

12 “(iv) For each of fiscal years 2026
13 through 2029, \$202,500,000.

14 “(B) SUPPLEMENTAL FUNDING FOR CER-
15 TAIN ACTIVITIES.—Of the total amounts made
16 available under subparagraph (A) for each of
17 fiscal years 2026 through 2029, a total amount
18 not to exceed \$50,000,000 for each such fiscal
19 year, shall be made available for the activities
20 under subtitles A through F (including the
21 amendments made by such subtitles) of title III
22 of this Act and section 1014 of the Federal
23 Food, Drug, and Cosmetic Act, as added by
24 section 3073 of this Act.

1 “(C) ADDITIONAL FDA ACTIVITIES.—In
2 addition to funding activities pursuant to sub-
3 paragraph (B), of the total amounts made
4 available under subparagraph (A), a total
5 amount not to exceed the following shall be
6 made available for the following categories of
7 activities:

8 “(i) For modernization of the tech-
9 nical infrastructure of the Food and Drug
10 Administration, including enhancements
11 such as interoperability across the agency,
12 and additional capabilities to develop an
13 advanced information technology infra-
14 structure to support the agency’s regu-
15 latory mission:

16 “(I) For fiscal year 2020,
17 \$180,000,000.

18 “(II) For each of fiscal years
19 2021 through 2029, \$60,000.

20 “(ii) For support for continuous man-
21 ufacturing of drugs and biological prod-
22 ucts, including complex biological products
23 such as regenerative medicine therapies,
24 through grants to institutions of higher
25 education and nonprofit organizations and

1 other appropriate mechanisms, for each of
2 fiscal years 2020 through 2029,
3 \$20,000,000.

4 “(iii) For support for the Commis-
5 sioner of Food and Drugs to engage ex-
6 perts, such as through the formation and
7 operation of public-private partnerships or
8 other appropriate collaborative efforts, to
9 advance the development and delivery of
10 individualized human gene therapy prod-
11 ucts:

12 “(I) For fiscal year 2020,
13 \$50,000,000.

14 “(II) For each of fiscal years
15 2021 through 2029, \$10,000,000.

16 “(iv) For support for inspections, en-
17 forcement, and quality surveillance activi-
18 ties across the Food and Drug Administra-
19 tion, including foreign and domestic in-
20 spections across products, for each of fiscal
21 years 2020 through 2029, \$20,000,000.

22 “(v) For support for activities of the
23 Food and Drug Administration related to
24 customs and border protection to provide
25 improvements to technologies, inspection

1 capacity, and sites of import (including
2 international mail facilities) in which the
3 Food and Drug Administration operates,
4 for each of fiscal years 2020 through
5 2029, \$10,000,000.

6 “(vi) To further advance the develop-
7 ment of a coordinated postmarket surveil-
8 lance system for all medical products, in-
9 cluding drugs, biological products, and de-
10 vices, linked to electronic health records in
11 furtherance of the Food and Drug Admin-
12 istration’s postmarket surveillance capabili-
13 ties:

14 “(I) For fiscal year 2020,
15 \$112,500,000.

16 “(II) For each of fiscal years
17 2021 through 2029, \$12,500,000.

18 “(vii) For support for Food and Drug
19 Administration activities to keep pace with
20 the projected product development of re-
21 generative therapies, including cellular and
22 somatic cell gene therapy products:

23 “(I) For each of fiscal years
24 2020 through 2022, \$10,000,000.

1 “(II) For each of fiscal years
2 2023 through 2029, \$5,000,000.

3 “(viii) For carrying out section 714A
4 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 379d–3a; relating to hiring
6 authority for scientific, technical, and pro-
7 fessional personnel), for each of fiscal
8 years 2020 through 2029, \$2,500,000.

9 “(ix) For the Food and Drug Admin-
10 istration to support improvements to the
11 technological infrastructure for reporting
12 and analysis of adverse events associated
13 with the use of drugs and biological prod-
14 ucts, for each of fiscal years 2020 through
15 2029, \$12,500,000.”.

16 (2) CONFORMING AMENDMENTS.—Section 1002
17 of the 21st Century Cures Act (Public Law 114–
18 255) is amended—

19 (A) in subsection (a), by inserting before
20 the period at the end the following: “or pursu-
21 ant to subparagraph (A) of subsection (b)(5) to
22 carry out the activities described in subpara-
23 graphs (B) and (C) of such subsection”; and

24 (B) in subsection (d)—

1 (i) by inserting “or pursuant to sub-
2 paragraph (A) of subsection (b)(5)” after
3 “subsection (b)(3)”; and

4 (ii) by striking “subsection (b)(4)”
5 and inserting “subsections (b)(4) and
6 (b)(5)”.

7 (b) ANNUAL REPORT.—Section 1002(c)(2)(A) of the
8 21st Century Cures Act (Public Law 114–255) is amend-
9 ed, in the matter preceding clause (i), by striking “2026”
10 and inserting “2030”.

11 (c) SUNSET.—Section 1002(e) of the 21st Century
12 Cures Act (Public Law 114–255) is amended by striking
13 “September 30, 2025” and inserting “September 30,
14 2030”.

15 **SEC. 712. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.**

16 (a) IN GENERAL.—Not later than 180 days after the
17 date of enactment of this Act, the Secretary of Health and
18 Human Services shall conduct a study to identify—

19 (1) diseases or conditions that lack a treatment
20 approved by the Food and Drug Administration and
21 instances in which development of a treatment for
22 such diseases or conditions could fill an unmet med-
23 ical need for the treatment of a serious or life-
24 threatening disease or condition or a rare disease or
25 condition; and

1 (2) appropriate incentives that would lead to
2 the development, approval, and marketing of such
3 treatments.

4 (b) REPORT TO CONGRESS; RECOMMENDATIONS.—

5 Not later than one year after the date of enactment of
6 this Act, the Secretary shall submit to the Congress a re-
7 port that includes—

8 (1) findings from the study under subsection
9 (a); and

10 (2) recommendations regarding legislation nec-
11 essary to create appropriate incentives identified
12 pursuant to subsection (a)(2).

13 **Subtitle C—Opioid Epidemic**
14 **Response**

15 **SEC. 721. OPIOID EPIDEMIC RESPONSE FUND.**

16 (a) IN GENERAL.—The Secretary of Health and
17 Human Services (referred to in this section as the “Sec-
18 retary”) shall use any funds made available pursuant to
19 subsection (b) to carry out the programs and activities de-
20 scribed in subsection (c) to address the opioid and sub-
21 stance use disorder epidemic. Such funds shall be in addi-
22 tion to any funds which are otherwise available to carry
23 out such programs and activities.

24 (b) OPIOID EPIDEMIC RESPONSE FUND.—

1 (1) ESTABLISHMENT OF ACCOUNT.—There is
2 established in the Treasury an account, to be known
3 as the Opioid Epidemic Response Fund (referred to
4 in this section as the “Fund”), for purposes of fund-
5 ing the programs and activities described in sub-
6 section (c).

7 (2) FUNDING.—There is authorized to be ap-
8 propriated, and there is appropriated, to the Fund,
9 out of any monies in the Treasury not otherwise ap-
10 propriated \$1,980,000,000 for each of fiscal years
11 2021 through 2025.

12 (3) AVAILABILITY.—Amounts made available by
13 paragraph (2) shall be made available to the agen-
14 cies specified in subsection (c) in accordance with
15 such subsection. Amounts made available to an
16 agency pursuant to the preceding sentence for a fis-
17 cal year shall remain available until expended.

18 (c) PROGRAMS AND ACTIVITIES.—Of the total
19 amount in the Fund for each of fiscal years 2021 through
20 2025, such amount shall be allocated as follows:

21 (1) SAMHSA.—For the Substance Abuse and
22 Mental Health Services Administration to carry out
23 programs and activities pursuant to section 722,
24 \$1,500,000,000 for each of fiscal years 2021
25 through 2025.

1 (2) CDC.—For the Centers for Disease Control
2 and Prevention to carry out programs and activities
3 pursuant to section 723, \$120,000,000 for each of
4 fiscal years 2021 through 2025.

5 (3) FDA.—For the Food and Drug Adminis-
6 tration to carry out programs and activities pursu-
7 ant to section 724, \$10,000,000 for each of fiscal
8 years 2021 through 2025.

9 (4) NIH.—For the National Institutes of
10 Health to carry out programs and activities pursu-
11 ant to section 725, \$240,000,000 for each of fiscal
12 years 2021 through 2025.

13 (5) HRSA.—For the Health Resources and
14 Services Administration to carry out programs and
15 activities pursuant to section 726, \$90,000,000 for
16 each of fiscal years 2021 through 2025.

17 (6) ACF.—For the Administration for Children
18 and Families to carry out programs and activities
19 pursuant to section 727, \$20,000,000 for each of
20 fiscal years 2021 through 2025.

21 (d) ACCOUNTABILITY AND OVERSIGHT.—

22 (1) WORK PLAN.—

23 (A) IN GENERAL.—Not later than 180
24 days after the date of enactment of this Act,
25 the Secretary of Health and Human Services

1 shall submit to the Committee on Health, Edu-
2 cation, Labor, and Pensions and the Committee
3 on Appropriations of the Senate and the Com-
4 mittee on Energy and Commerce, the Com-
5 mittee on Appropriations, and the Committee
6 on Education and Labor of the House of Rep-
7 resentatives, a work plan including the proposed
8 allocation of funds made available pursuant to
9 subsection (b) for each of fiscal years 2021
10 through 2025 and the contents described in
11 subparagraph (B).

12 (B) CONTENTS.—The work plan submitted
13 under subparagraph (A) shall include—

14 (i) the amount of money to be obli-
15 gated or expended out of the Fund in each
16 fiscal year for each program and activity
17 described in subsection (c); and

18 (ii) a description and justification of
19 each such program and activity.

20 (2) ANNUAL REPORTS.—Not later than October
21 1 of each of fiscal years 2022 through 2026, the
22 Secretary of Health and Human Services shall sub-
23 mit to the Committee on Health, Education, Labor,
24 and Pensions and the Committee on Appropriations
25 of the Senate and the Committee on Energy and

1 Commerce, the Committee on Appropriations, and
2 the Committee on Education and Labor of the
3 House of Representatives, a report including—

4 (A) the amount of money obligated or ex-
5 pended out of the Fund in the prior fiscal year
6 for each program and activity described in sub-
7 section (c);

8 (B) a description of all programs and ac-
9 tivities using funds made available pursuant to
10 subsection (b); and

11 (C) how the programs and activities are re-
12 sponding to the opioid and substance use dis-
13 order epidemic.

14 (e) LIMITATIONS.—Notwithstanding any authority in
15 this subtitle or any appropriations Act, any funds made
16 available pursuant to subsection (b) may not be used for
17 any purpose other than the programs and activities de-
18 scribed in subsection (c).

19 **SEC. 722. SUBSTANCE ABUSE AND MENTAL HEALTH SERV-**
20 **ICES ADMINISTRATION.**

21 (a) IN GENERAL.—The entirety of the funds made
22 available pursuant to section 721(c)(1) shall be for the As-
23 sistant Secretary for Mental Health and Substance Use
24 to continue to award the State Opioid Response Grants
25 funded by the heading “Substance Abuse And Mental

1 Health Services Administration—Substance Abuse Treat-
2 ment” in title II of the Departments of Labor, Health and
3 Human Services, and Education, and Related Agencies
4 Appropriations Act, 2018 (Public Law 115–141). Subject
5 to subsections (b) and (c), such grants shall be awarded
6 in the same manner and subject to the same conditions
7 as were applicable to such grants for fiscal year 2018.

8 (b) REQUIREMENT THAT TREATMENT BE EVI-
9 DENCE-BASED.—As a condition on receipt of a grant pur-
10 suant to subsection (a), a grantee shall agree that—

11 (1) treatments, practices, or interventions fund-
12 ed through the grant will be evidence-based; and

13 (2) such treatments, practices, and interven-
14 tions will include medication-assisted treatment for
15 individuals diagnosed with opioid use disorder, using
16 drugs only if the drugs have been approved or li-
17 censed by the Food and Drug Administration under
18 section 505 of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355) or section 351 of the
20 Public Health Service Act (42 U.S.C. 262).

21 (c) RESERVATIONS.—Of the amount made available
22 pursuant to section 731(c)(1) for a fiscal year—

23 (1) not less than \$75,000,000 shall be reserved
24 to make grants under subsection (a) to Indian
25 Tribes or Tribal organizations; and

1 (2) not less than \$50,000,000 shall be reserved
2 to make grants under subsection (a) to political sub-
3 divisions of States, such as counties, cities, or towns.

4 **SEC. 723. CENTERS FOR DISEASE CONTROL AND PREVEN-**
5 **TION.**

6 (a) ADDRESSING OPIOID USE DISORDER.—The en-
7 tirety of the funds made available pursuant to section
8 721(c)(2) shall be for the Director of the Centers for Dis-
9 ease Control and Prevention, pursuant to applicable au-
10 thorities in the Public Health Service Act (42 U.S.C. 201
11 et seq.), to continue and expand programs of the Centers
12 for Disease Control and Prevention to address opioid and
13 substance use disorder, including by—

14 (1) improving the timeliness and quality of data
15 on the opioid use disorder epidemic, including im-
16 provement of—

17 (A) data on fatal and nonfatal overdoses;

18 (B) syndromic surveillance;

19 (C) data on long-term sequelae (including
20 neonatal abstinence syndrome); and

21 (D) cause of death reporting related to
22 substance abuse or opioid overdose;

23 (2) expanding and strengthening evidence-based
24 prevention and education strategies;

1 (3) supporting responsible prescribing practices,
2 including through development and dissemination of
3 prescriber guidelines;

4 (4) improving access to and use of effective pre-
5 vention, treatment, and recovery support, including
6 through grants and the provision of technical assist-
7 ance to States and localities;

8 (5) strengthening partnerships with first re-
9 sponders, including to protect their safety;

10 (6) considering the needs of vulnerable popu-
11 lations;

12 (7) addressing infectious diseases linked to the
13 opioid crisis;

14 (8) strengthening prescription drug monitoring
15 programs; and

16 (9) providing financial and technical assistance
17 to State and local health department efforts to treat
18 and prevent substance use disorder.

19 (b) LIMITATION.—Of the funds made available pur-
20 suant to section 721(c)(2) for carrying out this section,
21 not more than 20 percent may be used for intramural pur-
22 poses.

23 **SEC. 724. FOOD AND DRUG ADMINISTRATION.**

24 The entirety of the funds made available pursuant to
25 section 721(c)(3) shall be for the Commissioner of Food

1 and Drugs, pursuant to applicable authorities in the Pub-
2 lic Health Service Act (42 U.S.C. 201 et seq.) or the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
4 seq.) and other applicable law, to support widespread inno-
5 vation in non-opioid and non-addictive medical products
6 for pain treatment, access to opioid addiction treatments,
7 appropriate use of approved opioids, and efforts to reduce
8 illicit importation of opioids. Such support may include the
9 following:

10 (1) Facilitating the development of non-opioid
11 and non-addictive pain treatments.

12 (2) Advancing guidance documents for sponsors
13 of non-opioid pain products.

14 (3) Developing evidence to inform the potential
15 for nonprescription overdose therapies.

16 (4) Examining expanded labeling indications for
17 medication-assisted treatment.

18 (5) Conducting public education and outreach,
19 including public workshops or public meetings, re-
20 garding the benefits of medication-assisted treat-
21 ment, including all drugs approved by the Food and
22 Drug Administration, and device treatment options
23 approved or cleared by the Food and Drug Adminis-
24 tration.

1 (6) Exploring the expansion and possible man-
2 datory nature of prescriber education regarding pain
3 management and appropriate opioid prescribing
4 through authorities under section 505–1 of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–
6 1).

7 (7) Examining options to limit the duration of
8 opioid prescriptions for acute pain, including
9 through packaging options.

10 (8) Increasing staff and infrastructure capacity
11 to inspect and analyze packages at international
12 mail facilities and pursue criminal investigations.

13 **SEC. 725. NATIONAL INSTITUTES OF HEALTH.**

14 The entirety of the funds made available pursuant to
15 section 721(c)(4) shall be for the Director of the National
16 Institutes of Health, pursuant to applicable authorities in
17 the Public Health Service Act (42 U.S.C. 201 et seq.),
18 to carry out activities related to—

19 (1) accelerating research for addressing the
20 opioid use disorder epidemic, including developing
21 non-opioid medications and interventions, including
22 non-addictive medications, to manage pain, as well
23 as developing medications and interventions to treat
24 and to prevent substance use disorders;

1 (2) conducting and supporting research on
2 which treatments (in terms of pain management as
3 well as treating and preventing substance use dis-
4 orders) are optimal for which patients; and

5 (3) conducting and supporting research on cre-
6 ating longer-lasting or faster-acting antidotes for
7 opioid overdose, particularly in response to the prev-
8 alence of fentanyl and carfentanyl overdoses.

9 **SEC. 726. HEALTH RESOURCES AND SERVICES ADMINIS-**
10 **TRATION.**

11 The entirety of the funds made available pursuant to
12 section 721(c)(5) shall be for the Administrator of the
13 Health Resources and Services Administration, pursuant
14 to applicable authorities in titles III, VII, and VIII of the
15 Public Health Service Act (42 U.S.C. 241 et seq.), to
16 carry out activities that increase the availability and ca-
17 pacity of the behavioral health workforce. Such activities
18 shall include providing loan repayment assistance for sub-
19 stance use disorder treatment providers.

20 **SEC. 727. ADMINISTRATION FOR CHILDREN AND FAMILIES.**

21 Of the funds made available pursuant to section
22 721(c)(6) for each of fiscal years 2021 through 2025,
23 \$20,000,000 for each such fiscal year shall be for the Sec-
24 retary of Health and Human Services to carry out title

1 I of the Child Abuse Prevention and Treatment Act (42
2 U.S.C. 5101 et seq.).

3 **Subtitle D—Reducing Administra-**
4 **tive Costs and Burdens in**
5 **Health Care**

6 **SEC. 731. REDUCING ADMINISTRATIVE COSTS AND BUR-**
7 **DENS IN HEALTH CARE.**

8 Title II of the Public Health Service Act (42 U.S.C.
9 202 et seq.) is amended by adding at the end the fol-
10 lowing:

11 **“PART E—REDUCING ADMINISTRATIVE COSTS**
12 **AND BURDENS IN HEALTH CARE**

13 **“SEC. 281. ELIMINATING UNNECESSARY ADMINISTRATIVE**
14 **BURDENS AND COSTS.**

15 “(a) REDUCING ADMINISTRATIVE BURDENS AND
16 COSTS.—The Secretary, in consultation with providers of
17 health services, health care suppliers of services, health
18 care payers, health professional societies, health vendors
19 and developers, health care standard development organi-
20 zations and operating rule entities, health care quality or-
21 ganizations, health care accreditation organizations, public
22 health entities, States, patients, and other appropriate en-
23 tities, shall, in accordance with subsection (b)—

24 “(1) establish a goal of reducing unnecessary
25 costs and administrative burdens across the health

1 care system, including the Medicare program under
2 title XVIII of the Social Security Act, the Medicaid
3 program under title XIX of such Act, and the pri-
4 vate health insurance market, by at least half over
5 a period of 10 years from the date of enactment of
6 this section;

7 “(2) develop strategies and benchmarks for
8 meeting the goal established under paragraph (1);

9 “(3) develop recommendations for meeting the
10 goal established under paragraph (1); and

11 “(4) take action to reduce unnecessary costs
12 and administrative burdens based on recommenda-
13 tions identified in this subsection.

14 “(b) STRATEGIES, RECOMMENDATIONS, AND AC-
15 TIONS.—

16 “(1) IN GENERAL.—To achieve the goal estab-
17 lished under subsection (a)(1), the Secretary, in con-
18 sultation with the entities described in such sub-
19 section, shall not later than 1 year after the date of
20 enactment of this section, develop strategies and rec-
21 ommendations and take actions to meet such goal in
22 accordance with this subsection. No strategies, rec-
23 ommendation, or action shall undermine the quality
24 of patient care or patient health outcomes.

1 “(2) STRATEGIES.—The strategies developed
2 under paragraph (1) shall address unnecessary costs
3 and administrative burdens. Such strategies shall in-
4 clude broad public comment and shall prioritize—

5 “(A) recommendations identified as a re-
6 sult of efforts undertaken to implement section
7 3001;

8 “(B) recommendations and best practices
9 identified as a result of efforts undertaken
10 under this part;

11 “(C) a review of regulations, rules, and re-
12 quirements of the Department of Health and
13 Human Services that could be modified or
14 eliminated to reduce unnecessary costs and ad-
15 ministrative burden imposed on patients, pro-
16 viders, payers, and other stakeholders across
17 the health care system; and

18 “(D) feedback from stakeholders in rural
19 or frontier areas on how to reduce unnecessary
20 costs and administrative burdens on the health
21 care system in those areas.

22 “(3) RECOMMENDATIONS.—The recommenda-
23 tions developed under paragraph (1) shall include—

1 “(A) actions that improve the standardiza-
2 tion and automation of administrative trans-
3 actions;

4 “(B) actions that integrate clinical and ad-
5 ministrative functions;

6 “(C) actions that improve patient care and
7 reduce unnecessary costs and administrative
8 burdens borne by patients, their families, and
9 other caretakers;

10 “(D) actions that advance the development
11 and adoption of open application programming
12 interfaces and other emerging technologies to
13 increase transparency and interoperability, em-
14 power patients, and facilitate better integration
15 of clinical and administrative functions;

16 “(E) actions to be taken by the Secretary
17 and actions that need to be taken by other enti-
18 ties; and

19 “(F) other areas, as the Secretary deter-
20 mines appropriate, to reduce unnecessary costs
21 and administrative burdens required of health
22 care providers.

23 “(4) CONSISTENCY.—Any improvements in
24 electronic processes proposed by the Secretary under
25 this section should leverage existing information

1 technology definitions under Federal Law. Specifi-
2 cally, any electronic processes should not be con-
3 strued to include a facsimile, a proprietary payer
4 portal that does not meet standards specified by the
5 Secretary, or an electronic form image.

6 “(5) ACTIONS.—The Secretary shall take action
7 to achieve the goal established under subsection
8 (a)(1), and, not later than 1 year after the date of
9 enactment of this section, and biennially thereafter,
10 submit to Congress and make publically available, a
11 report describing the actions taken by the Secretary
12 pursuant to goals, strategies, and recommendations
13 described in this subsection.

14 “(6) FACA.—The Federal Advisory Committee
15 Act (5 U.S.C. App.) shall not apply to the develop-
16 ment of the goal, strategies, recommendations, or
17 actions described in this section.

18 “(7) RULE OF CONSTRUCTION.—Nothing in
19 this subsection shall be construed to authorize, or be
20 used by, the Federal Government to inhibit or other-
21 wise restrain efforts made to reduce waste, fraud,
22 and abuse across the health care system.

1 **“SEC. 282. GRANTS TO STATES TO DEVELOP AND IMPLE-**
2 **MENT RECOMMENDATIONS TO ACCELERATE**
3 **STATE INNOVATION TO REDUCE HEALTH**
4 **CARE ADMINISTRATIVE COSTS.**

5 “(a) GRANTS.—

6 “(1) IN GENERAL.—Not later than 6 months
7 after the date of enactment of this section, the Sec-
8 retary shall award grants to at least 15 States, and
9 one coordinating entity designated as provided for
10 under subsection (e), to enable such States to estab-
11 lish and administer private-public multi-stakeholder
12 commissions for the purpose of reducing health care
13 administrative costs and burden within and across
14 States. Not less than 3 of such grants shall be
15 awarded to States that are primarily rural, frontier,
16 or a combination thereof, in nature.

17 “(2) ENTITIES.—For purposes of this section,
18 the term ‘State’ means a State, a State designated
19 entity, or a multi-State collaborative (as defined by
20 the Secretary).

21 “(3) PRIORITY.—In awarding grants under this
22 section, the Secretary shall give priority to applica-
23 tions submitted by States that propose to carry out
24 a pilot program or support the adoption of electronic
25 health care transactions and operating rules.

26 “(b) APPLICATION.—

1 “(1) IN GENERAL.—To be eligible to receive a
2 grant under subsection (a) a State shall submit to
3 the Secretary an application in such a manner and
4 containing such information as the Secretary may
5 reasonably require, including the information de-
6 scribed in paragraph (2).

7 “(2) REQUIRED INFORMATION.—In addition to
8 any additional information required by the Secretary
9 under this subsection, an application shall include a
10 description of—

11 “(A) the size and composition of the com-
12 mission to be established under the grant, in-
13 cluding the stakeholders represented and the
14 degree to which the commission reflects impor-
15 tant geographic and population characteristics
16 of the State;

17 “(B) the relationship of the commission to
18 the State official responsible for coordinating
19 and implementing the recommendations result-
20 ing from the commission, and the role and re-
21 sponsibilities of the State with respect to the
22 commission, including any participation, review,
23 oversight, implementation or other related func-
24 tions;

1 “(C) the history and experience of the
2 State in addressing health care administrative
3 costs, and any experience similar to the purpose
4 of the commission to improve health care ad-
5 ministrative processes and the exchange of
6 health care administrative data;

7 “(D) the resources and expertise that will
8 be made available to the commission by com-
9 mission members or other possible sources, and
10 how Federal funds will be used to leverage and
11 complement these resources;

12 “(E) the governance structure and proce-
13 dures that the commission will follow to make,
14 implement, and pilot recommendations;

15 “(F) the proposed objectives relating to the
16 simplification of administrative transactions
17 and operating rules, increased standardization,
18 and the efficiency and effectiveness of the
19 transmission of health information;

20 “(G) potential cost savings and other im-
21 provements in meeting the objectives described
22 in subparagraph (F); and

23 “(H) the method or methods by which the
24 recommendations described in subsection (c)

1 will be reviewed, tested, adopted, implemented,
2 and updated as needed.

3 “(c) MULTI-STAKEHOLDER COMMISSION.—

4 “(1) IN GENERAL.—Not later than 90 days
5 after the date on which a grant is awarded to a
6 State under this section, the State official described
7 in subsection (b)(2)(B), the State insurance commis-
8 sioner, or other appropriate State official shall con-
9 vene a multi-stakeholder commission, in accordance
10 with this subsection.

11 “(2) MEMBERSHIP.—The commission convened
12 under paragraph (1) shall include representatives
13 from health plans, health care providers, health ven-
14 dors, relevant State agencies, health care standard
15 development organizations, and operating rule enti-
16 ties, relevant professional and trade associations, pa-
17 tients, and other entities determined appropriate by
18 the State.

19 “(3) RECOMMENDATIONS.—Not later than one
20 year after the date on which a grant is awarded to
21 a State under this section, the commission shall
22 make recommendations and plans, consistent with
23 the application submitted by the State under sub-
24 section (b), and intended to meet the objectives de-
25 fined in the application. Such recommendations shall

1 comply with, and build upon, all relevant Federal re-
2 quirements and regulations, and may include—

3 “(A) common, uniform specifications, best
4 practices, and conventions, for the efficient, ef-
5 fective exchange of administrative transactions
6 adopted pursuant to the Health Insurance Port-
7 ability and Accountability Act of 1996 (Public
8 Law 104–191);

9 “(B) the development of streamlined busi-
10 ness processes for the exchange and use of
11 health care administrative data; and

12 “(C) specifications, incentives, require-
13 ments, tools, mechanisms, and resources to im-
14 prove—

15 “(i) the access, exchange, and use of
16 health care administrative information
17 through electronic means;

18 “(ii) the implementation of utilization
19 management protocols; and

20 “(iii) compliance with Federal and
21 State laws.

22 “(d) USE OF FUNDS FOR IMPLEMENTATION.—A
23 State may use amounts received under a grant under this
24 section for one or more of the following:

1 “(1) The development, implementation, and
2 best use of shared data infrastructure that supports
3 the electronic transmission of administrative data.

4 “(2) The development and provision of training
5 and educational materials, forums, and activities as
6 well as technical assistance to effectively implement,
7 use, and benefit from electronic health care trans-
8 actions and operating rules.

9 “(3) To accelerate the early adoption and im-
10 plementation of administrative transactions and op-
11 erating rules designated by the Secretary and that
12 have been adopted pursuant to the Health Insurance
13 Portability and Accountability Act of 1996 (Public
14 Law 104–191), including transactions and operating
15 rules described in section 1173(a)(2) of the Social
16 Security Act.

17 “(4) To accelerate the early adoption and im-
18 plementation of additional or updated administrative
19 transactions, operating rules, and related data ex-
20 change standards that are being considered for
21 adoption under the Health Insurance Portability and
22 Accountability Act of 1996 or are adopted pursuant
23 to such Act, or as designated by the Secretary, in-
24 cluding the electronic claim attachment.

1 “(5) To conduct pilot projects to test ap-
2 proaches to implement and use the electronic health
3 care transactions and operating rules in practice
4 under a variety of different settings. With respect to
5 the electronic attachment transaction, priority shall
6 be given to pilot projects that test and evaluate
7 methods and mechanisms to most effectively incor-
8 porate patient health data from electronic health
9 records and other electronic sources with the elec-
10 tronic attachment transaction.

11 “(6) To assess barriers to the adoption, imple-
12 mentation, and effective use of electronic health care
13 transactions and operating rules, as well as to ex-
14 plore, identify, and plan options, approaches, and re-
15 sources to address barriers and make improvements.

16 “(7) The facilitation of public and private ini-
17 tiatives to reduce administrative costs and accelerate
18 the adoption, implementation, and effective use of
19 electronic health care transactions and operating
20 rules for State programs.

21 “(8) Developing, testing, implementing, and as-
22 sessing additional data exchange specifications, oper-
23 ating rules, incentives, requirements, tools, mecha-
24 nisms, and resources to accelerate the adoption and
25 effective use of the transactions and operating rules.

1 “(9) Ongoing needs assessments and planning
2 related to the development and implementation of
3 administrative simplification initiatives.

4 “(e) COORDINATING ENTITY.—

5 “(1) FUNCTIONS.—Not later than 6 months
6 after the date of enactment of this section, the Sec-
7 retary shall designate a coordinating entity under
8 this subsection for the purpose of—

9 “(A) providing technical assistance to
10 States relating to the simplification of adminis-
11 trative transactions and operating rules, in-
12 creased standardization, and the efficiency and
13 effectiveness of the transmission of health care
14 information;

15 “(B) evaluating pilot projects and other ef-
16 forts conducted under this section for impact
17 and best practices to inform broader national
18 use;

19 “(C) using consistent evaluation meth-
20 odologies to compare return on investment
21 across efforts conducted under this section;

22 “(D) compiling, synthesizing, dissemi-
23 nating, and adopting lessons learned to promote
24 the adoption of electronic health care trans-

1 actions and operating rules across the health
2 care system; and

3 “(E) making recommendations to the Sec-
4 retary and the National Committee on Vital
5 and Health Statistics regarding the national
6 adoption of efforts conducted under this sec-
7 tion.

8 “(2) ELIGIBILITY.—The entity designated
9 under paragraph (1) shall be a qualified nonprofit
10 entity that—

11 “(A) focuses its mission on administrative
12 simplification;

13 “(B) has demonstrated experience using a
14 multi-stakeholder and consensus-based process
15 for the development of common, uniform speci-
16 fications, operating rules, best practices, and
17 conventions, for the efficient, effective exchange
18 of administrative transactions that includes rep-
19 resentation by or participation from health
20 plans, health care providers, vendors, States,
21 relevant Federal agencies, and other health care
22 standard development organizations;

23 “(C) has demonstrated experience pro-
24 viding technical assistance to health plans,
25 health care providers, vendors, and States relat-

1 ing to the simplification of administrative trans-
2 actions and operating rules, increased standard-
3 ization, and the efficiency and effectiveness of
4 the transmission of health care information;

5 “(D) has demonstrated experience evalu-
6 ating and measuring the adoption and return
7 on investment of administrative transactions
8 and operating rules;

9 “(E) has demonstrated experience gath-
10 ering, synthesizing, and adopting common, uni-
11 form specifications, operating rules, best prac-
12 tices, and conventions for national use based on
13 lessons learned to promote the adoption of elec-
14 tronic health care transactions and operating
15 rules across the health care system;

16 “(F) has a public set of guiding principles
17 that ensure processes are open and transparent,
18 and supports nondiscrimination and conflict of
19 interest policies that demonstrate a commit-
20 ment to open, fair, and nondiscriminatory prac-
21 tices;

22 “(G) builds on the transaction standards
23 issued under Health Insurance Portability and
24 Accountability Act of 1996; and

1 “(H) allows for public review and updates
2 of common, uniform specifications, operating
3 rules, best practices, and conventions to support
4 administrative simplification.

5 “(f) PERIOD AND AMOUNT.—A grant awarded to a
6 State under this section shall be for a period of 5 years
7 and shall not exceed \$50,000,000 for such 5-year period.
8 A grant awarded to the coordinating entity designated by
9 the Secretary under subsection (e) shall be for a period
10 of 5 years and shall not exceed \$15,000,000 for such 5-
11 year period.

12 “(g) REPORTS.—

13 “(1) STATES.—Not later than 1 year after re-
14 ceiving a grant under this section, and biennially
15 thereafter, a State shall submit to the Secretary a
16 report on the outcomes experienced by the State
17 under the grant.

18 “(2) COORDINATING ENTITY.—Not later than 1
19 year after receiving a grant under this section, and
20 at least biennially thereafter, the coordinating entity
21 shall submit to the Secretary and the National Com-
22 mittee on Vital and Health Statistics a report of
23 evaluations conducted under the grant under this
24 section and recommendations regarding the national
25 adoption of efforts conducted under this section.

1 “(3) SECRETARY.—Not later than 6 months
2 after the date on which the States and coordinating
3 entity submit the report required under paragraphs
4 (1) and (2), the Secretary, in consultation with Na-
5 tional Committee on Vital and Health Statistics,
6 shall submit to the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate and the
8 Committee on Energy and Commerce of the House
9 of Representatives, a report on the outcomes
10 achieved under the grants under this section.

11 “(4) GAO.—Not later than 6 months after the
12 date on which the Secretary submits the final report
13 under paragraph (3), the Comptroller General of the
14 United States shall conduct a study, and submit to
15 the Committee on Health, Education, Labor, and
16 Pensions of the Senate and the Committee on En-
17 ergy and Commerce of the House of Representa-
18 tives, a report on the outcomes of the activities car-
19 ried out under this section which shall contain a list
20 of best practices and recommendations to States
21 concerning administrative simplification.

22 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
23 is authorized to be appropriated to carry out this section,
24 \$250,000,000 for the 5-fiscal-year period beginning with
25 fiscal year 2020.”.

1 **TITLE VIII—MISCELLANEOUS**

2 **SEC. 801. GUARANTEED ISSUE OF CERTAIN MEDIGAP POLI-**
 3 **CIES.**

4 (a) GUARANTEED ISSUE OF MEDIGAP POLICIES TO
 5 ALL MEDIGAP-ELIGIBLE MEDICARE BENEFICIARIES.—

6 (1) IN GENERAL.—Section 1882(s) of the So-
 7 cial Security Act (42 U.S.C. 1395ss(s)) is amend-
 8 ed—

9 (A) in paragraph (2)(A), by striking “65
 10 years of age or older and is enrolled for benefits
 11 under part B” and inserting “entitled to, or en-
 12 rolled for, benefits under part A and enrolled
 13 for benefits under part B”;

14 (B) in paragraph (2)(D), by striking “who
 15 is 65 years of age or older as of the date of
 16 issuance and”;

17 (C) in paragraph (3)(B)(ii), by striking “is
 18 65 years of age or older and”; and

19 (D) in paragraph (3)(B)(vi), by striking
 20 “at age 65”.

21 (2) ADDITIONAL ENROLLMENT PERIOD FOR
 22 CERTAIN INDIVIDUALS.—

23 (A) ONE-TIME ENROLLMENT PERIOD.—

24 (i) IN GENERAL.—In the case of a
 25 specified individual, the Secretary shall es-

1 tablish a one-time enrollment period de-
2 scribed in clause (iii) during which such an
3 individual may enroll in any medicare sup-
4 plemental policy of the individual's choos-
5 ing.

6 (ii) APPLICATION.—The provisions
7 of—

8 (I) paragraph (2) of section
9 1882(s) of the Social Security Act (42
10 U.S.C. 1395ss(s)) shall apply with re-
11 spect to a specified individual who is
12 described in subclause (I) of subpara-
13 graph (B)(iii) as if references in such
14 paragraph (2) to the 6 month period
15 described in subparagraph (A) of such
16 paragraph were references to the one-
17 time enrollment period established
18 under clause (i); and

19 (II) paragraph (3) of such sec-
20 tion shall apply with respect to a spec-
21 ified individual who is described in
22 subclause (II) of subparagraph
23 (B)(iii) as if references in such para-
24 graph (3) to the period specified in
25 subparagraph (E) of such paragraph

1 were references to the one-time enroll-
2 ment period established under clause
3 (i).

4 (iii) PERIOD.—The enrollment period
5 established under clause (i) shall be the 6-
6 month period beginning on January 1,
7 2024.

8 (B) SPECIFIED INDIVIDUAL.—For pur-
9 poses of this paragraph, the term “specified in-
10 dividual” means an individual who—

11 (i) is entitled to hospital insurance
12 benefits under part A of title XVIII of the
13 Social Security Act (42 U.S.C. 1395c et
14 seq.) pursuant to section 226(b) or section
15 226A of such Act (42 U.S.C. 426(b); 426–
16 1);

17 (ii) is enrolled for benefits under part
18 B of such Act (42 U.S.C. 1395j et seq.);
19 and

20 (iii)(I) would not, but for the amend-
21 ments made by subparagraphs (A) and (B)
22 of paragraph (1) and the provisions of this
23 paragraph (if such provisions applied to
24 such individual), be eligible for the guaran-
25 teed issue of a medicare supplemental pol-

1 icy under paragraph (2) of section 1882(s)
2 of such Act (42 U.S.C. 1395ss(s)); or

3 (II) would not, but for the amend-
4 ments made by subparagraphs (C) and (D)
5 of paragraph (1) and the provisions of this
6 paragraph (if such provisions applied to
7 such individual), be eligible for the guaran-
8 teed issue of a medicare supplemental pol-
9 icy under paragraph (3) of such section.

10 (C) OUTREACH PLAN.—

11 (i) IN GENERAL.—The Secretary shall
12 develop an outreach plan to notify specified
13 individuals of the one-time enrollment pe-
14 riod established under subparagraph (A).

15 (ii) CONSULTATION.—In imple-
16 menting the outreach plan developed under
17 clause (i), the Secretary shall consult with
18 consumer advocates, brokers, insurers, the
19 National Association of Insurance Commis-
20 sioners, and State Health Insurance As-
21 sistance Programs.

22 (3) EFFECTIVE DATE.—The amendments made
23 by paragraph (1) shall apply to medicare supple-
24 mental policies effective on or after January 1,
25 2024.

1 (b) GUARANTEED ISSUE OF MEDIGAP POLICIES FOR
2 MEDICARE ADVANTAGE ENROLLEES.—

3 (1) IN GENERAL.—Section 1882(s)(3) of the
4 Social Security Act (42 U.S.C. 1395ss(s)(3)), as
5 amended by subsection (a), is further amended—

6 (A) in subparagraph (B), by adding at the
7 end the following new clause:

8 “(vii) The individual—

9 “(I) was enrolled in a Medicare Advantage
10 plan under part C for not less than 12 months;

11 “(II) subsequently disenrolled from such
12 plan;

13 “(III) elects to receive benefits under this
14 title through the original Medicare fee-for-serv-
15 ice program under parts A and B; and

16 “(IV) has not previously elected to receive
17 benefits under this title through the original
18 Medicare fee-for-service program pursuant to
19 disenrollment from a Medicare Advantage plan
20 under part C.”;

21 (B) by striking subparagraph (C)(iii) and
22 inserting the following:

23 “(iii) Subject to subsection (v)(1), for purposes of an
24 individual described in clause (vi) or (vii) of subparagraph
25 (B), a medicare supplemental policy described in this sub-

1 paragraph shall include any medicare supplemental pol-
2 icy.”; and

3 (C) in subparagraph (E)—

4 (i) in clause (iv), by striking “and” at
5 the end;

6 (ii) in clause (v), by striking the pe-
7 riod at the end and inserting “; and”; and

8 (iii) by adding at the end the fol-
9 lowing new clause—

10 “(vi) in the case of an individual described in
11 subparagraph (B)(vii), the annual, coordinated elec-
12 tion period (as defined in section 1851(e)(3)(B)) or
13 a continuous open enrollment period (as defined in
14 section 1851(e)(2)) during which the individual
15 disenrolls from a Medicare Advantage plan under
16 part C.”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by paragraph (1) shall apply to medicare supple-
19 mental policies effective on or after January 1,
20 2024.

1 **SEC. 802. REPORTING REQUIREMENTS FOR PDP SPONSORS**
2 **REGARDING POINT-OF-SALE REJECTIONS**
3 **UNDER MEDICARE PART D.**

4 Section 1860D–4(g) of the Social Security Act (42
5 U.S.C. 1395w–104(g)) is amended by adding at the end
6 the following new paragraph:

7 “(3) REPORTING REQUIREMENTS REGARDING
8 POINT-OF-SALE REJECTIONS.—

9 “(A) IN GENERAL.—With respect to a plan
10 year beginning on or after January 1, 2020, a
11 PDP sponsor offering a prescription drug plan
12 shall submit to the Secretary, in a form and
13 manner specified by the Secretary, information
14 on point-of-sale rejections made during a period
15 of time occurring in such plan year (as specified
16 by the Secretary), including each of the fol-
17 lowing:

18 “(i) The reason for each point-of-sale
19 rejection.

20 “(ii) Identifying information for each
21 drug with respect to which a point-of-sale
22 rejection was made.

23 “(iii) With respect to applicable types
24 of point-of-sale rejections (as specified by
25 the Secretary), each of the following:

1 “(I) Whether such a rejection
2 was consistent with the formulary of
3 the plan (as approved by the Sec-
4 retary).

5 “(II) Whether a coverage deter-
6 mination or appeal of a coverage de-
7 termination was requested for the
8 drug with respect to which such a re-
9 jection was made.

10 “(III) The outcome of any such
11 coverage determination or appeal of a
12 coverage determination.

13 “(IV) The length of time between
14 when such a rejection was made and
15 when the drug with respect to which
16 such rejection was made is dispensed,
17 as applicable.

18 “(B) PUBLIC AVAILABILITY OF INFORMA-
19 TION.—The Secretary shall make publicly avail-
20 able on the public website of the Centers for
21 Medicare & Medicaid Services information sub-
22 mitted under subparagraph (A).

23 “(C) USE OF INFORMATION.—The Sec-
24 retary may use information submitted under
25 subparagraph (A), as determined appropriate,

1 in developing measures for the 5-star rating
2 system under section 1853(o)(4).

3 “(D) IMPLEMENTATION.—Notwithstanding
4 any other provision of law, the Secretary may
5 implement this paragraph through program in-
6 struction or otherwise.

7 “(E) FUNDING.—The are authorized to be
8 appropriated to the Secretary from the Federal
9 Supplementary Medical Insurance Trust Fund
10 under section 1841 such sums as may be nec-
11 essary to implement this paragraph.”.

12 **SEC. 803. PROVIDING ACCESS TO ANNUAL MEDICARE NOTI-**
13 **FICATIONS IN MULTIPLE LANGUAGES.**

14 (a) IN GENERAL.—Section 1804 of the Social Secu-
15 rity Act (42 U.S.C. 1395b–2) is amended by adding at
16 the end the following new subsection:

17 “(e) The notice provided under subsection (a) shall
18 be translated into languages in addition to English and
19 Spanish. In carrying out the previous sentence, the Sec-
20 retary shall prioritize translation of the notice into lan-
21 guages in which documents provided by the Commissioner
22 of Social Security are translated and language that are
23 the most frequently requested for translation for purposes
24 of applying for old-age insurance benefits under title II.”.

1 (b) EFFECTIVE DATE.—The amendment made by
 2 subsection (a) shall apply to notices distributed prior to
 3 each Medicare open enrollment period beginning after
 4 January 1, 2020.

5 **SEC. 804. TEMPORARY INCREASE IN MEDICARE PART B**
 6 **PAYMENT FOR CERTAIN BIOSIMILAR BIO-**
 7 **LOGICAL PRODUCTS.**

8 Section 1847A(b)(8) of the Social Security Act (42
 9 U.S.C. 1395w–3a(b)(8)) is amended—

10 (1) by redesignating subparagraphs (A) and
 11 (B) as clauses (i) and (ii), respectively, and moving
 12 the margin of each such redesignated clause 2 ems
 13 to the right;

14 (2) by striking “PRODUCT.—The amount” and
 15 inserting the following: “PRODUCT.—

16 “(A) IN GENERAL.—Subject to subpara-
 17 graph (B), the amount”; and

18 (3) by adding at the end the following new sub-
 19 paragraph:

20 “(B) TEMPORARY PAYMENT INCREASE.—

21 “(i) IN GENERAL.—In the case of a
 22 qualifying biosimilar biological product
 23 that is furnished during the applicable 5-
 24 year period for such product, the amount
 25 specified in this paragraph for such prod-

uct with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting ‘8 percent’ for ‘6 percent’.

“(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a biosimilar biological product is—

“(I) in the case of such a product for which payment was made under this paragraph as of December 31, 2019, the 5-year period beginning on January 1, 2020; and

“(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning January 1, 2020, and ending December 31, 2024, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

“(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For pur-

poses of this subparagraph, the term
 ‘qualifying biosimilar biological product’
 means a biosimilar biological product de-
 scribed in paragraph (1)(C) with respect to
 which—

“(I) in the case of a product de-
 scribed in clause (ii)(I), the average
 sales price is not more than the aver-
 age sales price for the reference bio-
 logical product; and

“(II) in the case of a product de-
 scribed in clause (ii)(II), the wholesale
 acquisition cost is not more than the
 wholesale acquisition cost for the ref-
 erence biological product.”.

**SEC. 805. WAIVING MEDICARE COINSURANCE FOR
 COLORECTAL CANCER SCREENING TESTS.**

Section 1833(a) of the Social Security Act (42 U.S.C.
 1395l(a)) is amended—

(1) in the second sentence, by striking “section
 1834(0)” and inserting “section 1834(o)”;

(2) by moving such second sentence 2 ems to
 the left; and

(3) by inserting the following third sentence fol-
 lowing such second sentence: “For services furnished

1 on or after January 1, 2021, paragraph (1)(Y) shall
 2 apply with respect to a colorectal cancer screening
 3 test regardless of the code that is billed for the es-
 4 tablishment of a diagnosis as a result of the test, or
 5 for the removal of tissue or other matter or other
 6 procedure that is furnished in connection with, as a
 7 result of, and in the same clinical encounter as the
 8 screening test.”.

9 **SEC. 806. MEDICARE COVERAGE OF CERTAIN**
 10 **LYMPHEDEMA COMPRESSION TREATMENT**
 11 **ITEMS.**

12 (a) COVERAGE.—

13 (1) IN GENERAL.—Section 1861 of the Social
 14 Security Act (42 U.S.C. 1395x), as amended by sec-
 15 tion 601 and section 603, is further amended—

16 (A) in subsection (s)(2)—

17 (i) in subparagraph (II), by striking
 18 “and” after the semicolon at the end;

19 (ii) in subparagraph (JJ), by striking
 20 the period at the end and inserting “;
 21 and”; and

22 (iii) by adding at the end the fol-
 23 lowing new subparagraph:

24 “(KK) lymphedema compression treatment
 25 items (as defined in subsection (mmm));”; and

1 (B) by adding at the end the following new
2 subsection:

3 “(mmm) LYMPHEDEMA COMPRESSION TREATMENT
4 ITEMS.—The term ‘lymphedema compression treatment
5 items’ means compression garments, devices, bandaging
6 systems, components, and supplies, including multilayer
7 compression bandaging systems, standard fit gradient
8 compression garments, and other compression garments,
9 devices, bandaging systems, components, or supplies (as
10 determined by the Secretary), that are—

11 “(1) furnished on or after January 1, 2022, to
12 an individual with a diagnosis of lymphedema for the
13 treatment of such condition;

14 “(2) primarily and customarily used in the
15 medical treatment of lymphedema, as determined by
16 the Secretary; and

17 “(3) prescribed by a physician (or a physician
18 assistant, nurse practitioner, or a clinical nurse spe-
19 cialist (as those terms are defined in section
20 1861(aa)(5)) to the extent authorized under State
21 law).”.

22 (2) PAYMENT.—

23 (A) IN GENERAL.—Section 1833(a)(1) of
24 the Social Security Act (42 U.S.C.

1 1395l(a)(1)), as amended by section 601(c)(1),
2 is further amended—

3 (i) by striking “and” before “(DD)”;
4 and

5 (ii) by inserting before the semicolon
6 at the end the following: “, and (EE) with
7 respect to lymphedema compression treat-
8 ment items (as defined in section
9 1861(mmm)), the amount paid shall be
10 equal to 80 percent of the lesser of the ac-
11 tual charge or the amount determined
12 under the payment basis determined under
13 section 1834(z)”.

14 (B) PAYMENT BASIS AND LIMITATIONS.—
15 Section 1834 of the Social Security Act (42
16 U.S.C. 1395m), as amended by sections
17 601(c)(2) and 603(c), is further amended by
18 adding at the end the following new subsection:

19 “(z) PAYMENT FOR LYMPHEDEMA COMPRESSION
20 TREATMENT ITEMS.—

21 “(1) IN GENERAL.—The Secretary shall deter-
22 mine an appropriate payment basis for lymphedema
23 compression treatment items (as defined in section
24 1861(mmm)). In making such a determination, the
25 Secretary may take into account payment rates for

1 such items under State plans (or waivers of such
2 plans) under title XIX, the Veterans Health Admin-
3 istration, and group health plans and health insur-
4 ance coverage (as such terms are defined in section
5 2791 of the Public Health Service Act), and such
6 other information as the Secretary determines ap-
7 propriate.

8 “(2) FREQUENCY LIMITATION.—No payment
9 may be made under this part for lymphedema com-
10 pression treatment items furnished other than at
11 such frequency as the Secretary may establish.

12 “(3) APPLICATION OF COMPETITIVE ACQUISI-
13 TION.—In the case of lymphedema compression
14 treatment items that are included in a competitive
15 acquisition program in a competitive acquisition area
16 under section 1847(a)—

17 “(A) the payment basis under this sub-
18 section for such items furnished in such area
19 shall be the payment basis determined under
20 such competitive acquisition program; and

21 “(B) the Secretary may use information on
22 the payment determined under such competitive
23 acquisition programs to adjust the payment
24 amount otherwise determined under this sub-
25 section for an area that is not a competitive ac-

quisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.”.

(3) CONFORMING AMENDMENTS.—

(A) EXCLUSIONS.—Section 1862(a)(1) of the Social Security Act (42 U.S.C. 1395y(a)(1)), as amended by section 601(f) and section 603(g), is further amended—

(i) in subparagraph (Q), by striking “and” at the end;

(ii) in subparagraph (R), by striking the semicolon and inserting “, and”; and

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

“(S) in the case of lymphedema compression treatment items (as defined in section 1861(mmm)), which are furnished more frequently than is established pursuant to section 1834(z)(2);”.

(B) APPLICATION OF COMPETITIVE ACQUISITION.—

(i) IN GENERAL.—Section 1847(a)(2) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)), as amended by sections 601(e)(2)(B)(ii), 602(b)(3)(B)(i), and 603(f)(2)(B), is further amended by add-

1 ing at the end the following new subpara-
2 graph:

3 “(G) LYMPHEDEMA COMPRESSION TREAT-
4 MENT ITEMS.—Lymphedema compression treat-
5 ment items (as defined in section 1861(mmm))
6 for which payment would otherwise be made
7 under section 1834(z).”.

8 (b) INCLUSION IN REQUIREMENTS FOR SUPPLIERS
9 OF MEDICAL EQUIPMENT AND SUPPLIES.—Section
10 1834(j)(5) of the Social Security Act (42 U.S.C.
11 1395m(j)(5)) is amended—

12 (1) by redesignating subparagraphs (E) and
13 (F) as subparagraphs (F) and (G), respectively; and

14 (2) by inserting after subparagraph (D) the fol-
15 lowing new subparagraph:

16 “(E) lymphedema compression treatment
17 items (as defined in section 1861(mmm));”.

18 (c) STUDY AND REPORT ON IMPLEMENTATION.—

19 (1) STUDY.—The Secretary of Health and
20 Human Services (in this section referred to as the
21 “Secretary”) shall conduct a study on the implemen-
22 tation of Medicare coverage of certain lymphedema
23 compression treatment items under the amendments
24 made by this Act. Such study shall include an eval-
25 uation of the following:

1 (A) Medicare beneficiary utilization of
2 items and services under parts A and B of title
3 XVIII of the Social Security Act as a result of
4 the implementation of such amendments.

5 (B) Whether the Secretary has determined,
6 pursuant to section 1861(mmm) of the Social
7 Security Act, as added by subsection (a)(1),
8 that lymphedema compression treatment items
9 other than compression bandaging systems and
10 standard fit gradient compression garments are
11 covered under such section.

12 (2) REPORT.—Not later than January 1, 2024,
13 the Secretary shall submit to Congress and make
14 available to the public a report on the study con-
15 ducted under paragraph (1).

16 **SEC. 807. PHYSICIAN FEE UPDATE.**

17 Section 1848(d)(19) of the Social Security Act (42
18 U.S.C. 1395w-4(d)(19)) is amended to read as follows:

19 “(19) UPDATE FOR 2020 THROUGH 2025.—The
20 update to the single conversion factor established in
21 paragraph (1)(C)—

22 “(A) for each of 2020 through 2022 shall
23 be 0.5 percent; and

24 “(B) for each of 2023 through 2025 shall
25 be 0.0 percent.”.

1 **SEC. 808. ADDITIONAL COMMUNITY HEALTH CENTER**
2 **FUNDING.**

3 Section 10503 of the Patient Protection and Afford-
4 able Care Act (42 U.S.C. 254b–2) is amended by striking
5 subsection (c) and inserting the following:

6 “(c) **ADDITIONAL ENHANCED FUNDING; CAPITAL**
7 **PROJECTS.**—There is authorized to be appropriated, and
8 there is appropriated, out of any monies in the Treasury
9 not otherwise appropriated, to the CHC Fund—

10 “(1) to be transferred to the Secretary of
11 Health and Human Services to provide additional
12 enhanced funding for the community health center
13 program under section 330 of the Public Health
14 Service Act, \$1,000,000,000 for each of fiscal years
15 2021 through 2025; and

16 “(2) to be transferred to the Secretary of
17 Health and Human Services for capital projects of
18 the community health center program under section
19 330 of the Public Health Service Act,
20 \$5,000,000,000 for the period of fiscal years 2021
21 through 2025.”.

1 **SEC. 809. GRANTS TO IMPROVE TRAUMA SUPPORT SERV-**
2 **ICES AND MENTAL HEALTH CARE FOR CHIL-**
3 **DREN AND YOUTH IN EDUCATIONAL SET-**
4 **TINGS.**

5 (a) GRANTS, CONTRACTS, AND COOPERATIVE
6 AGREEMENTS AUTHORIZED.—The Secretary, in coordina-
7 tion with the Assistant Secretary for Mental Health and
8 Substance Use, is authorized to award grants to, or enter
9 into contracts or cooperative agreements with, State edu-
10 cational agencies, local educational agencies, Indian Tribes
11 (as defined in section 4 of the Indian Self-Determination
12 and Education Assistance Act) or their tribal educational
13 agencies, a school operated by the Bureau of Indian Edu-
14 cation, a Regional Corporation, or a Native Hawaiian edu-
15 cational organization, for the purpose of increasing stu-
16 dent access to evidence-based trauma support services and
17 mental health care by developing innovative initiatives, ac-
18 tivities, or programs to link local school systems with local
19 trauma-informed support and mental health systems, in-
20 cluding those under the Indian Health Service.

21 (b) DURATION.—With respect to a grant, contract,
22 or cooperative agreement awarded or entered into under
23 this section, the period during which payments under such
24 grant, contract, or agreement are made to the recipient
25 may not exceed 4 years.

1 (c) USE OF FUNDS.—An entity that receives a grant,
2 contract, or cooperative agreement under this section shall
3 use amounts made available through such grant, contract,
4 or cooperative agreement for evidence-based activities,
5 which shall include any of the following:

6 (1) Collaborative efforts between school-based
7 service systems and trauma-informed support and
8 mental health service systems to provide, develop, or
9 improve prevention, screening, referral, and treat-
10 ment and support services to students, such as pro-
11 viding trauma screenings to identify students in
12 need of specialized support.

13 (2) To implement schoolwide positive behavioral
14 interventions and supports, or other trauma-in-
15 formed models of support.

16 (3) To provide professional development to
17 teachers, teacher assistants, school leaders, special-
18 ized instructional support personnel, and mental
19 health professionals that—

20 (A) fosters safe and stable learning envi-
21 ronments that prevent and mitigate the effects
22 of trauma, including through social and emo-
23 tional learning;

24 (B) improves school capacity to identify,
25 refer, and provide services to students in need

1 of trauma support or behavioral health services;
2 or

3 (C) reflects the best practices for trauma-
4 informed identification, referral, and support
5 developed by the Interagency Task Force on
6 Trauma-Informed Care.

7 (4) Services at a full-service community school
8 that focuses on trauma-informed supports, which
9 may include a full-time site coordinator, or other ac-
10 tivities consistent with section 4625 of the Elemen-
11 tary and Secondary Education Act of 1965 (20
12 U.S.C. 7275).

13 (5) Engaging families and communities in ef-
14 forts to increase awareness of child and youth trau-
15 ma, which may include sharing best practices with
16 law enforcement regarding trauma-informed care
17 and working with mental health professionals to pro-
18 vide interventions, as well as longer term coordi-
19 nated care within the community for children and
20 youth who have experienced trauma and their fami-
21 lies.

22 (6) To provide technical assistance to school
23 systems and mental health agencies.

24 (7) To evaluate the effectiveness of the program
25 carried out under this section in increasing student

1 access to evidence-based trauma support services
2 and mental health care.

3 (8) To establish partnerships with or provide
4 subgrants to Head Start agencies (including Early
5 Head Start agencies), public and private preschool
6 programs, child care programs (including home-
7 based providers), or other entities described in sub-
8 section (a), to include such entities described in this
9 paragraph in the evidence-based trauma initiatives,
10 activities, support services, and mental health sys-
11 tems established under this section in order to pro-
12 vide, develop, or improve prevention, screening, re-
13 ferral, and treatment and support services to young
14 children and their families.

15 (d) APPLICATIONS.—To be eligible to receive a grant,
16 contract, or cooperative agreement under this section, an
17 entity described in subsection (a) shall submit an applica-
18 tion to the Secretary at such time, in such manner, and
19 containing such information as the Secretary may reason-
20 ably require, which shall include the following:

21 (1) A description of the innovative initiatives,
22 activities, or programs to be funded under the grant,
23 contract, or cooperative agreement, including how
24 such program will increase access to evidence-based
25 trauma support services and mental health care for

1 students, and, as applicable, the families of such stu-
2 dents.

3 (2) A description of how the program will pro-
4 vide linguistically appropriate and culturally com-
5 petent services.

6 (3) A description of how the program will sup-
7 port students and the school in improving the school
8 climate in order to support an environment condu-
9 cive to learning.

10 (4) An assurance that—

11 (A) persons providing services under the
12 grant, contract, or cooperative agreement are
13 adequately trained to provide such services; and

14 (B) teachers, school leaders, administra-
15 tors, specialized instructional support personnel,
16 representatives of local Indian Tribes or tribal
17 organizations as appropriate, other school per-
18 sonnel, and parents or guardians of students
19 participating in services under this section will
20 be engaged and involved in the design and im-
21 plementation of the services.

22 (5) A description of how the applicant will sup-
23 port and integrate existing school-based services
24 with the program in order to provide mental health
25 services for students, as appropriate.

1 (6) A description of the entities in the commu-
2 nity with which the applicant will partner or to
3 which the applicant will provide subgrants in accord-
4 ance with subsection (c)(8).

5 (e) INTERAGENCY AGREEMENTS.—

6 (1) LOCAL INTERAGENCY AGREEMENTS.—To
7 ensure the provision of the services described in sub-
8 section (c), a recipient of a grant, contract, or coop-
9 erative agreement under this section, or their des-
10 ignee, shall establish a local interagency agreement
11 among local educational agencies, agencies respon-
12 sible for early childhood education programs, Head
13 Start agencies (including Early Head Start agen-
14 cies), juvenile justice authorities, mental health
15 agencies, child welfare agencies, and other relevant
16 agencies, authorities, or entities in the community
17 that will be involved in the provision of such serv-
18 ices.

19 (2) CONTENTS.—In ensuring the provision of
20 the services described in subsection (c), the local
21 interagency agreement shall specify with respect to
22 each agency, authority, or entity that is a party to
23 such agreement—

24 (A) the financial responsibility for the serv-
25 ices;

1 (B) the conditions and terms of responsi-
2 bility for the services, including quality, ac-
3 countability, and coordination of the services;
4 and

5 (C) the conditions and terms of reimburse-
6 ment among such agencies, authorities, or enti-
7 ties, including procedures for dispute resolution.

8 (f) EVALUATION.—The Secretary shall reserve not
9 more than 3 percent of the funds made available under
10 subsection (l) for each fiscal year to—

11 (1) conduct a rigorous, independent evaluation
12 of the activities funded under this section; and

13 (2) disseminate and promote the utilization of
14 evidence-based practices regarding trauma support
15 services and mental health care.

16 (g) DISTRIBUTION OF AWARDS.—The Secretary shall
17 ensure that grants, contracts, and cooperative agreements
18 awarded or entered into under this section are equitably
19 distributed among the geographical regions of the United
20 States and among tribal, urban, suburban, and rural pop-
21 ulations.

22 (h) RULE OF CONSTRUCTION.—Nothing in this sec-
23 tion shall be construed—

24 (1) to prohibit an entity involved with a pro-
25 gram carried out under this section from reporting

1 a crime that is committed by a student to appro-
2 priate authorities; or

3 (2) to prevent Federal, State, and tribal law en-
4 forcement and judicial authorities from exercising
5 their responsibilities with regard to the application
6 of Federal, tribal, and State law to crimes com-
7 mitted by a student.

8 (i) SUPPLEMENT, NOT SUPPLANT.—Any services
9 provided through programs carried out under this section
10 shall supplement, and not supplant, existing mental health
11 services, including any special education and related serv-
12 ices provided under the Individuals with Disabilities Edu-
13 cation Act (20 U.S.C. 1400 et seq.).

14 (j) CONSULTATION WITH INDIAN TRIBES.—In car-
15 rying out subsection (a), the Secretary shall, in a timely
16 manner, meaningfully consult with Indian Tribes and their
17 representatives to ensure notice of eligibility.

18 (k) DEFINITIONS.—In this section:

19 (1) ELEMENTARY SCHOOL.—The term “elemen-
20 tary school” has the meaning given such term in
21 section 8101 of the Elementary and Secondary Edu-
22 cation Act of 1965 (20 U.S.C. 7801).

23 (2) EVIDENCE-BASED.—The term “evidence-
24 based” has the meaning given such term in section

1 8101(21)(A)(i) of the Elementary and Secondary
2 Education Act of 1965 (20 U.S.C. 7801(21)(A)(i)).

3 (3) NATIVE HAWAIIAN EDUCATIONAL ORGANI-
4 ZATION.—The term “Native Hawaiian educational
5 organization” has the meaning given such term in
6 section 6207 of the Elementary and Secondary Edu-
7 cation Act of 1965 (20 U.S.C. 7517).

8 (4) LOCAL EDUCATIONAL AGENCY.—The term
9 “local educational agency” has the meaning given
10 such term in section 8101 of the Elementary and
11 Secondary Education Act of 1965 (20 U.S.C. 7801).

12 (5) REGIONAL CORPORATION.—The term “Re-
13 gional Corporation” has the meaning given the term
14 in section 3 of the Alaska Native Claims Settlement
15 Act (43 U.S.C. 1602).

16 (6) SCHOOL.—The term “school” means a pub-
17 lic elementary school or public secondary school.

18 (7) SCHOOL LEADER.—The term “school lead-
19 er” has the meaning given such term in section
20 8101 of the Elementary and Secondary Education
21 Act of 1965 (20 U.S.C. 7801).

22 (8) SECONDARY SCHOOL.—The term “sec-
23 ondary school” has the meaning given such term in
24 section 8101 of the Elementary and Secondary Edu-
25 cation Act of 1965 (20 U.S.C. 7801).

1 (9) SECRETARY.—The term “Secretary” means
2 the Secretary of Education.

3 (10) SPECIALIZED INSTRUCTIONAL SUPPORT
4 PERSONNEL.—The term “specialized instructional
5 support personnel” has the meaning given such term
6 in section 8101 of the Elementary and Secondary
7 Education Act of 1965 (20 U.S.C. 7801).

8 (11) STATE EDUCATIONAL AGENCY.—The term
9 “State educational agency” has the meaning given
10 such term in section 8101 of the Elementary and
11 Secondary Education Act of 1965 (20 U.S.C. 7801).

12 (l) AUTHORIZATION OF APPROPRIATIONS.—There is
13 authorized to be appropriated, and there is appropriated,
14 out of any money in the Treasury not otherwise appro-
15 priated, to carry out this section, \$20,000,000 for each
16 of fiscal years 2021 through 2025.

17 **SEC. 810. PATHWAY TO HEALTH CAREERS ACT.**

18 (a) SHORT TITLE.—This section may be cited as the
19 “Pathways to Health Careers Act”.

20 (b) EXTENSION THROUGH FISCAL YEAR 2020 OF
21 FUNDING FOR DEMONSTRATION PROJECTS TO ADDRESS
22 HEALTH PROFESSIONS WORKFORCE NEEDS.—

23 (1) IN GENERAL.—Section 2008(c)(1) of the
24 Social Security Act (42 U.S.C. 1397g(c)(1)) is
25 amended by striking “2019.” and inserting “2020,

1 and to provide technical assistance and cover admin-
2 istrative costs associated with implementing the suc-
3 cessor to this section \$15,000,000 for fiscal year
4 2020.”.

5 (2) AVAILABILITY OF OTHER FUNDS.—Upon
6 the date of the enactment of this section—

7 (A) amounts expended pursuant to section
8 1501 of division B of Public Law 116–59, or
9 any other prior law making amounts available
10 for fiscal year 2020 for activities authorized by
11 section 2008 of the Social Security Act, shall be
12 charged to the appropriation made by sub-
13 section (c)(1) of such section 2008 for fiscal
14 year 2020 (not including the amount for tech-
15 nical assistance and administrative costs); and

16 (B) if such enactment occurs on or before
17 November 21, 2019, the availability of funds
18 appropriated in, and the authority provided
19 under, such section 1501 shall terminate.

20 (c) CAREER PATHWAYS THROUGH HEALTH PROFES-
21 SION OPPORTUNITY GRANTS.—Effective October 1, 2020,
22 section 2008 of the Social Security Act (42 U.S.C. 1397g)
23 is amended to read as follows:

1 **“SEC. 2008. CAREER PATHWAYS THROUGH HEALTH PRO-**
2 **FESSION OPPORTUNITY GRANTS.**

3 “(a) APPLICATION REQUIREMENTS.—An eligible en-
4 tity desiring a grant under this section for a project shall
5 submit to the Secretary an application for the grant, that
6 includes the following:

7 “(1) A description of how the applicant will use
8 a career pathways approach to train eligible individ-
9 uals for health professions that pay well or will put
10 eligible individuals on a career path to an occupation
11 that pays well, under the project.

12 “(2) A description of the adult basic education
13 and literacy activities, work readiness activities,
14 training activities, and case management and career
15 coaching services that the applicant will use to assist
16 eligible individuals to gain work experience, connec-
17 tion to employers, and job placement, and a descrip-
18 tion of the plan for recruiting, hiring, and training
19 staff to provide the case management, mentoring,
20 and career coaching services, under the project di-
21 rectly or through local governmental, apprenticeship,
22 educational, or charitable institutions.

23 “(3) In the case of an application for a grant
24 under this section for a demonstration project de-
25 scribed in subsection (c)(2)(B)(i)(I)—

1 “(A) a demonstration that the State in
2 which the demonstration project is to be con-
3 ducted has in effect policies or laws that permit
4 certain allied health and behavioral health care
5 credentials to be awarded to people with certain
6 arrest or conviction records (which policies or
7 laws shall include appeals processes, waivers,
8 certificates, and other opportunities to dem-
9 onstrate rehabilitation to obtain credentials, li-
10 censure, and approval to work in the proposed
11 health careers), and a plan described in the ap-
12 plication that will use a career pathway to as-
13 sist participants with such a record in acquiring
14 credentials, licensing, and employment in the
15 specified careers;

16 “(B) a discussion of how the project or fu-
17 ture strategic hiring decisions will demonstrate
18 the experience and expertise of the project in
19 working with job seekers who have arrest or
20 conviction records or employers with experience
21 working with people with arrest or conviction
22 records;

23 “(C) an identification of promising innova-
24 tions or best practices that can be used to pro-
25 vide the training;

1 “(D) a proof of concept or demonstration
2 that the applicant has done sufficient research
3 on workforce shortage or in-demand jobs for
4 which people with certain types of arrest or
5 conviction records can be hired;

6 “(E) a plan for recruiting students who
7 are eligible individuals into the project; and

8 “(F) a plan for providing post-employment
9 support and ongoing training as part of a ca-
10 reer pathway under the project.

11 “(4) In the case of an application for a grant
12 under this section for a demonstration project de-
13 scribed in subsection (c)(2)(B)(i)(II)—

14 “(A) a description of the partnerships,
15 strategic staff hiring decisions, tailored program
16 activities, or other programmatic elements of
17 the project, such as training plans for doulas
18 and other community health workers and train-
19 ing plans for midwives and other allied health
20 professions, that are designed to support a ca-
21 reer pathway in pregnancy, birth, or post-
22 partum services; and

23 “(B) a demonstration that the State in
24 which the demonstration project is to be con-

1 ducted recognizes doulas or midwives, as the
2 case may be.

3 “(5) A demonstration that the applicant has ex-
4 perience working with low-income populations, or a
5 description of the plan of the applicant to work with
6 a partner organization that has the experience.

7 “(6) A plan for providing post-employment sup-
8 port and ongoing training as part of a career path-
9 way under the project.

10 “(7) A description of the support services that
11 the applicant will provide under the project, includ-
12 ing a plan for how child care and transportation
13 support services will be guaranteed and, if the appli-
14 cant will provide a cash stipend or wage supplement,
15 how the stipend or supplement would be calculated
16 and distributed.

17 “(8) A certification by the applicant that the
18 project development included—

19 “(A) consultation with a local workforce
20 development board established under section
21 107 of the Workforce Innovation and Oppor-
22 tunity Act;

23 “(B) consideration of apprenticeship and
24 pre-apprenticeship models registered under the

1 Act of August 16, 1937 (also known as the
2 ‘National Apprenticeship Act’);

3 “(C) consideration of career pathway pro-
4 grams in the State in which the project is to be
5 conducted; and

6 “(D) a review of the State plan under sec-
7 tion 102 or 103 of the Workforce Innovation
8 and Opportunity Act.

9 “(9) A description of the availability and rel-
10 evance of recent labor market information and other
11 pertinent evidence of in-demand jobs or worker
12 shortages.

13 “(10) A certification that the applicant will di-
14 rectly provide or contract for the training services
15 described in the application.

16 “(11) A commitment by the applicant that, if
17 the grant is made to the applicant, the applicant
18 will—

19 “(A) during the planning period for the
20 project, provide the Secretary with any informa-
21 tion needed by the Secretary to establish ade-
22 quate data reporting and administrative struc-
23 ture for the project;

1 “(B) hire a person to direct the project not
2 later than the end of the planning period appli-
3 cable to the project;

4 “(C) accept all technical assistance offered
5 by the Secretary with respect to the grant;

6 “(D) participate in such in-person grantee
7 conferences as are regularly scheduled by the
8 Secretary;

9 “(E) provide all data required by the Sec-
10 retary under subsection (g); and

11 “(F) notify the local disabled veterans’
12 outreach program specialists under section
13 4103A of title 38, United States Code, and the
14 local veterans’ employment representatives
15 under section 4104 of such title, of the grant-
16 ee’s outreach plan for advertising training op-
17 portunities to potential participants in the
18 project.

19 “(b) PREFERENCES IN CONSIDERING APPLICA-
20 TIONS.—In considering applications for a grant under this
21 section, the Secretary shall give preference to—

22 “(1) applications submitted by applicants to
23 whom a grant was made under this section or any
24 predecessor to this section;

1 “(2) applications submitted by applicants who
2 have business and community partners in each of
3 the following categories:

4 “(A) State and local government agencies
5 and social service providers, including a State
6 or local entity that administers a State program
7 funded under part A of this title;

8 “(B) institutions of higher education, ap-
9 prenticeship programs, and local workforce de-
10 velopment boards established under section 107
11 of the Workforce Innovation and Opportunity
12 Act; and

13 “(C) health care employers, health care in-
14 dustry or sector partnerships, labor unions, and
15 labor-management partnerships;

16 “(3) applications that include opportunities for
17 mentoring or peer support, and make career coach-
18 ing available, as part of the case management plan;

19 “(4) applications which describe a project that
20 will serve a rural area in which—

21 “(A) the community in which the individ-
22 uals to be enrolled in the project reside is lo-
23 cated;

24 “(B) the project will be conducted; or

1 “(C) an employer partnership that has
2 committed to hiring individuals who successfully
3 complete all activities under the project is lo-
4 cated;

5 “(5) applications that include a commitment to
6 providing project participants with a cash stipend or
7 wage supplement; and

8 “(6) applications which have an emergency cash
9 fund to assist project participants financially in
10 emergency situations.

11 “(c) GRANTS.—

12 “(1) COMPETITIVE GRANTS.—

13 “(A) GRANT AUTHORITY.—

14 “(i) IN GENERAL.—The Secretary, in
15 consultation with the Secretary of Labor
16 and the Secretary of Education, may make
17 a grant in accordance with this paragraph
18 to an eligible entity whose application for
19 the grant is approved by the Secretary, to
20 conduct a project designed to train low-in-
21 come individuals for allied health profes-
22 sions, health information technology, physi-
23 cians assistants, nursing assistants, reg-
24 istered nurse, advanced practice nurse, and

1 other professions considered part of a
2 health care career pathway model.

3 “(ii) GUARANTEE OF GRANTEES IN
4 EACH STATE AND THE DISTRICT OF CO-
5 LUMBIA.—For each grant cycle, the Sec-
6 retary shall award a grant under this para-
7 graph to at least 2 eligible entities in each
8 State that is not a territory, to the extent
9 there are a sufficient number of applica-
10 tions submitted by the entities that meet
11 the requirements applicable with respect to
12 such a grant. If, for a grant cycle, there
13 are fewer than 2 such eligible entities in a
14 State, the Secretary shall include that in-
15 formation in the report required by sub-
16 section (g)(2) that covers the fiscal year.

17 “(B) GUARANTEE OF GRANTS FOR INDIAN
18 POPULATIONS.—From the amount reserved
19 under subsection (i)(2)(B) for each fiscal year,
20 the Secretary shall award a grant under this
21 paragraph to at least 10 eligible entities that
22 are an Indian tribe, a tribal organization, or a
23 tribal college or university, to the extent there
24 are a sufficient number of applications sub-

mitted by the entities that meet the requirements applicable with respect to such a grant.

“(C) GUARANTEE OF GRANTEE IN THE TERRITORIES.—From the amount reserved under subsection (i)(2)(C) for each fiscal year, the Secretary shall award a grant under this paragraph to at least 2 eligible entities that are located in a territory, to the extent there are a sufficient number of applications submitted by the entities that meet the requirements applicable with respect to such a grant.

“(2) GRANTS FOR DEMONSTRATION PROJECTS.—

“(A) GRANT AUTHORITY.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Education (and, with respect to demonstration projects of the type described in subparagraph (B)(i)(I), the Attorney General) shall make a grant in accordance with this subsection to an eligible entity whose application for the grant is approved by the Secretary, to conduct a demonstration project that meets the requirements of subparagraph (B).

“(B) REQUIREMENTS.—The requirements of this subparagraph are the following:

1 “(i) TYPE OF PROJECT.—The dem-
2 onstration project shall be of 1 of the fol-
3 lowing types:

4 “(I) INDIVIDUALS WITH ARREST
5 OR CONVICTION RECORDS DEM-
6 ONSTRATION.—The demonstration
7 project shall be of a type designed to
8 provide education and training for eli-
9 gible individuals with arrest or convic-
10 tion records to enter and follow a ca-
11 reer pathway in the health professions
12 through occupations that pay well and
13 are expected to experience a labor
14 shortage or be in high demand.

15 “(II) PREGNANCY AND CHILD-
16 BIRTH CAREER PATHWAY DEM-
17 ONSTRATION.—The demonstration
18 project shall be of a type designed to
19 provide education and training for eli-
20 gible individuals to enter and follow a
21 career pathway in the field of preg-
22 nancy, childbirth, or post-partum, in a
23 State that recognizes doulas or mid-
24 wives and that provides payment for
25 services provided by doulas or mid-

1 wives, as the case may be, under pri-
2 vate or public health insurance plans.

3 “(ii) DURATION.—The demonstration
4 project shall be conducted for not less than
5 5 years.

6 “(C) MINIMUM ALLOCATION OF FUNDS
7 FOR EACH TYPE OF DEMONSTRATION
8 PROJECT.—

9 “(i) INDIVIDUALS WITH ARREST OR
10 CONVICTION RECORDS DEMONSTRA-
11 TIONS.—Not less than 25 percent of the
12 amounts made available for grants under
13 this paragraph shall be used to make
14 grants for demonstration projects of the
15 type described in subparagraph (B)(i)(I).

16 “(ii) PREGNANCY AND CHILDBIRTH
17 CAREER PATHWAY DEMONSTRATIONS.—
18 Not less than 25 percent of the amounts
19 made available for grants under this para-
20 graph shall be used to make grants for
21 demonstration projects of the type de-
22 scribed in subparagraph (B)(i)(II).

23 “(3) GRANT CYCLE.—The grant cycle under
24 this section shall be not less than 5 years, with a
25 planning period of not more than the 1st 12 months

1 of the grant cycle. During the planning period, the
2 amount of the grant shall be in such lesser amount
3 as the Secretary determines appropriate.

4 “(d) USE OF GRANT.—

5 “(1) IN GENERAL.—An entity to which a grant
6 is made under this section shall use the grant in ac-
7 cordance with the approved application for the
8 grant.

9 “(2) SUPPORT TO BE PROVIDED.—

10 “(A) REQUIRED SUPPORT.—A project for
11 which a grant is made under this section shall
12 include the following:

13 “(i) An assessment for adult basic
14 skill competency, and provision of adult
15 basic skills education if necessary for
16 lower-skilled eligible individuals to enroll in
17 the project and go on to enter and com-
18 plete post-secondary training, through
19 means including the following:

20 “(I) Establishing a network of
21 partners that offer pre-training activi-
22 ties for project participants who need
23 to improve basic academic skills or
24 English language proficiency before

1 entering a health occupational train-
2 ing career pathway program.

3 “(II) Offering resources to enable
4 project participants to continue ad-
5 vancing adult basic skill proficiency
6 while enrolled in a career pathway
7 program.

8 “(III) Embedding adult basic
9 skill maintenance as part of ongoing
10 post-graduation career coaching and
11 mentoring.

12 “(ii) A guarantee that child care is an
13 available and affordable support service for
14 project participants through means such as
15 the following:

16 “(I) Referral to, and assistance
17 with, enrollment in a subsidized child
18 care program.

19 “(II) Direct payment to a child
20 care provider if a slot in a subsidized
21 child care program is not available or
22 reasonably accessible.

23 “(III) Payment of co-payments
24 or associated fees for child care.

1 “(iii) Case management plans that in-
2 clude career coaching (with the option to
3 offer appropriate peer support and men-
4 toring opportunities to help develop soft
5 skills and social capital), which may be of-
6 fered on an ongoing basis before, during,
7 and after initial training as part of a ca-
8 reer pathway model.

9 “(iv) A plan to provide project partici-
10 pants with transportation through means
11 such as the following:

12 “(I) Referral to, and assistance
13 with enrollment in, a subsidized trans-
14 portation program.

15 “(II) If a subsidized transpor-
16 tation program is not reasonably
17 available, direct payments to subsidize
18 transportation costs.

19 For purposes of this clause, the term
20 ‘transportation’ includes public transit, or
21 gasoline for a personal vehicle if public
22 transit is not reasonably accessible or
23 available.

24 “(v) In the case of a demonstration
25 project of the type described in subsection

1 (c)(2)(B)(i)(I), access to legal assistance
2 for project participants for the purpose of
3 addressing arrest or conviction records and
4 associated workforce barriers.

5 “(B) ALLOWED SUPPORT.—The goods and
6 services provided under a project for which a
7 grant is made under this section may include
8 the following:

9 “(i) A cash stipend that is at least
10 monthly.

11 “(ii) A reserve fund for financial as-
12 sistance to project participants in emer-
13 gency situations.

14 “(iii) Tuition, and training materials
15 such as books, software, uniforms, shoes,
16 and hair nets.

17 “(iv) In-kind resource donations such
18 as interview clothing and conference at-
19 tendance fees.

20 “(v) Assistance with accessing and
21 completing high school equivalency or adult
22 basic education courses as necessary to
23 achieve success in the project and make
24 progress toward career goals.

1 “(vi) Assistance with programs and
2 activities, including legal assistance,
3 deemed necessary to address arrest or con-
4 viction records as an employment barrier.

5 “(vii) Other support services as
6 deemed necessary for family well-being,
7 success in the project, and progress toward
8 career goals.

9 “(C) TREATMENT OF SUPPORT FOR PUR-
10 POSES OF MEANS-TESTED PROGRAMS.—Any
11 goods or services provided to an eligible indi-
12 vidual participating in a project for which a
13 grant is made under this section shall not be
14 considered income, and shall not be taken into
15 account for purposes of determining the eligi-
16 bility of the individual for, or amount of bene-
17 fits to be provided to the individual, under any
18 means-tested program.

19 “(3) TRAINING.—The number of hours of train-
20 ing provided to an eligible individual under a project
21 for which a grant is made under this section, for a
22 recognized postsecondary credential, including an in-
23 dustry-recognized credential, which is awarded in
24 recognition of attainment of measurable technical or
25 occupational skills necessary to gain employment or

1 advance within an occupation (including a certificate
2 awarded by a local workforce development board es-
3 tablished under section 107 of the Workforce Inno-
4 vation and Opportunity Act), shall be—

5 “(A) not less than the number of hours of
6 training required for certification in that level
7 of skill by the State in which the project is con-
8 ducted; or

9 “(B) if there is no such requirement, such
10 number of hours of training as the Secretary
11 finds is necessary to achieve that skill level.

12 “(4) INCOME LIMITATION.—An entity to which
13 a grant is made under this section shall not use the
14 grant to provide support to a person who is not an
15 eligible individual.

16 “(5) INCLUSION OF TANF RECIPIENTS.—In the
17 case of a project for which a grant is made under
18 this section that is conducted in a State that has a
19 program funded under part A of title IV, at least 10
20 percent of the eligible individuals to whom support
21 is provided under the project shall meet the income
22 eligibility requirements under that State program,
23 without regard to whether the individuals receive
24 benefits or services directly under that State pro-
25 gram.

1 “(6) PROHIBITION.—An entity to which a grant
2 is made under this section shall not use the grant
3 for purposes of entertainment, except that case man-
4 agement and career coaching services may include
5 celebrations of specific career-based milestones such
6 as completing a semester, graduation, or job place-
7 ment.

8 “(e) TECHNICAL ASSISTANCE.—

9 “(1) IN GENERAL.—The Secretary shall provide
10 technical assistance—

11 “(A) to assist eligible entities in applying
12 for grants under this section;

13 “(B) that is tailored to meet the needs of
14 grantees at each stage of the administration of
15 projects for which grants are made under this
16 section;

17 “(C) that is tailored to meet the specific
18 needs of Indian tribes, tribal organizations, and
19 tribal colleges and universities;

20 “(D) that is tailored to meet the specific
21 needs of the territories;

22 “(E) that is tailored to meet the specific
23 needs of eligible entities in carrying out dem-
24 onstration projects for which a grant is made
25 under this section; and

1 “(F) to facilitate the exchange of informa-
2 tion among eligible entities regarding best prac-
3 tices and promising practices used in the
4 projects.

5 “(2) CONTINUATION OF PEER TECHNICAL AS-
6 SISTANCE CONFERENCES.—The Secretary shall con-
7 tinue to hold peer technical assistance conferences
8 for entities to which a grant is made under this sec-
9 tion or was made under the immediate predecessor
10 of this section.

11 “(f) EVALUATION OF DEMONSTRATION PROJECTS.—

12 “(1) IN GENERAL.—The Secretary shall, by
13 grant, contract, or interagency agreement, conduct
14 rigorous and well-designed evaluations of the dem-
15 onstration projects for which a grant is made under
16 this section.

17 “(2) REQUIREMENT APPLICABLE TO INDIVID-
18 UALS WITH ARREST OR CONVICTION RECORDS DEM-
19 ONSTRATION.—In the case of a project of the type
20 described in subsection (c)(2)(B)(i)(I), the evalua-
21 tion shall include identification of successful activi-
22 ties for creating opportunities for developing and
23 sustaining, particularly with respect to low-income
24 individuals with arrest or conviction records, a
25 health professions workforce that has accessible

1 entry points, that meets high standards for edu-
2 cation, training, certification, and professional devel-
3 opment, and that provides increased wages and af-
4 fordable benefits, including health care coverage,
5 that are responsive to the needs of the workforce.

6 “(3) REQUIREMENT APPLICABLE TO PREG-
7 NANCY AND CHILDBIRTH CAREER PATHWAY DEM-
8 ONSTRATION.—In the case of a project of the type
9 described in subsection (c)(2)(B)(i)(II), the evalua-
10 tion shall include identification of successful activi-
11 ties for creating opportunities for developing and
12 sustaining, particularly with respect to low-income
13 individuals and other entry-level workers, a career
14 pathway that has accessible entry points, that meets
15 high standards for education, training, certification,
16 and professional development, and that provides in-
17 creased wages and affordable benefits, including
18 health care coverage, that are responsive to the
19 needs of the birth, pregnancy, and post-partum
20 workforce.

21 “(4) RULE OF INTERPRETATION.—Evaluations
22 conducted pursuant to this subsection may include a
23 randomized controlled trial, but this subsection shall
24 not be interpreted to require an evaluation to include
25 such a trial.

1 “(g) REPORTS.—

2 “(1) TO THE SECRETARY.—An eligible entity
3 awarded a grant to conduct a project under this sec-
4 tion shall submit interim reports to the Secretary on
5 the activities carried out under the project, and, on
6 the conclusion of the project, a final report on the
7 activities. Each such report shall include data on
8 participant outcomes related to earnings, employ-
9 ment in health professions, graduation rate, gradua-
10 tion timeliness, credential attainment, participant
11 demographics, and other data specified by the Sec-
12 retary.

13 “(2) TO THE CONGRESS.—During each Con-
14 gress, the Secretary shall submit to the Committee
15 on Ways and Means of the House of Representatives
16 and the Committee on Finance of the Senate a re-
17 port—

18 “(A) on the demographics of the partici-
19 pants in the projects for which a grant is made
20 under this section;

21 “(B) on the rate of which project partici-
22 pants completed all activities under the
23 projects;

24 “(C) on the employment credentials ac-
25 quired by project participants;

1 “(D) on the employment of project partici-
2 pants on completion of activities under the
3 projects, and the earnings of project partici-
4 pants at entry into employment;

5 “(E) on best practices and promising prac-
6 tices used in the projects;

7 “(F) on the nature of any technical assist-
8 ance provided to grantees under this section;

9 “(G) on, with respect to the period since
10 the period covered in the most recent prior re-
11 port submitted under this paragraph—

12 “(i) the number of applications sub-
13 mitted under this section, with a separate
14 statement of the number of applications re-
15 ferred to in subsection (b)(5);

16 “(ii) the number of applications that
17 were approved, with a separate statement
18 of the number of such applications referred
19 to in subsection (b)(5); and

20 “(iii) a description of how grants were
21 made in any case described in the last sen-
22 tence of subsection (c)(1)(A)(ii); and

23 “(H) that includes an assessment of the ef-
24 fectiveness of the projects with respect to ad-

1 dressing health professions workforce shortages
2 or in-demand jobs.

3 “(h) DEFINITIONS.—In this section:

4 “(1) ALLIED HEALTH PROFESSION.—The term
5 ‘allied health profession’ has the meaning given in
6 section 799B(5) of the Public Health Service Act.

7 “(2) CAREER PATHWAY.—The term ‘career
8 pathway’ has the meaning given that term in section
9 3(7) of the Workforce Innovation and Opportunity
10 Act.

11 “(3) DOULA.—The term ‘doula’ means an indi-
12 vidual who—

13 “(A) is certified by an organization that
14 has been established for not less than 5 years
15 and that requires the completion of continuing
16 education to maintain the certification, to pro-
17 vide non-medical advice, information, emotional
18 support, and physical comfort to an individual
19 during the individual’s pregnancy, childbirth,
20 and post-partum period; and

21 “(B) maintains the certification by com-
22 pleting the required continuing education.

23 “(4) ELIGIBLE ENTITY.—The term ‘eligible en-
24 tity’ means any of the following entities that dem-
25 onstrates in an application submitted under this sec-

1 tion that the entity has the capacity to fully develop
2 and administer the project described in the applica-
3 tion:

4 “(A) A local workforce development board
5 established under section 107 of the Workforce
6 Innovation and Opportunity Act.

7 “(B) A State or territory, a political sub-
8 division of a State or territory, or an agency of
9 a State, territory, or such a political subdivi-
10 sion, including a State or local entity that ad-
11 ministers a State program funded under part A
12 of this title.

13 “(C) An Indian tribe, a tribal organization,
14 or a tribal college or university.

15 “(D) An institution of higher education (as
16 defined in the Higher Education Act of 1965).

17 “(E) A hospital (as defined in section
18 1861(e)).

19 “(F) A high-quality skilled nursing facility.

20 “(G) A Federally qualified health center
21 (as defined in section 1861(aa)(4)).

22 “(H) A nonprofit organization described in
23 section 501(c)(3) of the Internal Revenue Code
24 of 1986, a labor organization, or an entity with
25 shared labor-management oversight, that has a

1 demonstrated history of providing health profes-
2 sion training to eligible individuals.

3 “(I) In the case of a demonstration project
4 of the type provided for in subsection
5 (c)(2)(B)(i)(II) of this section, an entity recog-
6 nized by a State, Indian tribe, or tribal organi-
7 zation as qualified to train doulas or midwives,
8 if midwives or doulas, as the case may be, are
9 permitted to practice in the State involved.

10 “(J) An opioid treatment program (as de-
11 fined in section 1861(jjj)(2)), and other high
12 quality comprehensive addiction care providers.

13 “(5) ELIGIBLE INDIVIDUAL.—The term ‘eligible
14 individual’ means an individual whose family income
15 does not exceed 200 percent of the Federal poverty
16 level.

17 “(6) FEDERAL POVERTY LEVEL.—The term
18 ‘Federal poverty level’ means the poverty line (as de-
19 fined in section 673(2) of the Omnibus Budget Rec-
20 onciliation Act of 1981, including any revision re-
21 quired by such section applicable to a family of the
22 size involved).

23 “(7) INDIAN TRIBE; TRIBAL ORGANIZATION.—
24 The terms ‘Indian tribe’ and ‘tribal organization’
25 have the meaning given the terms in section 4 of the

1 Indian Self-Determination and Education Assistance
2 Act (25 U.S.C. 450b).

3 “(8) INSTITUTION OF HIGHER EDUCATION.—
4 The term ‘institution of higher education’ has the
5 meaning given the term in section 101 or
6 102(a)(1)(B) of the Higher Education Act of 1965.

7 “(9) TERRITORY.—The term ‘territory’ means
8 the Commonwealth of Puerto Rico, the United
9 States Virgin Islands, Guam, the Northern Mariana
10 Islands, and American Samoa.

11 “(10) TRIBAL COLLEGE OR UNIVERSITY.—The
12 term ‘tribal college or university’ has the meaning
13 given the term in section 316(b) of the Higher Edu-
14 cation Act of 1965.

15 “(i) FUNDING.—

16 “(1) IN GENERAL.—Out of any funds in the
17 Treasury of the United States not otherwise appro-
18 priated, there are appropriated to the Secretary to
19 carry out this section \$425,000,000 for each of fis-
20 cal years 2021 through 2025.

21 “(2) ALLOCATION OF FUNDS.—Of the amount
22 appropriated for a fiscal year under paragraph (1)
23 of this subsection—

24 “(A) 75 percent shall be available for
25 grants under subsection (c)(1)(A);

1 “(B) 4 percent shall be reserved for grants
2 under subsection (c)(1)(B);

3 “(C) 5 percent shall be reserved for grants
4 under subsection (c)(1)(C);

5 “(D) 6 percent shall be available for dem-
6 onstration project grants under subsection
7 (c)(2);

8 “(E) 6 percent, plus all amounts referred
9 to in subparagraphs (A) through (D) of this
10 paragraph that remain unused after all grant
11 awards are made for the fiscal year, shall be
12 available for the provision of technical assist-
13 ance and associated staffing; and

14 “(F) 4 percent shall be available for study-
15 ing the effects of the demonstration and non-
16 demonstration projects for which a grant is
17 made under this section, and for associated
18 staffing, for the purpose of supporting the rig-
19 orous evaluation of the demonstration projects,
20 and supporting the continued study of the
21 short-, medium-, and long-term effects of all
22 such projects, including the effectiveness of new
23 or added elements of the non-demonstration
24 projects.

1 “(j) NONAPPLICABILITY OF PRECEDING SECTIONS
2 OF THIS SUBTITLE.—

3 “(1) IN GENERAL.—Except as provided in para-
4 graph (2), the preceding sections of this subtitle
5 shall not apply to a grant awarded under this sec-
6 tion.

7 “(2) EXCEPTION FOR CERTAIN LIMITATIONS ON
8 USE OF GRANTS.—Section 2005(a) (other than para-
9 graphs (2), (3), (5), (6), and (8)) shall apply to a
10 grant awarded under this section to the same extent
11 and in the same manner as such section applies to
12 payments to States under this subtitle.”.

13 **SEC. 811. HOME VISITING TO REDUCE MATERNAL MOR-**
14 **TALITY AND MORBIDITY ACT.**

15 (a) SHORT TITLE.—This section may be cited as the
16 “Home Visiting to Reduce Maternal Mortality and Mor-
17 bidity Act”.

18 (b) INCREASE IN TRIBAL SET-ASIDE PERCENT-
19 AGE.—

20 (1) IN GENERAL.—Section 511(j)(2)(A) of the
21 Social Security Act (42 U.S.C. 711(j)(2)(A)) is
22 amended by striking “3” and inserting “6”.

23 (2) EFFECTIVE DATE.—The amendment made
24 by paragraph (1) shall take effect on October 1,
25 2020.

1 (c) INCREASE IN FUNDING.—Section 511(j)(1) of
2 such Act (42 U.S.C. 711(j)(1)) is amended—

3 (1) by striking “and” at the end of subpara-
4 graph (G); and

5 (2) by striking subparagraph (H) and inserting
6 the following:

7 “(H) \$400,000,000 for each of fiscal years
8 2017 through 2020;

9 “(I) \$600,000,000 for fiscal year 2021;
10 and

11 “(J) \$800,000,000 for fiscal year 2022.”.

12 (d) USE OF ADDITIONAL FUNDS.—Section 511(c) of
13 such Act (42 U.S.C. 711(c)) is amended by adding at the
14 end the following:

15 “(6) USE OF CERTAIN FUNDS TO PROVIDE AD-
16 DITIONAL RESOURCES TO ADDRESS HIGH RATES OF
17 MATERNAL MORTALITY AND MORBIDITY, SUPPORT
18 UNMET NEEDS IDENTIFIED BY THE NEEDS ASSESS-
19 MENT, OR INCREASE ALLOCATIONS TO STATES AND
20 TERRITORIES BASED ON RELATIVE POPULATION OR
21 POVERTY.—The Secretary shall ensure that any
22 amounts exceeding \$400,000,000 that are used for
23 grants under this subsection for a fiscal year are
24 used to—

1 “(A) provide additional funding priority to
2 States, tribes, and territories to address high
3 rates of maternal mortality and morbidity;

4 “(B) address unmet needs identified by a
5 needs assessment conducted under subsection
6 (b); or

7 “(C) increase the amounts allocated under
8 this section to States and to Puerto Rico,
9 Guam, the Virgin Islands, the Northern Mar-
10 iana Islands, and American Samoa, based on
11 the proportion of children who have not at-
12 tained 5 years of age and are living in pov-
13 erty.”.

14 **SEC. 812. ADDITION OF NEW MEASURES BASED ON ACCESS**
15 **TO BIOSIMILAR BIOLOGICAL PRODUCTS TO**
16 **THE 5-STAR RATING SYSTEM UNDER MEDI-**
17 **CARE ADVANTAGE.**

18 (a) IN GENERAL.—Section 1853(o)(4) of the Social
19 Security Act (42 U.S.C. 1395w–23(o)(4)) is amended by
20 adding at the end the following new subparagraph:

21 “(E) ADDITION OF NEW MEASURES BASED
22 ON ACCESS TO BIOSIMILAR BIOLOGICAL PROD-
23 UCTS.—

24 “(i) IN GENERAL.—For 2021 and
25 subsequent years, the Secretary shall add a

1 new set of measures to the 5-star rating
2 system based on access to biosimilar bio-
3 logical products covered under part B and,
4 in the case of MA–PD plans, such prod-
5 ucts that are covered part D drugs. Such
6 measures shall assess the impact a plan’s
7 benefit structure may have on enrollees’
8 utilization of or ability to access biosimilar
9 biological products, including in compari-
10 son to the reference biological product, and
11 shall include measures, as applicable, with
12 respect to the following:

13 “(I) COVERAGE.—Assessing
14 whether a biosimilar biological prod-
15 uct is on the plan formulary in lieu of
16 or in addition to the reference biologi-
17 cal product.

18 “(II) PREFERENCING.—Assess-
19 ing tier placement or cost-sharing for
20 a biosimilar biological product relative
21 to the reference biological product.

22 “(III) UTILIZATION MANAGE-
23 MENT TOOLS.—Assessing whether and
24 how utilization management tools are
25 used with respect to a biosimilar bio-

1 logical product relative to the ref-
2 erence biological product.

3 “(IV) UTILIZATION.—Assessing
4 the percentage of enrollees prescribed
5 the biosimilar biological product when
6 the reference biological product is also
7 available.

8 “(ii) DEFINITIONS.—In this subpara-
9 graph, the terms ‘biosimilar biological
10 product’ and ‘reference biological product’
11 have the meaning given those terms in sec-
12 tion 1847A(c)(6).

13 “(iii) PROTECTING PATIENT INTER-
14 ESTS.—In developing such measures, the
15 Secretary shall ensure that each measure
16 developed to address coverage,
17 preferencing, or utilization management is
18 constructed such that patients retain equal
19 access to appropriate therapeutic options
20 without undue administrative burden.”.

21 (b) CLARIFICATION REGARDING APPLICATION TO
22 PRESCRIPTION DRUG PLANS.—To the extent the Sec-
23 retary of Health and Human Services applies the 5-star
24 rating system under section 1853(o)(4) of the Social Secu-
25 rity Act (42 U.S.C. 1395w–23(o)(4)), or a similar system,

1 to prescription drug plans under part D of title XVIII of
2 such Act, the provisions of subparagraph (E) of such sec-
3 tion, as added by subsection (a) of this section, shall apply
4 under the system with respect to such plans in the same
5 manner as such provisions apply to the 5-star rating sys-
6 tem under such section 1853(o)(4).

7 **SEC. 813. SENSE OF CONGRESS REGARDING THE IMPACT**
8 **OF THE HIGH COST OF PRESCRIPTION**
9 **DRUGS ON COMMUNITIES OF COLOR AND**
10 **PERSONS LIVING IN RURAL OR SPARSELY**
11 **POPULATED AREAS OF THE UNITED STATES.**

12 It is the sense of the Congress that—

13 (1) the United States has the highest drug
14 prices in the world and for millions of Americans the
15 cost of prescription drugs is increasing as a barrier
16 to proper disease treatment, especially for commu-
17 nities of color and for persons living in rural or
18 sparsely populated areas of the nation;

19 (2) the Patient Protection and Affordable Care
20 Act (Public Law 111–148) substantially reduced the
21 number of uninsured Americans, but over 28 million
22 Americans remain without insurance and approxi-
23 mately 55 percent of uninsured Americans under the
24 age of 65 are persons of color;

1 (3) without health insurance, paying retail
2 prices for medications is invariably burdensome or
3 financially impossible;

4 (4) the median net worth of Caucasian house-
5 holds in 2016 was 9.7 times higher than African-
6 American households and 8.3 times higher than His-
7 panic households, which contributes to disparities in
8 negative health consequences, including for example
9 the underuse of insulin among insured adults with
10 diabetes; and

11 (5) due to the high cost of prescription drugs
12 to communities of color and for persons living in
13 rural or sparsely populated areas of the nation, this
14 Act should positively impact such communities and
15 persons (and the Secretaries of Health and Human
16 Services, Labor, and Treasury should monitor such
17 impact).

18 **SEC. 814. REGULATIONS REQUIRING DIRECT-TO-CON-**
19 **SUMER ADVERTISEMENTS FOR PRESCRIP-**
20 **TION DRUGS AND BIOLOGICAL PRODUCTS TO**
21 **INCLUDE TRUTHFUL AND NOT MISLEADING**
22 **PRICING INFORMATION.**

23 (a) IN GENERAL.—Not later than the date that is
24 one year after the date of the enactment of the Elijah E.
25 Cummings Lower Drug Costs Now Act, the Secretary of

1 Health and Human Services, acting through the Adminis-
2 trator of the Centers for Medicare & Medicaid Services
3 (referred to in this section as the “Administrator”), shall
4 promulgate final regulations requiring each direct-to-con-
5 sumer advertisement on television (including broadcast,
6 cable, streaming, and satellite television) for a prescription
7 drug or biological product for which payment is available
8 under title XVIII or XIX of the Social Security Act to
9 include a textual statement, which shall be truthful and
10 not misleading, indicating the list price, as determined on
11 the first day of the quarter during which the advertise-
12 ment is being aired or otherwise broadcast, for a typical
13 30-day regimen or typical course of treatment (whichever
14 is most appropriate).

15 (b) DETERMINATIONS.—In promulgating final regu-
16 lations under subsection (a), the Administrator shall de-
17 termine—

- 18 (1) whether such regulations should apply with
19 respect to additional forms of advertising;
- 20 (2) the manner and format of textual state-
21 ments described in such subsection;
- 22 (3) appropriate enforcement mechanisms; and
- 23 (4) whether such textual statements should in-
24 clude any other price information, as appropriate.

1 **SEC. 815. IMPROVING TRANSPARENCY AND PREVENTING**
 2 **THE USE OF ABUSIVE SPREAD PRICING AND**
 3 **RELATED PRACTICES IN MEDICAID.**

4 (a) PASS-THROUGH PRICING REQUIRED.—

5 (1) IN GENERAL.—Section 1927(e) of the So-
 6 cial Security Act (42 U.S.C. 1396r–8(e)) is amended
 7 by adding at the end the following:

8 “(6) PASS-THROUGH PRICING REQUIRED.—A
 9 contract between the State and a pharmacy benefit
 10 manager (referred to in this paragraph as a ‘PBM’),
 11 or a contract between the State and a managed care
 12 entity or other specified entity (as such terms are
 13 defined in section 1903(m)(9)(D)) that includes pro-
 14 visions making the entity responsible for coverage of
 15 covered outpatient drugs dispensed to individuals en-
 16 rolled with the entity, shall require that payment for
 17 such drugs and related administrative services (as
 18 applicable), including payments made by a PBM on
 19 behalf of the State or entity, is based on a pass-
 20 through pricing model under which—

21 “(A) any payment made by the entity or
 22 the PBM (as applicable) for such a drug—

23 “(i) is limited to—

24 “(I) ingredient cost; and

25 “(II) a professional dispensing
 26 fee that is not less than the profes-

1 sional dispensing fee that the State
2 plan or waiver would pay if the plan
3 or waiver was making the payment di-
4 rectly;

5 “(ii) is passed through in its entirety
6 by the entity or PBM to the pharmacy
7 that dispenses the drug; and

8 “(iii) is made in a manner that is con-
9 sistent with section 1902(a)(30)(A) and
10 sections 447.512, 447.514, and 447.518 of
11 title 42, Code of Federal Regulations (or
12 any successor regulation) as if such re-
13 quirements applied directly to the entity or
14 the PBM;

15 “(B) payment to the entity or the PBM
16 (as applicable) for administrative services per-
17 formed by the entity or PBM is limited to a
18 reasonable administrative fee that covers the
19 reasonable cost of providing such services;

20 “(C) the entity or the PBM (as applicable)
21 shall make available to the State, and the Sec-
22 retary upon request, all costs and payments re-
23 lated to covered outpatient drugs and accom-
24 panying administrative services incurred, re-
25 ceived, or made by the entity or the PBM, in-

cluding ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees. Discounts, or related adjustments such as direct and indirect remuneration fees, and any and all remuneration; and

“(D) any form of spread pricing whereby any amount charged or claimed by the entity or the PBM (as applicable) that is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a reasonable administrative fee as described in subparagraph (B)), is not allowable for purposes of claiming Federal matching payments under this title.”.

(2) CONFORMING AMENDMENT.—Clause (xiii) of section 1903(m)(2)(A) of such Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(A) by striking “and (III)” and inserting “(III)”; and

(B) by inserting before the period at the end the following: “, and (IV) pharmacy benefit management services provided by the entity, or provided by a pharmacy benefit manager on be-

1 half of the entity under a contract or other ar-
2 rangement between the entity and the phar-
3 macy benefit manager, shall comply with the re-
4 quirements of section 1927(e)(6)”.
5

6 (3) EFFECTIVE DATE.—The amendments made
7 by this subsection apply to contracts between States
8 and managed care entities, other specified entities,
9 or pharmacy benefits managers that are entered into
10 or renewed on or after the date that is 18 months
11 after the date of enactment of this Act.

12 (b) SURVEY OF RETAIL PRICES.—

13 (1) IN GENERAL.—Section 1927(f) of the Social
14 Security Act (42 U.S.C. 1396r–8(f)) is amended—

15 (A) by striking “and” after the semicolon
16 at the end of paragraph (1)(A)(i) and all that
17 precedes it through “(1)” and inserting the fol-
18 lowing:

19 “(1) SURVEY OF RETAIL PRICES.—The Sec-
20 retary shall conduct a survey of retail community
21 drug prices, to include at least the national average
22 drug acquisition cost, as follows:

23 “(A) USE OF VENDOR.—The Secretary
24 may contract services for—

25 “(i) with respect to retail community
pharmacies, the determination on a month-

1 ly basis of retail survey prices of the na-
2 tional average drug acquisition cost for
3 covered outpatient drugs for such phar-
4 macies, net of all discounts and rebates (to
5 the extent any information with respect to
6 such discounts and rebates is available),
7 the average reimbursement received for
8 such drugs by such pharmacies from all
9 sources of payment, including third par-
10 ties, and, to the extent available, the usual
11 and customary charges to consumers for
12 such drugs; and”;

13 (B) by adding at the end of paragraph (1)
14 the following:

15 “(F) SURVEY REPORTING.—In order to
16 meet the requirement of section 1902(a)(54), a
17 State shall require that any retail community
18 pharmacy in the State that receives any pay-
19 ment, administrative fee, discount, or rebate re-
20 lated to the dispensing of covered outpatient
21 drugs to individuals receiving benefits under
22 this title, regardless of whether such payment,
23 fee, discount, or rebate is received from the
24 State or a managed care entity directly or from
25 a pharmacy benefit manager or another entity

1 that has a contract with the State or a man-
2 aged care entity, shall respond to surveys of re-
3 tail prices conducted under this subsection.

4 “(G) SURVEY INFORMATION.—Information
5 on retail community prices obtained under this
6 paragraph shall be made publicly available and
7 shall include at least the following:

8 “(i) The monthly response rate of the
9 survey including a list of pharmacies not in
10 compliance with subparagraph (F).

11 “(ii) The sampling frame and number
12 of pharmacies sampled monthly.

13 “(iii) Characteristics of reporting
14 pharmacies, including type (such as inde-
15 pendent or chain), geographic or regional
16 location, and dispensing volume.

17 “(iv) Reporting of a separate national
18 average drug acquisition cost for each drug
19 for independent retail pharmacies and
20 chain operated pharmacies.

21 “(v) Information on price concessions
22 including on and off invoice discounts, re-
23 bates, and other price concessions.

24 “(vi) Information on average profes-
25 sional dispensing fees paid.

1 “(H) PENALTIES.—

2 “(i) FAILURE TO PROVIDE TIMELY IN-
3 FORMATION.—A retail community phar-
4 macy that fails to respond to a survey con-
5 ducted under this subsection on a timely
6 basis may be subject to a civil monetary
7 penalty in the amount of \$10,000 for each
8 day in which such information has not
9 been provided.

10 “(ii) FALSE INFORMATION.—A retail
11 community pharmacy that knowingly pro-
12 vides false information in response to a
13 survey conducted under this subsection
14 may be subject to a civil money penalty in
15 an amount not to exceed \$100,000 for
16 each item of false information.

17 “(iii) OTHER PENALTIES.—Any civil
18 money penalties imposed under this sub-
19 paragraph shall be in addition to other
20 penalties as may be prescribed by law. The
21 provisions of section 1128A (other than
22 subsections (a) and (b)) shall apply to a
23 civil money penalty under this subpara-
24 graph in the same manner as such provi-

sions apply to a penalty or proceedings under section 1128A(a).

“(I) REPORT ON SPECIALTY PHARMACIES.—

“(i) IN GENERAL.—Not later than 1 year after the effective date of this subparagraph, the Secretary shall submit a report to Congress examining specialty drug coverage and reimbursement under this title.

“(ii) CONTENT OF REPORT.—Such report shall include a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs, the settings in which specialty drugs are dispensed (such as retail community pharmacies or specialty pharmacies), whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the survey of retail prices to ensure national aver-

1 age drug acquisition costs capture drugs
 2 sold at specialty pharmacies and how such
 3 specialty pharmacies should be defined.”;

4 (C) in paragraph (2)—

5 (i) in subparagraph (A), by inserting
 6 “, including payments rates under Med-
 7 icaid managed care plans,” after “under
 8 this title”; and

9 (ii) in subparagraph (B), by inserting
 10 “and the basis for such dispensing fees”
 11 before the semicolon; and

12 (D) in paragraph (4), by inserting “, and
 13 \$5,000,000 for fiscal year 2020 and each fiscal
 14 year thereafter,” after “2010”.

15 (2) EFFECTIVE DATE.—The amendments made
 16 by this subsection take effect on the 1st day of the
 17 1st quarter that begins on or after the date that is
 18 18 months after the date of enactment of this Act.

19 (c) MANUFACTURER REPORTING OF WHOLESALE
 20 ACQUISITION COST.—Section 1927(b)(3) of such Act (42
 21 U.S.C. 1396r–8(b)(3)) is amended—

22 (1) in subparagraph (A)(i)—

23 (A) in subclause (I), by striking “and”
 24 after the semicolon;

1 (B) in subclause (II), by adding “and”
2 after the semicolon;

3 (C) by moving the left margins of sub-
4 clause (I) and (II) 2 ems to the right; and

5 (D) by adding at the end the following:

6 “(III) in the case of rebate peri-
7 ods that begin on or after the date of
8 enactment of this subclause, on the
9 wholesale acquisition cost (as defined
10 in section 1847A(c)(6)(B)) for cov-
11 ered outpatient drugs for the rebate
12 period under the agreement (including
13 for all such drugs that are sold under
14 a new drug application approved
15 under section 505(c) of the Federal
16 Food, Drug, and Cosmetic Act);”;

17 (2) in subparagraph (D)—

18 (A) in the matter preceding clause (i), by
19 inserting “and clause (vii) of this subpara-
20 graph” after “1847A”;

21 (B) in clause (v), by striking “and” after
22 the comma;

23 (C) in clause (vi), by striking the period
24 and inserting “, and”; and

1 (D) by inserting after clause (vi) the fol-
 2 lowing:

3 “(vii) to the Secretary to disclose
 4 (through a website accessible to the public)
 5 the most recently reported wholesale acqui-
 6 sition cost (as defined in section
 7 1847A(c)(6)(B)) for each covered out-
 8 patient drug (including for all such drugs
 9 that are sold under a new drug application
 10 approved under section 505(c) of the Fed-
 11 eral Food, Drug, and Cosmetic Act), as re-
 12 ported under subparagraph (A)(i)(III).”.

13 **SEC. 816. GRADUATE MEDICAL EDUCATION IMPROVE-**
 14 **MENTS IN RURAL AND UNDERSERVED COM-**
 15 **MUNITIES.**

16 Part P of title III of the Public Health Service Act
 17 (42 U.S.C. 280g et seq.) is amended by adding at the end
 18 the following new section:

19 **“SEC. 399V-7. GRADUATE MEDICAL EDUCATION IMPROVE-**
 20 **MENTS IN RURAL AND UNDERSERVED COM-**
 21 **MUNITIES.**

22 “(a) RURAL AND UNDERSERVED COMMUNITY GME
 23 GRANT PROGRAM.—Not later than 1 year after the date
 24 of the enactment of this Act, the Secretary of Health and
 25 Human Services (in this section referred to as the ‘Sec-

1 retary’), acting through the Administrator of the Health
2 Resources and Services Administration, shall establish a
3 rural and underserved community graduate medical edu-
4 cation grant program under which the Secretary shall
5 award grants to specified hospitals (as defined in sub-
6 section (b)) that have not established an approved medical
7 residency training program (as defined for purposes of
8 section 1886(h) of the Social Security Act (42 U.S.C.
9 1395ww(h))) in order to encourage such hospitals to es-
10 tablish such a program, or to establish an affiliation with
11 a hospital that has established such a program in order
12 to host residents under such program.

13 “(b) USE OF FUNDS.—Grants awarded under sub-
14 section (a) may be used by a specified hospital for any
15 initial costs associated with establishing such a program
16 or such an affiliation, including costs associated with fac-
17 ulty development, administration, infrastructure, supplies,
18 and legal and consultant services.

19 “(c) SPECIFIED HOSPITAL DEFINED.—For purposes
20 of subsection (a), the term ‘specified hospital’ means a
21 hospital or critical access hospital (as such terms are de-
22 fined in section 1861 of the Social Security Act (42 U.S.C.
23 1395x)) that—

24 “(1) is—

1 “(A) located in a rural area (as defined in
2 section 1886(d)(2)(D) of such Act (42 U.S.C.
3 1395ww(d)(2)(D))); or

4 “(B) treated as being located in a rural
5 area pursuant to section 1886(d)(8)(E) of such
6 Act (42 U.S.C. 1395ww(d)(8)(E)); and

7 “(2) is located in a medically underserved area
8 (as defined in section 330I(a) of the Public Health
9 Service Act (42 U.S.C. 254c–14(a))).

10 “(d) CRITICAL ACCESS HOSPITAL GRANT PRO-
11 GRAM.—Not later than 1 year after the date of the enact-
12 ment of this Act, the Secretary, acting through the Admin-
13 istrator of the Health Resources and Services Administra-
14 tion, shall establish a grant program under which the Sec-
15 retary awards grants to critical access hospitals (as de-
16 fined in section 1861 of the Social Security Act (42 U.S.C.
17 1395x)) that do not have in effect an affiliation with a
18 hospital with an approved medical residency training pro-
19 gram to host residents of such program in order to assist
20 such critical access hospitals in setting up such affiliations
21 in order to host such residents.

22 “(e) LIMITATION ON GRANT AMOUNTS.—No hospital
23 may receive an aggregate amount of grants under this sec-
24 tion in excess of \$250,000.

25 “(f) REPORTS.—

1 “(1) HHS.—Not later than 5 years after the
2 date of the enactment of this Act, the Secretary of
3 Health and Human Services shall submit to the
4 Committee on Energy and Commerce of the House
5 of Representatives and the Committee on Health,
6 Education, Labor, and Pensions of the Senate a re-
7 port on graduate medical residency training pro-
8 grams of hospitals that received a grant under sub-
9 section (a) or (d). Such report shall include the fol-
10 lowing:

11 “(A) The number of hospitals that applied
12 for a grant under this section.

13 “(B) The number of hospitals that were
14 awarded such a grant.

15 “(C) The number of residency positions
16 created by hospitals receiving such a grant.

17 “(D) An estimate of the number of such
18 positions such hospitals will create after the
19 date of the submission of such report.

20 “(E) A description of any challenges faced
21 by hospitals in applying for such a grant or
22 using funds awarded under such a grant.

23 “(2) GAO.—Not later than 10 years after the
24 date of the enactment of this Act, the Comptroller

1 General of the United States shall submit to Con-
2 gress a report containing an analysis of—

3 “(A) the number of residents who trained
4 at a hospital or critical access hospital that re-
5 ceived a grant under subsection (a) or (d); and

6 “(B) whether such residents continued to
7 practice medicine in a rural area (as defined in
8 section 1886(d)(2)(D) of the Social Security
9 Act (42 U.S.C. 1395ww(d)(2)(D))) or in a
10 medically underserved area (as defined in sec-
11 tion 330I(a) of the Public Health Service Act
12 (42 U.S.C. 254c-14(a))) after completing such
13 training.

14 “(g) FUNDING.—There are authorized to be appro-
15 priated such sums as are necessary for purposes of making
16 grants under this section for each of fiscal years 2020
17 through 2029.”.

 Passed the House of Representatives December 12,
2019.

Attest: CHERYL L. JOHNSON,
 Clerk.

Calendar No. 521

116TH CONGRESS
2D Session

H. R. 3

AN ACT

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

SEPTEMBER 8, 2020

Read the second time and placed on the calendar