

DECEMBER 6, 2019

RULES COMMITTEE PRINT 116-41
TEXT OF H.R. 3, ELIJAH E. CUMMINGS LOWER
DRUG COSTS NOW ACT

[Showing the text of H.R. 3, as ordered reported by the Committee on Energy and Commerce, the Committee on Ways and Means, and the Committee on Education and Labor, with modifications.]

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Elijah E. Cummings Lower Drug Costs Now Act”.

4 (b) TABLE OF CONTENTS.—The table of contents is
5 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 Drug 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.

Subtitle B—Investing in Safety and Innovation

- Sec. 711. Food and Drug Administration.

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.

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.

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

1 as the ‘program’). Under the program, with respect to
2 each price applicability period, the Secretary shall—

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

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

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

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

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

15 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
16 term ‘initial price applicability year’ means a plan
17 year (beginning with plan year 2023) or, if agreed
18 to in an agreement under section 1193 by the Sec-
19 retary and manufacturer involved, a period of more
20 than one plan year (beginning on or after January
21 1, 2023).

22 “(2) PRICE APPLICABILITY PERIOD.—The term
23 ‘price applicability period’ means, with respect to a
24 drug, the period beginning with the initial price ap-
25 plicability year with respect to which such drug is a

1 selected drug and ending with the last plan year
2 during which the drug is a selected drug.

3 “(3) SELECTED DRUG PUBLICATION DATE.—

4 The term ‘selected drug publication date’ means,
5 with respect to each initial price applicability year,
6 April 15 of the plan year that begins 2 years prior
7 to such year.

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

12 “(A) beginning on the sooner of—

13 “(i) the date on which the manufac-
14 turer of the drug and the Secretary enter
15 into an agreement under section 1193 with
16 respect to such drug; or

17 “(ii) June 15 following the selected
18 drug publication date with respect to such
19 selected drug; and

20 “(B) ending on March 31 of the year that
21 begins one year prior to the initial price appli-
22 cability year.

23 “(c) OTHER DEFINITIONS.—For purposes of this
24 part:

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

4 “(A) in the case such drug is furnished or
5 dispensed to the individual at a pharmacy or by
6 a mail order service—

7 “(i) an individual who is enrolled
8 under a prescription drug plan under part
9 D of title XVIII or an MA–PD plan under
10 part C of such title if coverage is provided
11 under such plan for such selected drug;
12 and

13 “(ii) an individual who is enrolled
14 under a group health plan or health insur-
15 ance coverage offered in the group or indi-
16 vidual market (as such terms are defined
17 in section 2791 of the Public Health Serv-
18 ice Act) with respect to which there is in
19 effect an agreement with the Secretary
20 under section 1197 with respect to such se-
21 lected drug as so furnished or dispensed;
22 and

23 “(B) in the case such drug is furnished or
24 administered to the individual by a hospital,

1 physician, or other provider of services or sup-
2 plier—

3 “(i) an individual who is entitled to
4 benefits under part A of title XVIII or en-
5 rolled under part B of such title if such se-
6 lected drug is covered under the respective
7 part; and

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

18 “(2) MAXIMUM FAIR PRICE.—The term ‘max-
19 imum fair price’ means, with respect to a plan year
20 during a price applicability period and with respect
21 to a selected drug (as defined in section 1192(c))
22 with respect to such period, the price published pur-
23 suant to section 1195 in the Federal Register for
24 such drug and year.

1 “(3) AVERAGE INTERNATIONAL MARKET PRICE
2 DEFINED.—

3 “(A) IN GENERAL.—The terms ‘average
4 international market price’ and ‘AIM price’
5 mean, with respect to a drug, the average price
6 (which shall be the net average price, if prac-
7 ticable, and volume-weighted, if practicable) for
8 a unit (as defined in paragraph (4)) of the drug
9 for sales of such drug (calculated across dif-
10 ferent dosage forms and strengths of the drug
11 and not based on the specific formulation or
12 package size or package type), as computed (as
13 of the date of publication of such drug as a se-
14 lected drug under section 1192(a)) in all coun-
15 tries described in clause (ii) of subparagraph
16 (B) that are applicable countries (as described
17 in clause (i) of such subparagraph) with respect
18 to such drug.

19 “(B) APPLICABLE COUNTRIES.—

20 “(i) IN GENERAL.—For purposes of
21 subparagraph (A), a country described in
22 clause (ii) is an applicable country de-
23 scribed in this clause with respect to a
24 drug if there is available an average price

1 for any unit for the drug for sales of such
2 drug in such country.

3 “(ii) COUNTRIES DESCRIBED.—For
4 purposes of this paragraph, the following
5 are countries described in this clause:

6 “(I) Australia.

7 “(II) Canada.

8 “(III) France.

9 “(IV) Germany.

10 “(V) Japan.

11 “(VI) The United Kingdom.

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

16 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
17 **AS SELECTED DRUGS.**

18 “(a) IN GENERAL.—Not later than the selected drug
19 publication date with respect to an initial price applica-
20 bility year, the Secretary shall select and publish in the
21 Federal Register a list of—

22 “(1)(A) with respect to an initial price applica-
23 bility year during the period beginning with 2023
24 and ending with 2027, at least 25 negotiation-eli-
25 ble drugs described in subparagraphs (A) and (B),

1 but not subparagraph (C), of subsection (d)(1) (or,
2 with respect to an initial price applicability year dur-
3 ing such period beginning after 2023, the maximum
4 number (if such number is less than 25) of such ne-
5 gotation-eligible drugs for the year) with respect to
6 such year;

7 “(B) with respect to an initial price applica-
8 bility year during the period beginning with 2028
9 and ending with 2032, at least 30 negotiation-eli-
10 ble drugs described in subparagraphs (A) and (B),
11 but not subparagraph (C), of subsection (d)(1) (or,
12 with respect to an initial price applicability year dur-
13 ing such period, the maximum number (if such num-
14 ber is less than 30) of such negotiation-eligible drugs
15 for the year) with respect to such year; and

16 “(C) with respect to an initial price applicability
17 year beginning after 2032, at least 35 negotiation-
18 eligible drugs described in subparagraphs (A) and
19 (B), but not subparagraph (C), of subsection (d)(1)
20 (or, with respect to an initial price applicability year
21 during such period, the maximum number (if such
22 number is less than 35) of such negotiation-eligible
23 drugs for the year) with respect to such year;

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

4 “(3) all new-entrant negotiation-eligible drugs
5 (as defined in subsection (g)(1)) with respect to such
6 year.

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

20 “(b) SELECTION OF DRUGS.—In carrying out sub-
21 section (a)(1) the Secretary shall select for inclusion on
22 the published list described in subsection (a) with respect
23 to a price applicability period, the negotiation-eligible
24 drugs that the Secretary projects will result in the greatest
25 savings to the Federal Government or fair price eligible

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

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

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

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

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

25 “(2) continue to be marketed.

1 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

16 “(B) OTHER DRUGS.—The drug is among
17 the 125 drugs for which there was an estimated
18 greatest net spending in the United States (in-
19 cluding the 50 States, the District of Columbia,
20 and the territories of the United States), as de-
21 termined by the Secretary, during the most re-
22 cent plan year prior to such drug publication
23 date for which data are available.

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

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

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

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

20 “(1) DRUG PRODUCTS.—A drug that—

21 “(A) is approved under section 505(c) of
22 the Federal Food, Drug, and Cosmetic Act and
23 continues to be marketed pursuant to such ap-
24 proval; and

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

4 “(2) BIOLOGICAL PRODUCTS.—A biological
5 product that—

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

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

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

1 censed under section 351(a) of the Public Health
2 Service Act pursuant to section 7002(e)(4) of the
3 Biologics Price Competition and Innovation Act of
4 2009 and continues to be marketed pursuant to such
5 licensure.

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

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

23 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE
24 DRUGS.—

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

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

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

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

1 gible drug with respect to the subsequent selected
2 drug publication date, based on the projected spend-
3 ing under title XVIII or in the United States on
4 such drug. For purposes of this paragraph the term
5 ‘United States’ includes the 50 States, the District
6 of Columbia, and the territories of the United
7 States.

8 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

9 “(a) IN GENERAL.—For purposes of section
10 1191(a)(2), the Secretary shall enter into agreements with
11 manufacturers of selected drugs with respect to a price
12 applicability period, by not later than June 15 following
13 the selected drug publication date with respect to such se-
14 lected drug, under which—

15 “(1) during the voluntary negotiation period for
16 the initial price applicability year for the selected
17 drug, the Secretary and manufacturer, in accordance
18 with section 1194, negotiate to determine (and, by
19 not later than the last date of such period and in ac-
20 cordance with subsection (c), agree to) a maximum
21 fair price for such selected drug of the manufacturer
22 in order to provide access to such price—

23 “(A) to fair price eligible individuals who
24 with respect to such drug are described in sub-
25 paragraph (A) of section 1191(c)(1) and are

1 furnished or dispensed such drug during, sub-
2 ject to subparagraph (2), the price applicability
3 period; and

4 “(B) to hospitals, physicians, and other
5 providers of services and suppliers with respect
6 to fair price eligible individuals who with re-
7 spect to such drug are described in subpara-
8 graph (B) of such section and are furnished or
9 administered such drug during, subject to sub-
10 paragraph (2), the price applicability period;

11 “(2) the Secretary and the manufacturer shall,
12 in accordance with a process and during a period
13 specified by the Secretary pursuant to rulemaking,
14 renegotiate (and, by not later than the last date of
15 such period and in accordance with subsection (e),
16 agree to) the maximum fair price for such drug if
17 the Secretary determines that there is a material
18 change in any of the factors described in section
19 1194(d) relating to the drug, including changes in
20 the AIM price for such drug, in order to provide ac-
21 cess to such maximum fair price (as so renegoti-
22 ated)—

23 “(A) to fair price eligible individuals who
24 with respect to such drug are described in sub-
25 paragraph (A) of section 1191(c)(1) and are

1 furnished or dispensed such drug during any
2 year during the price applicability period (be-
3 ginning after such renegotiation) with respect
4 to such selected drug; and

5 “(B) to hospitals, physicians, and other
6 providers of services and suppliers with respect
7 to fair price eligible individuals who with re-
8 spect to such drug are described in subpara-
9 graph (B) of such section and are furnished or
10 administered such drug during any year de-
11 scribed in subparagraph (A);

12 “(3) the maximum fair price (including as re-
13 negotiated pursuant to paragraph (2)), with respect
14 to such a selected drug, shall be provided to fair
15 price eligible individuals, who with respect to such
16 drug are described in subparagraph (A) of section
17 1191(e)(1), at the pharmacy or by a mail order serv-
18 ice at the point-of-sale of such drug;

19 “(4) the manufacturer, subject to subsection
20 (d), submits to the Secretary, in a form and manner
21 specified by the Secretary—

22 “(A) for the voluntary negotiation period
23 for the price applicability period (and, if appli-
24 cable, before any period of renegotiation speci-
25 fied pursuant to paragraph (2)) with respect to

1 such drug all information that the Secretary re-
2 quires to carry out the negotiation (or renegoti-
3 ation process) under this part, including infor-
4 mation described in section 1192(f) and section
5 1194(d)(1); and

6 “(B) on an ongoing basis, information on
7 changes in prices for such drug that would af-
8 fect the AIM price for such drug or otherwise
9 provide a basis for renegotiation of the max-
10 imum fair price for such drug pursuant to
11 paragraph (2);

12 “(5) the manufacturer agrees that in the case
13 the selected drug of a manufacturer is a drug de-
14 scribed in subsection (c), the manufacturer will, in
15 accordance with such subsection, make any payment
16 required under such subsection with respect to such
17 drug; and

18 “(6) the manufacturer complies with require-
19 ments imposed by the Secretary for purposes of ad-
20 ministering the program, including with respect to
21 the duties described in section 1196.

22 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO
23 LONGER A SELECTED DRUG.—An agreement entered into
24 under this section shall be effective, with respect to a drug,

1 until such drug is no longer considered a selected drug
2 under section 1192(c).

3 “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS
4 WITHOUT AIM PRICE.—

5 “(1) IN GENERAL.—In the case of a selected
6 drug for which there is no AIM price available with
7 respect to the initial price applicability year for such
8 drug and for which an AIM price becomes available
9 beginning with respect to a subsequent plan year
10 during the price applicability period for such drug,
11 if the Secretary determines that the amount de-
12 scribed in paragraph (2)(A) for a unit of such drug
13 is greater than the amount described in paragraph
14 (2)(B) for a unit of such drug, then by not later
15 than one year after the date of such determination,
16 the manufacturer of such selected drug shall pay to
17 the Treasury an amount equal to the product of—

18 “(A) the difference between such amount
19 described in paragraph (2)(A) for a unit of
20 such drug and such amount described in para-
21 graph (2)(B) for a unit of such drug; and

22 “(B) the number of units of such drug sold
23 in the United States, including the 50 States,
24 the District of Columbia, and the territories of

1 the United States, during the period described
2 in paragraph (2)(B).

3 “(2) AMOUNTS DESCRIBED.—

4 “(A) WEIGHTED AVERAGE PRICE BEFORE
5 AIM PRICE AVAILABLE.—For purposes of para-
6 graph (1), the amount described in this sub-
7 paragraph for a selected drug described in such
8 paragraph, is the amount equal to the weighted
9 average manufacturer price (as defined in sec-
10 tion 1927(k)(1)) for such dosage strength and
11 form for the drug during the period beginning
12 with the first plan year for which the drug is
13 included on the list of negotiation-eligible drugs
14 published under section 1192(d) and ending
15 with the last plan year during the price applica-
16 bility period for such drug with respect to which
17 there is no AIM price available for such drug.

18 “(B) AMOUNT MULTIPLIER AFTER AIM
19 PRICE AVAILABLE.—For purposes of paragraph
20 (1), the amount described in this subparagraph
21 for a selected drug described in such paragraph,
22 is the amount equal to 200 percent of the AIM
23 price for such drug with respect to the first
24 plan year during the price applicability period

1 for such drug with respect to which there is an
2 AIM price available for such drug.

3 “(d) CONFIDENTIALITY OF INFORMATION.—Infor-
4 mation submitted to the Secretary under this part by a
5 manufacturer of a selected drug that is proprietary infor-
6 mation of such manufacturer (as determined by the Sec-
7 retary) may be used only by the Secretary or disclosed
8 to and used by the Comptroller General of the United
9 States or the Medicare Payment Advisory Commission for
10 purposes of carrying out this part.

11 “(e) REGULATIONS.—

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

16 “(2) INFORMATION SPECIFIED.—Information
17 described in paragraph (1), with respect to a se-
18 lected drug, shall include information on sales of the
19 drug (by the manufacturer of the drug or by another
20 entity under license or other agreement with the
21 manufacturer, with respect to the sales of such drug,
22 regardless of the name under which the drug is sold)
23 in any foreign country that is part of the AIM price.
24 The Secretary shall verify, to the extent practicable,

1 such sales from appropriate officials of the govern-
2 ment of the foreign country involved.

3 “(f) COMPLIANCE WITH REQUIREMENTS FOR AD-
4 MINISTRATION OF PROGRAM.—Each manufacturer with
5 an agreement in effect under this section shall comply with
6 requirements imposed by the Secretary or a third party
7 with a contract under section 1196(e)(1), as applicable,
8 for purposes of administering the program.

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

10 “(a) IN GENERAL.—For purposes of this part, under
11 an agreement under section 1193 between the Secretary
12 and a manufacturer of a selected drug, with respect to
13 the period for which such agreement is in effect and in
14 accordance with subsections (b) and (c), the Secretary and
15 the manufacturer—

16 “(1) shall during the voluntary negotiation pe-
17 riod with respect to the initial price applicability
18 year for such drug, in accordance with this section,
19 negotiate a maximum fair price for such drug for
20 the purpose described in section 1193(a)(1); and

21 “(2) as applicable pursuant to section
22 1193(a)(2) and in accordance with the process speci-
23 fied pursuant to such section, renegotiate such max-
24 imum fair price for such drug for the purpose de-
25 scribed in such section.

1 “(b) NEGOTIATING METHODOLOGY AND OBJEC-
2 TIVE.—

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

9 “(2) PRIORITIZING FACTORS.—In considering
10 the factors described in subsection (d) in negotiating
11 (and, as applicable, renegotiating) the maximum fair
12 price for a selected drug, the Secretary shall, to the
13 extent practicable, consider all of the available fac-
14 tors listed but shall prioritize the following factors:

15 “(A) RESEARCH AND DEVELOPMENT
16 COSTS.—The factor described in paragraph
17 (1)(A) of subsection (d).

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

20 “(C) UNIT COSTS OF PRODUCTION AND
21 DISTRIBUTION.—The factor described in para-
22 graph (1)(C) of such subsection.

23 “(D) COMPARISON TO EXISTING THERA-
24 PEUTIC ALTERNATIVES.—The factor described
25 in paragraph (2)(A) of such subsection.

1 “(3) REQUIREMENT.—

2 “(A) IN GENERAL.—In negotiating the
3 maximum fair price of a selected drug, with re-
4 spect to an initial price applicability year for
5 the selected drug, and, as applicable, in renegoti-
6 ating the maximum fair price for such drug,
7 with respect to a subsequent year during the
8 price applicability period for such drug, in the
9 case that the manufacturer of the selected drug
10 offers under the negotiation or renegotiation, as
11 applicable, a price for such drug that is not
12 more than the target price described in sub-
13 paragraph (B) for such drug for the respective
14 year, the Secretary shall agree under such ne-
15 gotiation or renegotiation, respectively, to such
16 offered price as the maximum fair price.

17 “(B) TARGET PRICE.—

18 “(i) IN GENERAL.—Subject to clause
19 (ii), the target price described in this sub-
20 paragraph for a selected drug with respect
21 to a year, is the average price (which shall
22 be the net average price, if practicable, and
23 volume-weighted, if practicable) for a unit
24 of such drug for sales of such drug, as
25 computed (across different dosage forms

1 and strengths of the drug and not based
2 on the specific formulation or package size
3 or package type of the drug) in the appli-
4 cable country described in section
5 1191(c)(3)(B) with respect to such drug
6 that, with respect to such year, has the
7 lowest average price for such drug as com-
8 pared to the average prices (as so com-
9 puted) of such drug with respect to such
10 year in the other applicable countries de-
11 scribed in such section with respect to such
12 drug.

13 “(ii) SELECTED DRUGS WITHOUT AIM
14 PRICE.—In applying this paragraph in the
15 case of negotiating the maximum fair price
16 of a selected drug for which there is no
17 AIM price available with respect to the ini-
18 tial price applicability year for such drug,
19 or, as applicable, renegotiating the max-
20 imum fair price for such drug with respect
21 to a subsequent year during the price ap-
22 plicability period for such drug before the
23 first plan year for which there is an AIM
24 price available for such drug, the target
25 price described in this subparagraph for

1 such drug and respective year is the
2 amount that is 80 percent of the average
3 manufacturer price (as defined in section
4 1927(k)(1)) for such drug and year.

5 “(4) ANNUAL REPORT.—After the completion
6 of each voluntary negotiation period, the Secretary
7 shall submit to Congress a report on the maximum
8 fair prices negotiated (or, as applicable, renegoti-
9 ated) for such period. Such report shall include in-
10 formation on how such prices so negotiated (or re-
11 negotiated) meet the requirements of this part, in-
12 cluding the requirements of this subsection.

13 “(c) LIMITATION.—

14 “(1) IN GENERAL.—Subject to paragraph (2),
15 the maximum fair price negotiated (including as re-
16 negotiated) under this section for a selected drug,
17 with respect to each plan year during a price appli-
18 cability period for such drug, shall not exceed 120
19 percent of the AIM price applicable to such drug
20 with respect to such year.

21 “(2) SELECTED DRUGS WITHOUT AIM PRICE.—
22 In the case of a selected drug for which there is no
23 AIM price available with respect to the initial price
24 applicability year for such drug, for each plan year
25 during the price applicability period before the first

1 plan year for which there is an AIM price available
2 for such drug, the maximum fair price negotiated
3 (including as renegotiated) under this section for the
4 selected drug shall not exceed the amount equal to
5 85 percent of the average manufacturer price for the
6 drug with respect to such year.

7 “(d) CONSIDERATIONS.—For purposes of negotiating
8 and, as applicable, renegotiating (including for purposes
9 of determining whether to renegotiate) the maximum fair
10 price of a selected drug under this part with the manufac-
11 turer of the drug, the Secretary, consistent with sub-
12 section (b)(2), shall take into consideration the factors de-
13 scribed in paragraphs (1), (2), (3), and (5), and may take
14 into consideration the factor described in paragraph (4):

15 “(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as sub-
16 mitted by the manufacturer:
17

18 “(A) Research and development costs of
19 the manufacturer for the drug and the extent to
20 which the manufacturer has recouped research
21 and development costs.

22 “(B) Market data for the drug, including
23 the distribution of sales across different pro-
24 grams and purchasers and projected future rev-
25 enues for the drug.

1 “(C) Unit costs of production and distribu-
2 tion of the drug.

3 “(D) Prior Federal financial support for
4 novel therapeutic discovery and development
5 with respect to the drug.

6 “(E) Data on patents and on existing and
7 pending exclusivity for the drug.

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

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

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

14 “(A) The extent to which the drug rep-
15 resents a therapeutic advance as compared to
16 existing therapeutic alternatives and, to the ex-
17 tent such information is available, the costs of
18 such existing therapeutic alternatives.

19 “(B) Information on approval by the Food
20 and Drug Administration of alternative drug
21 products.

22 “(C) Information on comparative effective-
23 ness analysis for such products, taking into
24 consideration the effects of such products on
25 specific populations, such as individuals with

1 disabilities, the elderly, terminally ill, children,
2 and other patient populations.

3 In considering information described in subpara-
4 graph (C), the Secretary shall not use evidence or
5 findings from comparative clinical effectiveness re-
6 search in a manner that treats extending the life of
7 an elderly, disabled, or terminally ill individual as of
8 lower value than extending the life of an individual
9 who is younger, nondisabled, or not terminally ill.
10 Nothing in the previous sentence shall affect the ap-
11 plication or consideration of an AIM price for a se-
12 lected drug.

13 “(3) FOREIGN SALES INFORMATION.—To the
14 extent available on a timely basis, including as pro-
15 vided by a manufacturer of the selected drug or oth-
16 erwise, information on sales of the selected drug in
17 each of the countries described in section
18 1191(c)(3)(B).

19 “(4) VA DRUG PRICING INFORMATION.—Infor-
20 mation disclosed to the Secretary pursuant to sub-
21 section (f).

22 “(5) ADDITIONAL INFORMATION.—Information
23 submitted to the Secretary, in accordance with a
24 process specified by the Secretary, by other parties

1 that are affected by the establishment of a maximum
2 fair price for the selected drug.

3 “(e) REQUEST FOR INFORMATION.—For purposes of
4 negotiating and, as applicable, renegotiating (including for
5 purposes of determining whether to renegotiate) the max-
6 imum fair price of a selected drug under this part with
7 the manufacturer of the drug, with respect to a price ap-
8 plicability period, and other relevant data for purposes of
9 this section—

10 “(1) the Secretary shall, not later than the se-
11 lected drug publication date with respect to the ini-
12 tial price applicability year of such period, request
13 drug pricing information from the manufacturer of
14 such selected drug, including information described
15 in subsection (d)(1); and

16 “(2) by not later than October 1 following the
17 selected drug publication date, the manufacturer of
18 such selected drug shall submit to the Secretary
19 such requested information in such form and man-
20 ner as the Secretary may require.

21 The Secretary shall request, from the manufacturer or
22 others, such additional information as may be needed to
23 carry out the negotiation and renegotiation process under
24 this section.

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

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

7 “(a) IN GENERAL.—With respect to an initial price
8 applicability year and selected drug with respect to such
9 year, not later than April 1 of the plan year prior to such
10 initial price applicability year, the Secretary shall publish
11 in the Federal Register the maximum fair price for such
12 drug negotiated under this part with the manufacturer of
13 such drug.

14 “(b) UPDATES.—

15 “(1) SUBSEQUENT YEAR MAXIMUM FAIR
16 PRICES.—For a selected drug, for each plan year
17 subsequent to the initial price applicability year for
18 such drug with respect to which an agreement for
19 such drug is in effect under section 1193, the Sec-
20 retary shall publish in the Federal Register—

21 “(A) subject to subparagraph (B), the
22 amount equal to the maximum fair price pub-
23 lished for such drug for the previous year, in-
24 creased by the annual percentage increase in
25 the consumer price index for all urban con-

1 sumers (all items; U.S. city average) as of Sep-
2 tember of such previous year; or

3 “(B) in the case the maximum fair price
4 for such drug was renegotiated, for the first
5 year for which such price as so renegotiated ap-
6 plies, such renegotiated maximum fair price.

7 “(2) PRICES NEGOTIATED AFTER DEADLINE.—
8 In the case of a selected drug with respect to an ini-
9 tial price applicability year for which the maximum
10 fair price is determined under this part after the
11 date of publication under this section, the Secretary
12 shall publish such maximum fair price in the Fed-
13 eral Register by not later than 30 days after the
14 date such maximum price is so determined.

15 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
16 **VISIONS.**

17 “(a) ADMINISTRATIVE DUTIES.—

18 “(1) IN GENERAL.—For purposes of section
19 1191, the administrative duties described in this sec-
20 tion are the following:

21 “(A) The establishment of procedures (in-
22 cluding through agreements with manufacturers
23 under this part, contracts with prescription
24 drug plans under part D of title XVIII and
25 MA–PD plans under part C of such title, and

1 agreements under section 1197 with group
2 health plans and health insurance issuers of
3 health insurance coverage offered in the indi-
4 vidual or group market) under which the max-
5 imum fair price for a selected drug is provided
6 to fair price eligible individuals, who with re-
7 spect to such drug are described in subpara-
8 graph (A) of section 1191(c)(1), at pharmacies
9 or by mail order service at the point-of-sale of
10 the drug for the applicable price period for such
11 drug and providing that such maximum fair
12 price is used for determining cost-sharing under
13 such plans or coverage for the selected drug.

14 “(B) The establishment of procedures (in-
15 cluding through agreements with manufacturers
16 under this part and contracts with hospitals,
17 physicians, and other providers of services and
18 suppliers and agreements under section 1197
19 with group health plans and health insurance
20 issuers of health insurance coverage offered in
21 the individual or group market) under which, in
22 the case of a selected drug furnished or admin-
23 istered by such a hospital, physician, or other
24 provider of services or supplier to fair price eli-
25 gible individuals (who with respect to such drug

1 are described in subparagraph (B) of section
2 1191(c)(1)), the maximum fair price for the se-
3 lected drug is provided to such hospitals, physi-
4 cians, and other providers of services and sup-
5 pliers (as applicable) with respect to such indi-
6 viduals and providing that such maximum fair
7 price is used for determining cost-sharing under
8 the respective part, plan, or coverage for the se-
9 lected drug.

10 “(C) The establishment of procedures (in-
11 cluding through agreements and contracts de-
12 scribed in subparagraphs (A) and (B)) to en-
13 sure that, not later than 90 days after the dis-
14 pensing of a selected drug to a fair price eligi-
15 ble individual by a pharmacy or mail order serv-
16 ice, the pharmacy or mail order service is reim-
17 bursed for an amount equal to the difference
18 between—

19 “(i) the lesser of—

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

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

24 “(III) any other similar deter-
25 mination of pharmacy acquisition

1 costs of the drug, as determined by
2 the Secretary; and

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

5 “(D) The establishment of procedures to
6 ensure that the maximum fair price for a se-
7 lected drug is applied before—

8 “(i) any coverage or financial assist-
9 ance under other health benefit plans or
10 programs that provide coverage or finan-
11 cial assistance for the purchase or provi-
12 sion of prescription drug coverage on be-
13 half of fair price eligible individuals as the
14 Secretary may specify; and

15 “(ii) any other discounts.

16 “(E) The establishment of procedures to
17 enter into appropriate agreements and protocols
18 for the ongoing computation of AIM prices for
19 selected drugs, including, to the extent possible,
20 to compute the AIM price for selected drugs
21 and including by providing that the manufac-
22 turer of such a selected drug should provide in-
23 formation for such computation not later than
24 3 months after the first date of the voluntary
25 negotiation period for such selected drug.

1 “(F) The establishment of procedures to
2 compute and apply the maximum fair price
3 across different strengths and dosage forms of
4 a selected drug and not based on the specific
5 formulation or package size or package type of
6 the drug.

7 “(G) The establishment of procedures to
8 negotiate and apply the maximum fair price in
9 a manner that does not include any dispensing
10 or similar fee.

11 “(H) The establishment of procedures to
12 carry out the provisions of this part, as applica-
13 ble, with respect to—

14 “(i) fair price eligible individuals who
15 are enrolled under a prescription drug plan
16 under part D of title XVIII or an MA–PD
17 plan under part C of such title;

18 “(ii) fair price eligible individuals who
19 are enrolled under a group health plan or
20 health insurance coverage offered by a
21 health insurance issuer in the individual or
22 group market with respect to which there
23 is an agreement in effect under section
24 1197; and

1 “(iii) fair price eligible individuals who
2 are entitled to benefits under part A of
3 title XVIII or enrolled under part B of
4 such title.

5 “(I) The establishment of a negotiation
6 process and renegotiation process in accordance
7 with section 1194, including a process for ac-
8 quiring information described in subsection (d)
9 of such section and determining amounts de-
10 scribed in subsection (b) of such section.

11 “(J) The provision of a reasonable dispute
12 resolution mechanism to resolve disagreements
13 between manufacturers, fair price eligible indi-
14 viduals, and the third party with a contract
15 under subsection (c)(1).

16 “(2) MONITORING COMPLIANCE.—

17 “(A) IN GENERAL.—The Secretary shall
18 monitor compliance by a manufacturer with the
19 terms of an agreement under section 1193, in-
20 cluding by establishing a mechanism through
21 which violations of such terms may be reported.

22 “(B) NOTIFICATION.—If a third party
23 with a contract under subsection (c)(1) deter-
24 mines that the manufacturer is not in compli-
25 ance with such agreement, the third party shall

1 notify the Secretary of such noncompliance for
2 appropriate enforcement under section 4192 of
3 the Internal Revenue Code of 1986 or section
4 1198, as applicable.

5 “(b) COLLECTION OF DATA.—

6 “(1) FROM PRESCRIPTION DRUG PLANS AND
7 MA–PD PLANS.—The Secretary may collect appro-
8 priate data from prescription drug plans under part
9 D of title XVIII and MA–PD plans under part C of
10 such title in a timeframe that allows for maximum
11 fair prices to be provided under this part for selected
12 drugs.

13 “(2) FROM HEALTH PLANS.—The Secretary
14 may collect appropriate data from group health
15 plans or health insurance issuers offering group or
16 individual health insurance coverage in a timeframe
17 that allows for maximum fair prices to be provided
18 under this part for selected drugs.

19 “(3) COORDINATION OF DATA COLLECTION.—
20 To the extent feasible, as determined by the Sec-
21 retary, the Secretary shall ensure that data collected
22 pursuant to this subsection is coordinated with, and
23 not duplicative of, other Federal data collection ef-
24 forts.

25 “(c) CONTRACT WITH THIRD PARTIES.—

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

7 “(A) receive and transmit information be-
8 tween the Secretary, manufacturers, and other
9 individuals or entities the Secretary determines
10 appropriate;

11 “(B) receive, distribute, or facilitate the
12 distribution of funds of manufacturers to ap-
13 propriate individuals or entities in order to
14 meet the obligations of manufacturers under
15 agreements under this part;

16 “(C) provide adequate and timely informa-
17 tion to manufacturers, consistent with the
18 agreement with the manufacturer under this
19 part, as necessary for the manufacturer to ful-
20 fill its obligations under this part; and

21 “(D) permit manufacturers to conduct
22 periodic audits, directly or through contracts, of
23 the data and information used by the third
24 party to determine discounts for applicable
25 drugs of the manufacturer under the program.

1 “(2) PERFORMANCE REQUIREMENTS.—The
2 Secretary shall establish performance requirements
3 for a third party with a contract under paragraph
4 (1) and safeguards to protect the independence and
5 integrity of the activities carried out by the third
6 party under the program under this part.

7 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
8 **HEALTH PLANS.**

9 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-
10 GRAM.—

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 under the program under this part the Secretary
13 shall be treated as having in effect an agreement
14 with a group health plan or health insurance issuer
15 offering group or individual health insurance cov-
16 erage (as such terms are defined in section 2791 of
17 the Public Health Service Act), with respect to a
18 price applicability period and a selected drug with
19 respect to such period—

20 “(A) with respect to such selected drug
21 furnished or dispensed at a pharmacy or by
22 mail order service if coverage is provided under
23 such plan or coverage during such period for
24 such selected drug as so furnished or dispensed;
25 and

1 “(B) with respect to such selected drug
2 furnished or administered by a hospital, physi-
3 cian, or other provider of services or supplier if
4 coverage is provided under such plan or cov-
5 erage during such period for such selected drug
6 as so furnished or administered.

7 “(2) OPTING OUT OF AGREEMENT.—The Sec-
8 retary shall not be treated as having in effect an
9 agreement under the program under this part with
10 a group health plan or health insurance issuer offer-
11 ing group or individual health insurance coverage
12 with respect to a price applicability period and a se-
13 lected drug with respect to such period if such a
14 plan or issuer affirmatively elects, through a process
15 specified by the Secretary, not to participate under
16 the program with respect to such period and drug.

17 “(b) PUBLICATION OF ELECTION.—With respect to
18 each price applicability period and each selected drug with
19 respect to such period, the Secretary and the Secretary
20 of Labor and the Secretary of the Treasury, as applicable,
21 shall make public a list of each group health plan and each
22 health insurance issuer offering group or individual health
23 insurance coverage, with respect to which coverage is pro-
24 vided under such plan or coverage for such drug, that has

1 elected under subsection (a) not to participate under the
2 program with respect to such period and drug.

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

4 “(a) VIOLATIONS RELATING TO OFFERING OF MAX-
5 IMUM FAIR PRICE.—Any manufacturer of a selected drug
6 that has entered into an agreement under section 1193,
7 with respect to a plan year during the price applicability
8 period for such drug, that does not provide access to a
9 price that is not more than the maximum fair price (or
10 a lesser price) for such drug for such year—

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

15 “(2) to a hospital, physician, or other provider
16 of services or supplier with respect to fair price eligi-
17 ble individuals who with respect to such drug is de-
18 scribed in subparagraph (B) of such section and is
19 furnished or administered such drug by such hos-
20 pital, physician, or provider or supplier during such
21 year;

22 shall be subject to a civil monetary penalty equal to ten
23 times the amount equal to the difference between the price
24 for such drug made available for such year by such manu-
25 facturer with respect to such individual or hospital, physi-

1 cian, provider, or supplier and the maximum fair price for
2 such drug for such year.

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

11 “(c) APPLICATION.—The provisions of section 1128A
12 (other than subsections (a) and (b)) shall apply to a civil
13 monetary penalty under this section in the same manner
14 as such provisions apply to a penalty or proceeding under
15 section 1128A(a).

16 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

20 “(b) NATIONAL ACADEMY OF MEDICINE STUDY.—
21 Not later than December 31, 2025, the National Academy
22 of Medicine shall conduct a study, and submit to Congress
23 a report, on recommendations for improvements to the
24 program under this part, including the determination of
25 the limits applied under section 1194(c).

1 “(c) MEDPAC STUDY.—Not later than December 31,
2 2025, the Medicare Payment Advisory Commission shall
3 conduct a study, and submit to Congress a report, on the
4 program under this part with respect to the Medicare pro-
5 gram under title XVIII, including with respect to the ef-
6 fect of the program on individuals entitled to benefits or
7 enrolled under such title.

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

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

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

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

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

18 “(e) COORDINATION.—In carrying out this part with
19 respect to group health plans or health insurance coverage
20 offered in the group market that are subject to oversight
21 by the Secretary of Labor or the Secretary of the Treas-
22 ury, the Secretary of Health and Human Services shall
23 coordinate with such respective Secretary.

24 “(f) DATA SHARING.—The Secretary shall share with
25 the Secretary of the Treasury such information as is nec-

1 essary to determine the tax imposed by section 4192 of
2 the Internal Revenue Code of 1986.

3 “(g) GAO STUDY.—Not later than December 31,
4 2025, the Comptroller General of the United States shall
5 conduct a study of, and submit to Congress a report on,
6 the implementation of the Fair Price Negotiation Program
7 under this part.”.

8 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
9 CONFORMING AMENDMENTS.—

10 (1) UNDER MEDICARE.—

11 (A) APPLICATION TO PAYMENTS UNDER
12 PART B.—Section 1847A(b)(1)(B) of the Social
13 Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is
14 amended by inserting “or in the case of such a
15 drug or biological that is a selected drug (as de-
16 fined in section 1192(c)), with respect to a
17 price applicability period (as defined in section
18 1191(b)(2)), 106 percent of the maximum fair
19 price (as defined in section 1191(c)(2) applica-
20 ble for such drug and a plan year during such
21 period” after “paragraph (4)”.

22 (B) EXCEPTION TO PART D NON-INTER-
23 FERENCE.—Section 1860D–11(i) of the Social
24 Security Act (42 U.S.C. 1395w–111(i)) is

1 amended by inserting “, except as provided
2 under part E of title XI” after “the Secretary”.

3 (C) APPLICATION AS NEGOTIATED PRICE
4 UNDER PART D.—Section 1860D–2(d)(1) of the
5 Social Security Act (42 U.S.C. 1395w–
6 102(d)(1)) is amended—

7 (i) in subparagraph (B), by inserting
8 “, subject to subparagraph (D),” after
9 “negotiated prices”; and

10 (ii) by adding at the end the following
11 new subparagraph:

12 “(D) APPLICATION OF MAXIMUM FAIR
13 PRICE FOR SELECTED DRUGS.—In applying this
14 section, in the case of a covered part D drug
15 that is a selected drug (as defined in section
16 1192(c)), with respect to a price applicability
17 period (as defined in section 1191(b)(2)), the
18 negotiated prices used for payment (as de-
19 scribed in this subsection) shall be the max-
20 imum fair price (as defined in section
21 1191(c)(2)) for such drug and for each plan
22 year during such period.”.

23 (D) INFORMATION FROM PRESCRIPTION
24 DRUG PLANS AND MA–PD PLANS REQUIRED.—

1 (i) PRESCRIPTION DRUG PLANS.—Sec-
2 tion 1860D–12(b) of the Social Security
3 Act (42 U.S.C. 1395w–112(b)) is amended
4 by adding at the end the following new
5 paragraph:

6 “(8) PROVISION OF INFORMATION RELATED TO
7 MAXIMUM FAIR PRICES.—Each contract entered into
8 with a PDP sponsor under this part with respect to
9 a prescription drug plan offered by such sponsor
10 shall require the sponsor to provide information to
11 the Secretary as requested by the Secretary in ac-
12 cordance with section 1196(b).”.

13 (ii) MA–PD PLANS.—Section
14 1857(f)(3) of the Social Security Act (42
15 U.S.C. 1395w–27(f)(3)) is amended by
16 adding at the end the following new sub-
17 paragraph:

18 “(E) PROVISION OF INFORMATION RE-
19 LATED TO MAXIMUM FAIR PRICES.—Section
20 1860D–12(b)(8).”.

21 (2) UNDER GROUP HEALTH PLANS AND
22 HEALTH INSURANCE COVERAGE.—

23 (A) PHSA.—Part A of title XXVII of the
24 Public Health Service Act is amended by insert-

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

4 “(B) if coverage of such selected drug is
5 provided under such plan or coverage if the
6 drug is furnished or administered by a hospital,
7 physician, or other provider of services or sup-
8 plier, to the plans or coverage offered by such
9 plan or issuers, to the individuals enrolled
10 under such plans or coverage, and to hospitals,
11 physicians, and other providers of services and
12 suppliers during such period, with respect to
13 such drug in the same manner as such provi-
14 sions apply to the Secretary, to individuals enti-
15 tled to benefits under part A of title XVIII or
16 enrolled under part B of such title, and to hos-
17 pitals, physicians, and other providers and sup-
18 pliers participating under title XVIII during
19 such period;

20 “(2) the plan or issuer shall apply any cost-
21 sharing responsibilities under such plan or coverage,
22 with respect to such selected drug, by substituting
23 an amount not more than the maximum fair price
24 negotiated under such part E of title XI for such
25 drug in lieu of the drug price upon which the cost-

1 sharing would have otherwise applied, and such cost-
2 sharing responsibilities with respect to such selected
3 drug may not exceed such maximum fair price; and

4 “(3) the Secretary shall apply the provisions of
5 such part E to such plan, issuer, and coverage, such
6 individuals so enrolled in such plans and coverage,
7 and such hospitals, physicians, and other providers
8 and suppliers participating in such plans and cov-
9 erage.

10 “(b) NOTIFICATION REGARDING NONPARTICIPATION
11 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group
12 health plan or a health insurance issuer offering group or
13 individual health insurance coverage shall publicly disclose
14 in a manner and in accordance with a process specified
15 by the Secretary any election made under section 1197
16 of the Social Security Act by the plan or issuer to not
17 participate in the Fair Drug Price Negotiation Program
18 under part E of title XI of such Act with respect to a
19 selected drug (as defined in section 1192(c) of such Act)
20 for which coverage is provided under such plan or coverage
21 before the beginning of the plan year for which such elec-
22 tion was made.”.

23 (B) ERISA.—

24 (i) IN GENERAL.—Subpart B of part
25 7 of subtitle B of title I of the Employee

1 Retirement Income Security Act of 1974
2 (29 U.S.C. 1181 et. seq.) is amended by
3 adding at the end the following new sec-
4 tion:

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

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

18 “(1) the provisions of such part shall apply, as
19 applicable—

20 “(A) if coverage of such selected drug is
21 provided under such plan or coverage if the
22 drug is furnished or dispensed at a pharmacy
23 or by a mail order service, to the plans or cov-
24 erage offered by such plan or issuer, and to the
25 individuals enrolled under such plans or cov-

1 erage, during such period, with respect to such
2 selected drug, in the same manner as such pro-
3 visions apply to prescription drug plans and
4 MA-PD plans, and to individuals enrolled
5 under such prescription drug plans and MA-
6 PD plans during such period; and

7 “(B) if coverage of such selected drug is
8 provided under such plan or coverage if the
9 drug is furnished or administered by a hospital,
10 physician, or other provider of services or sup-
11 plier, to the plans or coverage offered by such
12 plan or issuers, to the individuals enrolled
13 under such plans or coverage, and to hospitals,
14 physicians, and other providers of services and
15 suppliers during such period, with respect to
16 such drug in the same manner as such provi-
17 sions apply to the Secretary, to individuals enti-
18 tled to benefits under part A of title XVIII or
19 enrolled under part B of such title, and to hos-
20 pitals, physicians, and other providers and sup-
21 pliers participating under title XVIII during
22 such period;

23 “(2) the plan or issuer shall apply any cost-
24 sharing responsibilities under such plan or coverage,
25 with respect to such selected drug, by substituting

1 an amount not more than the maximum fair price
2 negotiated under such part E of title XI for such
3 drug in lieu of the drug price upon which the cost-
4 sharing would have otherwise applied, and such cost-
5 sharing responsibilities with respect to such selected
6 drug may not exceed such maximum fair price; and

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

10 “(b) NOTIFICATION REGARDING NONPARTICIPATION
11 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group
12 health plan or a health insurance issuer offering group
13 health insurance coverage shall publicly disclose in a man-
14 ner and in accordance with a process specified by the Sec-
15 retary any election made under section 1197 of the Social
16 Security Act by the plan or issuer to not participate in
17 the Fair Drug Price Negotiation Program under part E
18 of title XI of such Act with respect to a selected drug (as
19 defined in section 1192(c) of such Act) for which coverage
20 is provided under such plan or coverage before the begin-
21 ning of the plan year for which such election was made.”.

22 (ii) APPLICATION TO RETIREE AND
23 CERTAIN SMALL GROUP HEALTH PLANS.—
24 Section 732(a) of the Employee Retire-
25 ment Income Security Act of 1974 (29

1 U.S.C. 1191a(a)) is amended by striking
2 “section 711” and inserting “sections 711
3 and 716”.

4 (iii) CLERICAL AMENDMENT.—The
5 table of sections for subpart B of part 7 of
6 subtitle B of title I of the Employee Re-
7 tirement Income Security Act of 1974 is
8 amended by adding at the end the fol-
9 lowing:

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

10 (C) IRC.—

11 (i) IN GENERAL.—Subchapter B of
12 chapter 100 of the Internal Revenue Code
13 of 1986 is amended by adding at the end
14 the following new section:

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

17 “(a) IN GENERAL.—In the case of a group health
18 plan that is treated under section 1197 of the Social Secu-
19 rity Act as having in effect an agreement with the Sec-
20 retary under the Fair Price Negotiation Program under
21 part E of title XI of such Act, with respect to a price
22 applicability period (as defined in section 1191(b) of such
23 Act) and a selected drug (as defined in section 1192(c)

1 of such Act) with respect to such period with respect to
2 which coverage is provided under such plan—

3 “(1) the provisions of such part shall apply, as
4 applicable—

5 “(A) if coverage of such selected drug is
6 provided under such plan if the drug is fur-
7 nished or dispensed at a pharmacy or by a mail
8 order service, to the plan, and to the individuals
9 enrolled under such plan during such period,
10 with respect to such selected drug, in the same
11 manner as such provisions apply to prescription
12 drug plans and MA–PD plans, and to individ-
13 uals enrolled under such prescription drug
14 plans and MA–PD plans during such period;
15 and

16 “(B) if coverage of such selected drug is
17 provided under such plan if the drug is fur-
18 nished or administered by a hospital, physician,
19 or other provider of services or supplier, to the
20 plan, to the individuals enrolled under such
21 plan, and to hospitals, physicians, and other
22 providers of services and suppliers during such
23 period, with respect to such drug in the same
24 manner as such provisions apply to the Sec-
25 retary, to individuals entitled to benefits under

1 part A of title XVIII or enrolled under part B
2 of such title, and to hospitals, physicians, and
3 other providers and suppliers participating
4 under title XVIII during such period;

5 “(2) the plan shall apply any cost-sharing re-
6 sponsibilities under such plan, with respect to such
7 selected drug, by substituting an amount not more
8 than the maximum fair price negotiated under such
9 part E of title XI for such drug in lieu of the drug
10 price upon which the cost-sharing would have other-
11 wise applied, and such cost-sharing responsibilities
12 with respect to such selected drug may not exceed
13 such maximum fair price; and

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

17 “(b) NOTIFICATION REGARDING NONPARTICIPATION
18 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group
19 health plan shall publicly disclose in a manner and in ac-
20 cordance with a process specified by the Secretary any
21 election made under section 1197 of the Social Security
22 Act by the plan to not participate in the Fair Drug Price
23 Negotiation Program under part E of title XI of such Act
24 with respect to a selected drug (as defined in section
25 1192(c) of such Act) for which coverage is provided under

1 such plan before the beginning of the plan year for which
2 such election was made.”.

3 (ii) APPLICATION TO RETIREE AND
4 CERTAIN SMALL GROUP HEALTH PLANS.—
5 Section 9831(a)(2) of the Internal Revenue
6 Code of 1986 is amended by inserting
7 “other than with respect to section 9816,”
8 before “any group health plan”.

9 (iii) CLERICAL AMENDMENT.—The
10 table of sections for subchapter B of chap-
11 ter 100 of such Code is amended by add-
12 ing at the end the following new item:

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

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

17 (A) in subsection (c)(1)(C)(ii)—

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

20 (ii) in subclause (IV), by striking at
21 the end the period and inserting “; and”;
22 and

23 (iii) by adding at the end the fol-
24 lowing new subclause:

1 “(V) in the case of a rebate pe-
2 riod and a covered outpatient drug
3 that is a selected drug (as defined in
4 section 1192(c)) during such rebate
5 period, shall be inclusive of the price
6 for such drug made available from the
7 manufacturer during the rebate period
8 by reason of application of part E of
9 title XI to any wholesaler, retailer,
10 provider, health maintenance organi-
11 zation, nonprofit entity, or govern-
12 mental entity within the United
13 States.”; and

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

16 “(iii) CLARIFICATION.—Notwith-
17 standing clause (i), in the case of a rebate
18 period and a covered outpatient drug that
19 is a selected drug (as defined in section
20 1192(c)) during such rebate period, any
21 reduction in price paid during the rebate
22 period to the manufacturer for the drug by
23 a wholesaler or retail community pharmacy
24 described in subparagraph (A) by reason of
25 application of part E of title XI shall be

1 included in the average manufacturer price
2 for the covered outpatient drug.”.

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

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

9 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
10 **PERIODS.**

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

16 “(1) such tax, divided by

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

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

22 “(1) The period beginning on the June 16th
23 immediately following the selected drug publication
24 date and ending on the first date during which the
25 manufacturer of the drug has in place an agreement

1 described in subsection (a) of section 1193 of the
2 Social Security Act with respect to such drug.

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

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

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

22 “(5) In the case of a selected drug with respect
23 to which a payment is due under subsection (c) of
24 such section 1193, the period beginning on the date
25 on which the Secretary of Health and Human Serv-

1 ices certifies that such payment is overdue and end-
2 ing on the date that such payment is made in full.

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

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

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

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

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

17 “(d) SELECTED DRUG.—For purposes of this sec-
18 tion—

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

1 “(2) UNITED STATES.—The term ‘United
2 States’ has the meaning given such term by section
3 4612(a)(4).

4 “(3) COORDINATION WITH RULES FOR POSSES-
5 SIONS OF THE UNITED STATES.—Rules similar to
6 the rules of paragraphs (2) and (4) of section
7 4132(e) shall apply for purposes of this section.

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

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

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

20 (c) CONFORMING AMENDMENTS.—

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

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

1 (d) CLERICAL AMENDMENTS.—

2 (1) The heading of subchapter E of chapter 32
3 of the Internal Revenue Code of 1986 is amended by
4 striking “**Medical Devices**” and inserting
5 “**Other Medical Products**”.

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

13 (e) EFFECTIVE DATE.—The amendments made by
14 this section shall apply to sales after the date of the enact-
15 ment of this Act.

16 **SEC. 103. FAIR DRUG PRICE NEGOTIATION IMPLEMENTA-**
17 **TION FUND.**

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

1 (b) FUNDING.—There is authorized to be appro-
2 priated, and there is hereby appropriated, out of any mon-
3 ies in the Treasury not otherwise appropriated, to the
4 Fund \$3,000,000,000, to remain available until expended,
5 of which—

6 (1) \$600,000,000 shall become available on the
7 date of the enactment of this Act;

8 (2) \$600,000,000 shall become available on Oc-
9 tober 1, 2020;

10 (3) \$600,000,000 shall become available on Oc-
11 tober 1, 2021;

12 (4) \$600,000,000 shall become available on Oc-
13 tober 1, 2022; and

14 (5) \$600,000,000 shall become available on Oc-
15 tober 1, 2023.

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

1 **TITLE II—MEDICARE PARTS B**
2 **AND D PRESCRIPTION DRUG**
3 **INFLATION REBATES**

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

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

8 “(x) REBATE BY MANUFACTURERS FOR SINGLE
9 SOURCE DRUGS WITH PRICES INCREASING FASTER
10 THAN INFLATION.—

11 “(1) REQUIREMENTS.—

12 “(A) SECRETARIAL PROVISION OF INFOR-
13 MATION.—Not later than 6 months after the
14 end of each calendar quarter beginning on or
15 after July 1, 2021, the Secretary shall, for each
16 part B rebatable drug, report to each manufac-
17 turer of such part B rebatable drug the fol-
18 lowing for such calendar quarter:

19 “(i) Information on the total number
20 of units of the billing and payment code
21 described in subparagraph (A)(i) of para-
22 graph (3) with respect to such drug and
23 calendar quarter.

24 “(ii) Information on the amount (if
25 any) of the excess average sales price in-

1 crease described in subparagraph (A)(ii) of
2 such paragraph for such drug and calendar
3 quarter.

4 “(iii) The rebate amount specified
5 under such paragraph for such part B
6 rebtable drug and calendar quarter.

7 “(B) MANUFACTURER REQUIREMENT.—
8 For each calendar quarter beginning on or after
9 July 1, 2021, the manufacturer of a part B
10 rebtable drug shall, for such drug, not later
11 than 30 days after the date of receipt from the
12 Secretary of the information described in sub-
13 paragraph (A) for such calendar quarter, pro-
14 vide to the Secretary a rebate that is equal to
15 the amount specified in paragraph (3) for such
16 drug for such calendar quarter.

17 “(2) PART B REBTABLE DRUG DEFINED.—

18 “(A) IN GENERAL.—In this subsection, the
19 term ‘part B rebtable drug’ means a single
20 source drug or biological (as defined in sub-
21 paragraph (D) of section 1847A(c)(6)), includ-
22 ing a biosimilar biological product (as defined
23 in subparagraph (H) of such section), paid for
24 under this part, except such term shall not in-
25 clude such a drug or biological—

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

6 “(ii) that is a vaccine described in
7 subparagraph (A) or (B) of section
8 1861(s)(10).

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

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

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

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

4 “(3) REBATE AMOUNT.—

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

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

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

17 “(I) the payment amount under
18 subparagraph (B) or (C) of section
19 1847A(b)(1), as applicable, for such
20 part B rebatable drug during the cal-
21 endar quarter; exceeds

22 “(II) the inflation-adjusted pay-
23 ment amount determined under sub-
24 paragraph (C) for such part B

1 rebatable drug during the calendar
2 quarter.

3 “(B) EXCLUDED UNITS.—For purposes of
4 subparagraph (A)(i), the total number of units
5 of the billing and payment code for each part
6 B rebatable drug furnished during a calendar
7 quarter shall not include—

8 “(i) units packaged into the payment
9 for a procedure or service under section
10 1833(t) or under section 1833(i) (instead
11 of separately payable under such respective
12 section);

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

16 “(iii) units of a part B rebatable drug
17 of a manufacturer furnished to an indi-
18 vidual, if such manufacturer, with respect
19 to the furnishing of such units of such
20 drug, provides for discounts under section
21 340B of the Public Health Service Act or
22 for rebates under section 1927.

23 “(C) DETERMINATION OF INFLATION-AD-
24 JUSTED PAYMENT AMOUNT.—The inflation-ad-
25 justed payment amount determined under this

1 subparagraph for a part B rebatable drug for
2 a calendar quarter is—

3 “(i) the payment amount for the bill-
4 ing and payment code for such drug in the
5 payment amount benchmark quarter (as
6 defined in subparagraph (D)); increased by

7 “(ii) the percentage by which the re-
8 bate period CPI-U (as defined in subpara-
9 graph (F)) for the calendar quarter ex-
10 ceeds the benchmark period CPI-U (as de-
11 fined in subparagraph (E)).

12 “(D) PAYMENT AMOUNT BENCHMARK
13 QUARTER.—The term ‘payment amount bench-
14 mark quarter’ means the calendar quarter be-
15 ginning January 1, 2016.

16 “(E) BENCHMARK PERIOD CPI-U.—The
17 term ‘benchmark period CPI-U’ means the con-
18 sumer price index for all urban consumers
19 (United States city average) for July 2015.

20 “(F) REBATE PERIOD CPI-U.—The term
21 ‘rebate period CPI-U’ means, with respect to a
22 calendar quarter described in subparagraph
23 (C), the greater of the benchmark period CPI-
24 U and the consumer price index for all urban
25 consumers (United States city average) for the

1 first month of the calendar quarter that is two
2 calendar quarters prior to such described cal-
3 endar quarter.

4 “(G) COUNTING UNITS.—

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

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

1 such drug so furnished in the total number
2 of billing units for such drug for a subse-
3 quent quarter, as the Secretary determines
4 appropriate.

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

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

23 “(B) TIMELINE FOR PROVISION OF RE-
24 BATES FOR SUBSEQUENTLY APPROVED
25 DRUGS.—In the case of a part B rebatable drug

1 first approved or licensed by the Food and
2 Drug Administration after July 1, 2015, para-
3 graph (1)(B) shall be applied as if the reference
4 to ‘July 1, 2021’ under such paragraph were a
5 reference to the later of the 6th full calendar
6 quarter after the day on which the drug was
7 first marketed or July 1, 2021.

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

17 “(D) SELECTED DRUGS.—In the case of a
18 part B rebatable drug that is a selected drug
19 (as defined in section 1192(e)) for a price appli-
20 cability period (as defined in section
21 1191(b)(2))—

22 “(i) for calendar quarters during such
23 period for which a maximum fair price (as
24 defined in section 1191(c)(2)) for such
25 drug has been determined and is applied

1 under part E of title XI, the rebate
2 amount under paragraph (1)(B) shall be
3 waived; and

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

23 “(5) APPLICATION TO BENEFICIARY COINSUR-
24 ANCE.—In the case of a part B rebatable drug, if

1 the payment amount for a quarter exceeds the infla-
2 tion adjusted payment for such quarter—

3 “(A) in computing the amount of any coin-
4 surance applicable under this title to an indi-
5 vidual with respect to such drug, the computa-
6 tion of such coinsurance shall be based on the
7 inflation-adjusted payment amount determined
8 under paragraph (3)(C) for such part B
9 rebatable drug; and

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

13 “(6) REBATE DEPOSITS.—Amounts paid as re-
14 bates under paragraph (1)(B) shall be deposited into
15 the Federal Supplementary Medical Insurance Trust
16 Fund established under section 1841.

17 “(7) CIVIL MONEY PENALTY.—If a manufac-
18 turer of a part B rebatable drug has failed to com-
19 ply with the requirements under paragraph (1)(B)
20 for such drug for a calendar quarter, the manufac-
21 turer shall be subject to, in accordance with a proc-
22 ess established by the Secretary pursuant to regula-
23 tions, a civil money penalty in an amount equal to
24 at least 125 percent of the amount specified in para-
25 graph (3) for such drug for such calendar quarter.

1 The provisions of section 1128A (other than sub-
2 sections (a) (with respect to amounts of penalties or
3 additional assessments) and (b)) shall apply to a
4 civil money penalty under this paragraph in the
5 same manner as such provisions apply to a penalty
6 or proceeding under section 1128A(a).

7 “(8) STUDY AND REPORT.—

8 “(A) STUDY.—The Secretary shall conduct
9 a study of the feasibility of and operational
10 issues involved with the following:

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

14 “(ii) Including drugs and biologicals
15 paid for under MA plans under part C in
16 the rebate system under this subsection.

17 “(iii) Including drugs excluded under
18 paragraph (2)(A) and units of the billing
19 and payment code of the drugs excluded
20 under paragraph (3)(B) in the rebate sys-
21 tem under this subsection.

22 “(B) REPORT.—Not later than 3 years
23 after the date of the enactment of this sub-
24 section, the Secretary shall submit to Congress

1 a report on the study conducted under subpara-
2 graph (A).

3 “(9) APPLICATION TO MULTIPLE SOURCE
4 DRUGS.—The Secretary may, based on the report
5 submitted under paragraph (8) and pursuant to
6 rulemaking, apply the provisions of this subsection
7 to multiple source drugs (as defined in section
8 1847A(c)(6)(C)), including, for purposes of deter-
9 mining the rebate amount under paragraph (3), by
10 calculating manufacturer-specific average sales
11 prices for the benchmark period and the rebate pe-
12 riod.”.

13 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
14 1833 of the Social Security Act (42 U.S.C. 1395l) is
15 amended—

16 (1) in subsection (a)—

17 (A) in paragraph (1)—

18 (i) in subparagraph (S), by striking
19 “with respect to” and inserting “subject to
20 subparagraph (DD), with respect to”;

21 (ii) by striking “and (CC)” and in-
22 serting “(CC)”; and

23 (iii) by inserting before the semicolon
24 at the end the following: “, and (DD) with
25 respect to a part B rebatable drug (as de-

1 fined in paragraph (2) of section 1834(x))
2 for which the payment amount for a cal-
3 endar quarter under paragraph
4 (3)(A)(ii)(I) of such section for such quar-
5 ter exceeds the inflation-adjusted payment
6 under paragraph (3)(A)(ii)(II) of such sec-
7 tion for such quarter, the amounts paid
8 shall be the difference between (i) the pay-
9 ment amount under paragraph
10 (3)(A)(ii)(I) of such section for such drug,
11 and (ii) 20 percent of the inflation-ad-
12 justed payment amount under paragraph
13 (3)(A)(ii)(II) of such section for such
14 drug”;

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

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

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

1 “(9) In the case of a part B rebatable drug (as de-
2 fined in paragraph (2) of section 1834(x)) for which pay-
3 ment under this subsection is not packaged into a payment
4 for a covered OPD service (as defined in subsection
5 (t)(1)(B)) (or group of services) furnished on or after July
6 1, 2021, under the system under this subsection, in lieu
7 of calculation of coinsurance and the amount of payment
8 otherwise applicable under this subsection, the provisions
9 of section 1834(x)(5), paragraph (1)(DD) of subsection
10 (a), and the flush left matter following paragraph (9) of
11 subsection (a), shall, as determined appropriate by the
12 Secretary, apply under this subsection in the same manner
13 as such provisions of section 1834(x)(5) and subsection
14 (a) apply under such section and subsection.”; and

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

17 “(F) PART B REBATABLE DRUGS.—In the
18 case of a part B rebatable drug (as defined in
19 paragraph (2) of section 1834(x)) for which
20 payment under this part is not packaged into a
21 payment for a service furnished on or after July
22 1, 2021, under the system under this sub-
23 section, in lieu of calculation of coinsurance and
24 the amount of payment otherwise applicable
25 under this subsection, the provisions of section

1 1834(x)(5), paragraph (1)(DD) of subsection
2 (a), and the flush left matter following para-
3 graph (9) of subsection (a), shall, as determined
4 appropriate by the Secretary, apply under this
5 subsection in the same manner as such provi-
6 sions of section 1834(x)(5) and subsection (a)
7 apply under such section and subsection.”.

8 (c) CONFORMING AMENDMENTS.—

9 (1) TO PART B ASP CALCULATION.—Section
10 1847A(c)(3) of the Social Security Act (42 U.S.C.
11 1395w–3a(c)(3)) is amended by inserting “or section
12 1834(x)” after “section 1927”.

13 (2) EXCLUDING PARTS B DRUG INFLATION RE-
14 BATE FROM BEST PRICE.—Section
15 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
16 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-
17 serting “or section 1834(x)” after “this section”.

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

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

22 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
23 **DRUGS WITH PRICES INCREASING FASTER**
24 **THAN INFLATION.**

25 “(a) IN GENERAL.—

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

9 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT
10 COVERED UNDER AGREEMENTS.—Paragraph (1)
11 shall not apply to the dispensing of a covered part
12 D drug if—

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

16 “(B) the Secretary determines that in the
17 period beginning on January 1, 2022, and end-
18 ing on December 31, 2022, there were extenu-
19 ating circumstances.

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

23 “(b) AGREEMENTS.—

24 “(1) TERMS OF AGREEMENT.—An agreement
25 described in this subsection, with respect to a manu-

1 factorer of a part D rebatable drug, is an agreement
2 under which the following shall apply:

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

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

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

21 “(iii) The rebate amount specified
22 under subsection (c) for each dosage form
23 and strength with respect to such drug and
24 year.

1 “(B) MANUFACTURER REQUIREMENTS.—

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

13 “(2) LENGTH OF AGREEMENT.—

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

21 “(B) TERMINATION.—

22 “(i) BY SECRETARY.—The Secretary
23 may provide for termination of an agree-
24 ment under this section for violation of the
25 requirements of the agreement or other

1 good cause shown. Such termination shall
2 not be effective earlier than 30 days after
3 the date of notice of such termination. The
4 Secretary shall provide, upon request, a
5 manufacturer with a hearing concerning
6 such a termination, but such hearing shall
7 not delay the effective date of the termi-
8 nation.

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

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

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

22 “(C) EFFECTIVENESS OF TERMINATION.—
23 Any termination under this paragraph shall not
24 affect rebates due under the agreement under

1 this section before the effective date of its ter-
2 mination.

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

12 “(c) REBATE AMOUNT.—

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

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

22 “(B) the amount (if any) by which—

23 “(i) the annual manufacturer price
24 (as determined in paragraph (2)) paid for
25 such dosage form and strength with re-

1 spect to such part D rebatable drug for the
2 year; exceeds

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

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

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

19 “(B) the ratio of—

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

23 “(ii) the total number of units of such
24 dosage form and strength dispensed during
25 such year.

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

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

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

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

22 “(A) the average manufacturer price (as
23 defined in subsection (h)(6)) of such dosage
24 form and strength, as calculated for a unit of
25 such drug, with respect to each calendar quar-

1 ter of the payment amount benchmark year (as
2 defined in subsection (h)(3)); and

3 “(B) the ratio of—

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

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

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

13 “(A) SUBSEQUENTLY APPROVED DRUGS.—

14 In the case of a part D rebatable drug first ap-
15 proved or licensed by the Food and Drug Ad-
16 ministration after January 1, 2016, subpara-
17 graphs (A) and (B) of paragraph (4) shall be
18 applied as if the term ‘payment amount bench-
19 mark year’ were defined under subsection
20 (h)(3) as the first calendar year beginning after
21 the day on which the drug was first marketed
22 by any manufacturer and subparagraph (B) of
23 paragraph (3) shall be applied as if the term
24 ‘benchmark period CPI-U’ were defined under
25 subsection (h)(4) as if the reference to ‘January

1 2016’ under such subsection were a reference to
2 ‘January of the first year beginning after the
3 date on which the drug was first marketed by
4 any manufacturer’.

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

13 “(C) TREATMENT OF NEW FORMULA-
14 TIONS.—

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

24 “(ii) LINE EXTENSION DEFINED.—In
25 this subparagraph, the term ‘line exten-

1 sion’ means, with respect to a part D
2 rebtable drug, a new formulation of the
3 drug (as determined by the Secretary),
4 such as an extended release formulation,
5 but does not include an abuse-deterrent
6 formulation of the drug (as determined by
7 the Secretary), regardless of whether such
8 abuse-deterrent formulation is an extended
9 release formulation.

10 “(D) SELECTED DRUGS.—In the case of a
11 part D rebtable drug that is a selected drug
12 (as defined in section 1192(c)) for a price appli-
13 cability period (as defined in section
14 1191(b)(2))—

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

21 “(ii) in the case such drug is deter-
22 mined (pursuant to such section 1192(c))
23 to no longer be a selected drug, for each
24 applicable year beginning after the price
25 applicability period with respect to such

1 drug, subparagraphs (A) and (B) of para-
2 graph (4) shall be applied as if the term
3 ‘payment amount benchmark year’ were
4 defined under subsection (h)(3) as the last
5 year beginning during such price applica-
6 bility period with respect to such selected
7 drug and subparagraph (B) of paragraph
8 (3) shall be applied as if the term ‘bench-
9 mark period CPI-U’ were defined under
10 subsection (h)(4) as if the reference to
11 ‘January 2016’ under such subsection were
12 a reference to January of the last year be-
13 ginning during such price applicability pe-
14 riod with respect to such drug.

15 “(d) REBATE DEPOSITS.—Amounts paid as rebates
16 under subsection (c) shall be deposited into the Medicare
17 Prescription Drug Account in the Federal Supplementary
18 Medical Insurance Trust Fund established under section
19 1841.

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

23 “(f) CIVIL MONEY PENALTY.—In the case of a man-
24 ufacturer of a part D rebatable drug with an agreement
25 in effect under this section who has failed to comply with

1 the terms of the agreement under subsection (b)(1)(B)
2 with respect to such drug for an applicable year, the Sec-
3 retary may impose a civil money penalty on such manufac-
4 turer in an amount equal to 125 percent of the amount
5 specified in subsection (c) for such drug for such year.
6 The provisions of section 1128A (other than subsections
7 (a) (with respect to amounts of penalties or additional as-
8 sessments) and (b)) shall apply to a civil money penalty
9 under this subsection in the same manner as such provi-
10 sions apply to a penalty or proceeding under section
11 1128A(a).

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

14 “(1) The determination of units under this sec-
15 tion.

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

18 “(3) The calculation of the rebate amount
19 under this section.

20 “(h) DEFINITIONS.—In this section:

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

22 “(A) IN GENERAL.—The term ‘part D
23 rebatable drug’ means a drug or biological that
24 would (without application of this section) be a
25 covered part D drug, except such term shall,

1 with respect to an applicable year, not include
2 such a drug or biological if the average annual
3 total cost under this part for such year per in-
4 dividual who uses such a drug or biological, as
5 determined by the Secretary, is less than, sub-
6 ject to subparagraph (B), \$100, as determined
7 by the Secretary using the most recent data
8 available or, if data is not available, as esti-
9 mated by the Secretary.

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

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

19 “(ii) for a subsequent year, shall be
20 the dollar amount specified in this sub-
21 paragraph for the previous year, increased
22 by the percentage increase in the consumer
23 price index for all urban consumers
24 (United States city average) for the 12-

1 month period beginning with January of
2 the previous year.

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

6 “(2) UNIT DEFINED.—The term ‘unit’ means,
7 with respect to a part D rebatable drug, the lowest
8 identifiable quantity (such as a capsule or tablet,
9 milligram of molecules, or grams) of the part D
10 rebatable drug that is dispensed to individuals under
11 this part.

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

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

19 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-
20 plicable year CPI–U’ means, with respect to an ap-
21 plicable year, the consumer price index for all urban
22 consumers (United States city average) for January
23 of such year.

24 “(6) AVERAGE MANUFACTURER PRICE.—The
25 term ‘average manufacturer price’ has the meaning,

1 with respect to a part D rebatable drug of a manu-
2 facturer, given such term in section 1927(k)(1), with
3 respect to a covered outpatient drug of a manufac-
4 turer for a rebate period under section 1927.”.

5 (b) CONFORMING AMENDMENTS.—

6 (1) TO PART B ASP CALCULATION.—Section
7 1847A(c)(3) of the Social Security Act (42 U.S.C.
8 1395w–3a(c)(3)), as amended by section 201(c)(1),
9 is further amended by striking “section 1927 or sec-
10 tion 1834(x)” and inserting “section 1927, section
11 1834(x), or section 1860D–14B”.

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

19 **SEC. 203. PROVISION REGARDING INFLATION REBATES**
20 **FOR GROUP HEALTH PLANS AND GROUP**
21 **HEALTH INSURANCE COVERAGE.**

22 Not later than December 31, 2021, the Secretary of
23 Labor, in consultation with the Secretary of Health and
24 Human Services and the Secretary of the Treasury, shall
25 submit to Congress a report on—

1 (1) potential models for an agreement process
2 with manufacturers of prescription drugs under
3 which such manufacturers provide for inflation re-
4 bates with respect to such drugs that are furnished
5 or dispensed to participants and beneficiaries of
6 group health plans and health insurance coverage of-
7 fered in the group market in a manner similar to
8 how manufacturers provide for rebates under section
9 1834(x) of the Social Security Act, as added by sec-
10 tion 201, and section 1860D–14B of such Act, as
11 added by section 202, with respect to prescription
12 drugs that are furnished or dispensed under part B
13 of title XVIII of such Act and part D of such title,
14 respectively;

15 (2) potential models for enforcement mecha-
16 nisms with respect to such an agreement process
17 that ensure that such inflation rebates are propor-
18 tionally distributed, with respect to costs, to group
19 health plans and health insurance issuers offering
20 health insurance coverage in the group market, to
21 participants and beneficiaries of such plans and cov-
22 erage, or to both; and

23 (3) for each potential model under paragraphs
24 (1) and (2) any additional statutory authority need-
25 ed to implement such model.

1 **SEC. 204. ANNUAL REPORT ON DRUG COSTS IN GROUP**
2 **HEALTH PLANS AND GROUP HEALTH INSUR-**
3 **ANCE COVERAGE.**

4 (a) INITIAL REPORT.—Not later than December 31,
5 2021, the Secretary of Labor shall, in consultation with
6 the Secretary of Health and Human Services and the Sec-
7 retary of the Treasury, submit to Congress a report, with
8 respect to a period (as determined by the Secretary of
9 Labor), on—

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

18 (2) whether there are mechanisms by which
19 manufacturers of prescription drugs have attempted
20 to recover rebate payments required of such manu-
21 facturers under section 1834(x) of the Social Secu-
22 rity Act, as added by section 201, and section
23 1860D–14B of such Act, as added by section 202,
24 with respect to prescription drugs that are furnished
25 or dispensed under part B of title XVIII of such Act
26 and part D of such title, respectively, through in-

1 creased prices charged with respect to drugs that are
2 furnished or dispensed to participants and bene-
3 ficiaries of group health plans and health insurance
4 coverage offered in the group market during such
5 period.

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

15 **SEC. 205. COLLECTION OF DATA.**

16 (a) MANUFACTURERS OF PRESCRIPTION DRUGS.—
17 Manufacturers of prescription drugs shall submit to the
18 Secretary of Health and Human Services, Secretary of
19 Labor, and the Secretary of the Treasury appropriate data
20 as necessary for the Secretaries to obtain information
21 needed to provide the reports under sections 203 and 204.

22 (b) GROUP HEALTH PLANS AND HEALTH INSUR-
23 ANCE ISSUERS OFFERING HEALTH INSURANCE COV-
24 ERAGE IN THE GROUP MARKET.—Group health plans and
25 health insurance issuers offering health insurance cov-

1 erage in the group market shall submit to the Secretary
2 of Health and Human Services, Secretary of Labor, and
3 the Secretary of the Treasury appropriate data as nec-
4 essary for the Secretaries to obtain information needed to
5 provide the reports under sections 203 and 204.

6 **TITLE III—PART D IMPROVE-**
7 **MENTS AND MAXIMUM OUT-**
8 **OF-POCKET CAP FOR MEDI-**
9 **CARE BENEFICIARIES**

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

11 (a) BENEFIT STRUCTURE REDESIGN.—Section
12 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
13 102(b)) is amended—

14 (1) in paragraph (2)—

15 (A) in subparagraph (A), in the matter
16 preceding clause (i), by inserting “for a year
17 preceding 2022 and for costs above the annual
18 deductible specified in paragraph (1) and up to
19 the annual out-of-pocket threshold specified in
20 paragraph (4)(B) for 2022 and each subsequent
21 year” after “paragraph (3)”;

22 (B) in subparagraph (C)—

23 (i) in clause (i), in the matter pre-
24 ceding subclause (I), by inserting “for a

1 year preceding 2022,” after “paragraph
2 (4),”; and

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

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2022,” after “paragraph
11 (4),”; and

12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2018 through
15 2021”; and

16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2021”;

20 (2) in paragraph (3)(A)—

21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2022,” after
23 “and (4),”; and

1 (B) in clause (ii), by striking “for a subse-
2 quent year” and inserting “for each of years
3 2007 through 2021”; and

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

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

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

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

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

22 (IV) by adding at the end the fol-
23 lowing:

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

1 (ii) in clause (ii), by striking “clause
2 (i)(I)” and inserting “clause (i)(I)(aa)”;
3 (B) in subparagraph (B)—
4 (i) in clause (i)—
5 (I) in subclause (V), by striking
6 “or” at the end;
7 (II) in subclause (VI)—
8 (aa) by striking “for a sub-
9 sequent year” and inserting “for
10 2021”; and
11 (bb) by striking the period
12 at the end and inserting a semi-
13 colon; and
14 (III) by adding at the end the
15 following new subclauses:
16 “(VII) for 2022, is equal to
17 \$2,000; or
18 “(VIII) for a subsequent year, is
19 equal to the amount specified in this
20 subparagraph for the previous year,
21 increased by the annual percentage in-
22 crease described in paragraph (6) for
23 the year involved.”; and
24 (ii) in clause (ii), by striking “clause
25 (i)(II)” and inserting “clause (i)”;

1 (C) in subparagraph (C)(i), by striking
2 “and for amounts” and inserting “and, for a
3 year preceding 2022, for amounts”; and

4 (D) in subparagraph (E), by striking “In
5 applying” and inserting “For each of years
6 2011 through 2021, in applying”.

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

12 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

19 “(a) ESTABLISHMENT.—The Secretary shall estab-
20 lish a manufacturer discount program (in this section re-
21 ferred to as the ‘program’). Under the program, the Sec-
22 retary shall enter into agreements described in subsection
23 (b) with manufacturers and provide for the performance
24 of the duties described in subsection (c). The Secretary
25 shall establish a model agreement for use under the pro-

1 gram by not later than January 1, 2021, in consultation
2 with manufacturers, and allow for comment on such model
3 agreement.

4 “(b) TERMS OF AGREEMENT.—

5 “(1) IN GENERAL.—

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

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

18 “(C) TIMING OF AGREEMENT.—

19 “(i) SPECIAL RULE FOR 2022.—In
20 order for an agreement with a manufac-
21 turer to be in effect under this section with
22 respect to the period beginning on January
23 1, 2022, and ending on December 31,
24 2022, the manufacturer shall enter into
25 such agreement not later than 30 days

1 after the date of the establishment of a
2 model agreement under subsection (a).

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

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

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

1 under subparagraph (A) of subsection (c)(1) or pro-
2 cedures established under such subsection (c)(1).

3 “(4) LENGTH OF AGREEMENT.—

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

10 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

20 “(i) the negotiated price of the appli-
21 cable drug; and

22 “(ii) the discounted price of the appli-
23 cable drug;

24 “(D) the establishment of procedures to
25 ensure that the discounted price for an applica-

1 ble drug under this section is applied before any
2 coverage or financial assistance under other
3 health benefit plans or programs that provide
4 coverage or financial assistance for the pur-
5 chase or provision of prescription drug coverage
6 on behalf of applicable beneficiaries as the Sec-
7 retary may specify; and

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

13 “(2) MONITORING COMPLIANCE.—

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

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

23 “(3) COLLECTION OF DATA FROM PRESCRIP-
24 TION DRUG PLANS AND MA-PD PLANS.—The Sec-
25 retary may collect appropriate data from prescrip-

1 tion drug plans and MA–PD plans in a timeframe
2 that allows for discounted prices to be provided for
3 applicable drugs under this section.

4 “(d) ADMINISTRATION.—

5 “(1) IN GENERAL.—Subject to paragraph (2),
6 the Secretary shall provide for the implementation of
7 this section, including the performance of the duties
8 described in subsection (e).

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

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

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

24 “(B) receive, distribute, or facilitate the
25 distribution of funds of manufacturers to ap-

1 appropriate individuals or entities in order to
2 meet the obligations of manufacturers under
3 agreements under this section;

4 “(C) provide adequate and timely informa-
5 tion to manufacturers, consistent with the
6 agreement with the manufacturer under this
7 section, as necessary for the manufacturer to
8 fulfill its obligations under this section; and

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

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

20 “(5) IMPLEMENTATION.—Notwithstanding any
21 other provision of law, the Secretary may implement
22 the program under this section by program instruc-
23 tion or otherwise.

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

4 “(e) ENFORCEMENT.—

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

8 “(2) CIVIL MONEY PENALTY.—

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

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

22 “(ii) 25 percent of such amount.

23 “(B) APPLICATION.—The provisions of
24 section 1128A (other than subsections (a) and
25 (b)) shall apply to a civil money penalty under

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

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

11 “(g) DEFINITIONS.—In this section:

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

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

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

19 “(C) has incurred costs, as determined in
20 accordance with section 1860D–2(b)(4)(C), for
21 covered part D drugs in the year that are equal
22 to or exceed the annual deductible with respect
23 to such individual for such year, as specified in
24 section 1860D–2(b)(1), section 1860D–

1 14(a)(1)(B), or section 1860D–14(a)(2)(B), as
2 applicable.

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

5 “(A) means a covered part D drug—

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

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

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

1 “(III) is provided through an excep-
2 tion or appeal; and

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

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

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

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

14 “(4) DISCOUNTED PRICE.—

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

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

1 for the year, 90 percent of the negotiated
2 price of such drug; and

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

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

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

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

1 that falls at or above such annual deduct-
2 ible.

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”;
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)”;

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

1 the annual out-of-pocket threshold specified in
2 paragraph (4)(B) for such plan year, provide
3 such individual with the option to make the co-
4 insurance payment required under subpara-
5 graph (A) (for the portion of such costs that
6 are not above such annual out-of-pocket thresh-
7 old) in the form of periodic installments over
8 the remainder of such plan year.”.

9 **SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
10 **URES UNDER MEDICARE PART D.**

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

13 (1) by redesignating the paragraph (6), as
14 added by section 50354 of division E of the Bipar-
15 tisan Budget Act of 2018 (Public Law 115–123), as
16 paragraph (7); and

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

19 “(8) APPLICATION OF PHARMACY QUALITY
20 MEASURES.—

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

1 paragraph (B) with respect to payment for cov-
2 ered part D drugs dispensed by such pharmacy.

3 “(B) STANDARD PHARMACY QUALITY
4 MEASURES.—The Secretary shall establish or
5 approve standard quality measures from a con-
6 sensus and evidence-based organization for pay-
7 ments described in subparagraph (A). Such
8 measures shall focus on patient health outcomes
9 and be based on proven criteria measuring
10 pharmacy performance.

11 “(C) EFFECTIVE DATE.—The requirement
12 under subparagraph (A) shall take effect for
13 plan years beginning on or after January 1,
14 2021, or such earlier date specified by the Sec-
15 retary if the Secretary determines there are suf-
16 ficient measures established or approved under
17 subparagraph (B) to meet the requirement
18 under subparagraph (A).”.

19 **TITLE IV—DRUG PRICE** 20 **TRANSPARENCY**

21 **SEC. 401. DRUG PRICE TRANSPARENCY.**

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

24 **“SEC. 1150C. REPORTING ON DRUG PRICES.**

25 “(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, 2024,
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, 2024, 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, 2024, 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, 2024,
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 shall not be counted as
13 income.”.

14 (3) CONFORMING AMENDMENTS.—

15 (A) Section 1902(a)(10)(E) of the Social
16 Security Act (42 U.S.C. 1396a(a)(10)(E)) is
17 amended—

18 (i) in clause (iii), by striking “for
19 making medical” and inserting “before
20 January 1, 2024, for making medical”;
21 and

22 (ii) in clause (iv), by striking “subject
23 to sections” and inserting “before January
24 1, 2024, 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, 2023.”.

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, 2024, 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)”;

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, 2024, 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, 2024, 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, 2024—

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 ACQUI-
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.”.

1 (4) INCLUSION OF AUDIOLOGISTS AS CERTAIN
2 PRACTITIONERS TO RECEIVE PAYMENT ON AN AS-
3 SIGNMENT-RELATED BASIS.—Section
4 1842(b)(18)(C) of the Social Security Act (42
5 U.S.C. 1395u(b)(18)(C)), as amended by section
6 601(d)(4), is further amended by adding at the end
7 the following new clause:

8 “(viii) With respect to 2024 and each
9 subsequent year, a qualified audiologist (as
10 defined in section 1861(ll)(4)(B)).”.

11 (c) EXCLUSION MODIFICATION.—Section 1862(a)(7)
12 of the Social Security Act (42 U.S.C. 1395y(a)(7)) is
13 amended by inserting “(except such hearing aids or exami-
14 nations therefor as described in and otherwise allowed
15 under section 1861(s)(8))” after “hearing aids or exami-
16 nations therefor”.

17 (d) CERTAIN NON-APPLICATION.—

18 (1) IN GENERAL.—The last sentence of section
19 1839(a)(1) of the Social Security Act (42 U.S.C.
20 1395r(a)(1)), as added by section 601(g)(1), is
21 amended by striking “section 601 (other than sub-
22 section (g))” and inserting “sections 601 (other than
23 subsection (g)), 602 (other than subsection (d))”.

24 (2) PAYMENT.—Paragraph (4) of section
25 1844(a) of such Act (42 U.S.C. 1395w(a)), as added

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, 2024, 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, 2024, 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, 2024, 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, 2024—

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(lII); 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(III)) 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-

1 eases or conditions, not to exceed a total of
2 \$530,600,000, as follows:

3 “(I) For fiscal year 2021,
4 \$40,000,000.

5 “(II) For fiscal year 2022,
6 \$45,000,000.

7 “(III) For fiscal year 2023,
8 \$48,000,000.

9 “(IV) For each of fiscal years
10 2024 and 2025, \$52,400,000.

11 “(V) For fiscal year 2026,
12 \$55,800,000.

13 “(VI) For fiscal year 2027,
14 \$56,000,000.

15 “(VII) For fiscal year 2028,
16 \$57,000,000.

17 “(VIII) For each of fiscal years
18 2029 and 2030, \$62,000,000.”.

19 (2) CONFORMING AMENDMENTS.—Section 1001
20 of the 21st Century Cures Act (Public Law 114–
21 255) is amended—

22 (A) in subsection (a), by striking “sub-
23 section (b)(4)” and inserting “subsections
24 (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 the degree to which the medical
15 product or therapy that is the subject of such
16 clinical 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 \$500,000,000 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 **Subtitle B—Investing in Safety and**
2 **Innovation**

3 **SEC. 711. FOOD AND DRUG ADMINISTRATION.**

4 (a) FDA INNOVATION ACCOUNT.—

5 (1) IN GENERAL.—Section 1002(b) of the 21st
6 Century Cures Act (Public Law 114–255) is amend-
7 ed—

8 (A) in paragraph (1), by striking “para-
9 graph (4)” and inserting “paragraphs (4) and
10 (5)”; and

11 (B) by adding at the end the following new
12 paragraph:

13 “(5) SUPPLEMENTAL FUNDING AND ADDI-
14 TIONAL ACTIVITIES.—

15 “(A) IN GENERAL.—In addition to the
16 funds made available under paragraph (2),
17 there are authorized to be appropriated, and
18 are hereby appropriated, to the Account, out of
19 any monies in the Treasury not otherwise ap-
20 propriated, to be available until expended with-
21 out further appropriation, the following:

22 “(i) For fiscal year 2020,
23 \$417,500,000.

24 “(ii) For each of fiscal years 2021
25 and 2022, \$157,500,000.

1 “(iii) For each of fiscal years 2023
2 through 2025, \$152,500,000.

3 “(iv) For each of fiscal years 2026
4 through 2029, \$202,500,000.

5 “(B) SUPPLEMENTAL FUNDING FOR CER-
6 TAIN ACTIVITIES.—Of the total amounts made
7 available under subparagraph (A) for each of
8 fiscal years 2026 through 2029, a total amount
9 not to exceed \$50,000,000 for each such fiscal
10 year, shall be made available for the activities
11 under subtitles A through F (including the
12 amendments made by such subtitles) of title III
13 of this Act and section 1014 of the Federal
14 Food, Drug, and Cosmetic Act, as added by
15 section 3073 of this Act.

16 “(C) ADDITIONAL FDA ACTIVITIES.—In
17 addition to funding activities pursuant to sub-
18 paragraph (B), of the total amounts made
19 available under subparagraph (A), a total
20 amount not to exceed the following shall be
21 made available for the following categories of
22 activities:

23 “(i) For modernization of the tech-
24 nical infrastructure of the Food and Drug
25 Administration, including enhancements

1 such as interoperability across the agency,
2 and additional capabilities to develop an
3 advanced information technology infra-
4 structure to support the agency’s regu-
5 latory mission:

6 “(I) For fiscal year 2020,
7 \$180,000,000.

8 “(II) For each of fiscal years
9 2021 through 2029, \$60,000.

10 “(ii) For support for continuous man-
11 ufacturing of drugs and biological prod-
12 ucts, including complex biological products
13 such as regenerative medicine therapies,
14 through grants to institutions of higher
15 education and nonprofit organizations and
16 other appropriate mechanisms, for each of
17 fiscal years 2020 through 2029,
18 \$20,000,000.

19 “(iii) For support for the Commis-
20 sioner of Food and Drugs to engage ex-
21 perts, such as through the formation and
22 operation of public-private partnerships or
23 other appropriate collaborative efforts, to
24 advance the development and delivery of

1 individualized human gene therapy prod-
2 ucts:

3 “(I) For fiscal year 2020,
4 \$50,000,000.

5 “(II) For each of fiscal years
6 2021 through 2029, \$10,000,000.

7 “(iv) For support for inspections, en-
8 forcement, and quality surveillance activi-
9 ties across the Food and Drug Administra-
10 tion, including foreign and domestic in-
11 spections across products, for each of fiscal
12 years 2020 through 2029, \$20,000,000.

13 “(v) For support for activities of the
14 Food and Drug Administration related to
15 customs and border protection to provide
16 improvements to technologies, inspection
17 capacity, and sites of import (including
18 international mail facilities) in which the
19 Food and Drug Administration operates,
20 for each of fiscal years 2020 through
21 2029, \$10,000,000.

22 “(vi) To further advance the develop-
23 ment of a coordinated postmarket surveil-
24 lance system for all medical products, in-
25 cluding drugs, biological products, and de-

1 vices, linked to electronic health records in
2 furtherance of the Food and Drug Admin-
3 istration’s postmarket surveillance capabili-
4 ties:

5 “(I) For fiscal year 2020,
6 \$112,500,000.

7 “(II) For each of fiscal years
8 2021 through 2029, \$12,500,000.

9 “(vii) For support for Food and Drug
10 Administration activities to keep pace with
11 the projected product development of re-
12 generative therapies, including cellular and
13 somatic cell gene therapy products:

14 “(I) For each of fiscal years
15 2020 through 2022, \$10,000,000.

16 “(II) For each of fiscal years
17 2023 through 2029, \$5,000,000.

18 “(viii) For carrying out section 714A
19 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 379d–3a; relating to hiring
21 authority for scientific, technical, and pro-
22 fessional personnel), for each of fiscal
23 years 2020 through 2029, \$2,500,000.

24 “(ix) For the Food and Drug Admin-
25 istration to support improvements to the

1 technological infrastructure for reporting
2 and analysis of adverse events associated
3 with the use of drugs and biological prod-
4 ucts, for each of fiscal years 2020 through
5 2029, \$12,500,000.”.

6 (2) CONFORMING AMENDMENTS.—Section 1002
7 of the 21st Century Cures Act (Public Law 114–
8 255) is amended—

9 (A) in subsection (a), by inserting before
10 the period at the end the following: “or pursu-
11 ant to subparagraph (A) of subsection (b)(5) to
12 carry out the activities described in subpara-
13 graphs (B) and (C) of such subsection”; and

14 (B) in subsection (d)—

15 (i) by inserting “or pursuant to sub-
16 paragraph (A) of subsection (b)(5)” after
17 “subsection (b)(3)”; and

18 (ii) by striking “subsection (b)(4)”
19 and inserting “subsections (b)(4) and
20 (b)(5)”.

21 (b) ANNUAL REPORT.—Section 1002(c)(2)(A) of the
22 21st Century Cures Act (Public Law 114–255) is amend-
23 ed, in the matter preceding clause (i), by striking “2026”
24 and inserting “2030”.

1 (c) SUNSET.—Section 1002(e) of the 21st Century
2 Cures Act (Public Law 114–255) is amended by striking
3 “September 30, 2025” and inserting “September 30,
4 2030”.

5 **Subtitle C—Opioid Epidemic**
6 **Response**

7 **SEC. 721. OPIOID EPIDEMIC RESPONSE FUND.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”) shall use any funds made available pursuant to
11 subsection (b) to carry out the programs and activities de-
12 scribed in subsection (c) to address the opioid and sub-
13 stance use disorder epidemic. Such funds shall be in addi-
14 tion to any funds which are otherwise available to carry
15 out such programs and activities.

16 (b) OPIOID EPIDEMIC RESPONSE FUND.—

17 (1) ESTABLISHMENT OF ACCOUNT.—There is
18 established in the Treasury an account, to be known
19 as the Opioid Epidemic Response Fund (referred to
20 in this section as the “Fund”), for purposes of fund-
21 ing the programs and activities described in sub-
22 section (c).

23 (2) FUNDING.—There is authorized to be ap-
24 propriated, and there is appropriated, to the Fund,
25 out of any monies in the Treasury not otherwise ap-

1 appropriated \$1,980,000,000 for each of fiscal years
2 2021 through 2025.

3 (3) AVAILABILITY.—Amounts made available by
4 paragraph (2) shall be made available to the agen-
5 cies specified in subsection (c) in accordance with
6 such subsection. Amounts made available to an
7 agency pursuant to the preceding sentence for a fis-
8 cal year shall remain available until expended.

9 (c) PROGRAMS AND ACTIVITIES.—Of the total
10 amount in the Fund for each of fiscal years 2021 through
11 2025, such amount shall be allocated as follows:

12 (1) SAMHSA.—For the Substance Abuse and
13 Mental Health Services Administration to carry out
14 programs and activities pursuant to section 732,
15 \$1,500,000,000 for each of fiscal years 2021
16 through 2025.

17 (2) CDC.—For the Centers for Disease Control
18 and Prevention to carry out programs and activities
19 pursuant to section 733, \$120,000,000 for each of
20 fiscal years 2021 through 2025.

21 (3) FDA.—For the Food and Drug Adminis-
22 tration to carry out programs and activities pursu-
23 ant to section 734, \$10,000,000 for each of fiscal
24 years 2021 through 2025.

1 (4) NIH.—For the National Institutes of
2 Health to carry out programs and activities pursu-
3 ant to section 735, \$240,000,000 for each of fiscal
4 years 2021 through 2025.

5 (5) HRSA.—For the Health Resources and
6 Services Administration to carry out programs and
7 activities pursuant to section 736, \$90,000,000 for
8 each of fiscal years 2021 through 2025.

9 (6) ACF.—For the Administration for Children
10 and Families to carry out programs and activities
11 pursuant to section 737, \$20,000,000 for each of
12 fiscal years 2021 through 2025.

13 (d) ACCOUNTABILITY AND OVERSIGHT.—

14 (1) WORK PLAN.—

15 (A) IN GENERAL.—Not later than 180
16 days after the date of enactment of this Act,
17 the Secretary of Health and Human Services
18 shall submit to the Committee on Health, Edu-
19 cation, Labor, and Pensions and the Committee
20 on Appropriations of the Senate and the Com-
21 mittee on Energy and Commerce, the Com-
22 mittee on Appropriations, and the Committee
23 on Education and Labor of the House of Rep-
24 resentatives, a work plan including the proposed
25 allocation of funds made available pursuant to

1 subsection (b) for each of fiscal years 2021
2 through 2025 and the contents described in
3 subparagraph (B).

4 (B) CONTENTS.—The work plan submitted
5 under subparagraph (A) shall include—

6 (i) the amount of money to be obli-
7 gated or expended out of the Fund in each
8 fiscal year for each program and activity
9 described in subsection (c); and

10 (ii) a description and justification of
11 each such program and activity.

12 (2) ANNUAL REPORTS.—Not later than October
13 1 of each of fiscal years 2022 through 2026, the
14 Secretary of Health and Human Services shall sub-
15 mit to the Committee on Health, Education, Labor,
16 and Pensions and the Committee on Appropriations
17 of the Senate and the Committee on Energy and
18 Commerce, the Committee on Appropriations, and
19 the Committee on Education and Labor of the
20 House of Representatives, a report including—

21 (A) the amount of money obligated or ex-
22 pended out of the Fund in the prior fiscal year
23 for each program and activity described in sub-
24 section (c);

1 (B) a description of all programs and ac-
2 tivities using funds made available pursuant to
3 subsection (b); and

4 (C) how the programs and activities are re-
5 sponding to the opioid and substance use dis-
6 order epidemic.

7 (e) LIMITATIONS.—Notwithstanding any authority in
8 this subtitle or any appropriations Act, any funds made
9 available pursuant to subsection (b) may not be used for
10 any purpose other than the programs and activities de-
11 scribed in subsection (c).

12 **SEC. 722. SUBSTANCE ABUSE AND MENTAL HEALTH SERV-**
13 **ICES ADMINISTRATION.**

14 (a) IN GENERAL.—The entirety of the funds made
15 available pursuant to section 731(c)(1) shall be for the As-
16 sistant Secretary for Mental Health and Substance Use
17 to continue to award the State Opioid Response Grants
18 funded by the heading “Substance Abuse And Mental
19 Health Services Administration—Substance Abuse Treat-
20 ment” in title II of the Departments of Labor, Health and
21 Human Services, and Education, and Related Agencies
22 Appropriations Act, 2018 (Public Law 115–141). Subject
23 to subsections (b) and (c), such grants shall be awarded
24 in the same manner and subject to the same conditions
25 as were applicable to such grants for fiscal year 2018.

1 (b) REQUIREMENT THAT TREATMENT BE EVIDENCE-BASED.—As a condition on receipt of a grant pursuant to subsection (a), a grantee shall agree that—

2 (1) treatments, practices, or interventions funded through the grant will be evidence-based; and

3 (2) such treatments, practices, and interventions will include medication-assisted treatment for individuals diagnosed with opioid use disorder, using drugs only if the drugs have been approved or licensed by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

4 (c) RESERVATIONS.—Of the amount made available pursuant to section 731(c)(1) for a fiscal year—

5 (1) not less than \$75,000,000 shall be reserved to make grants under subsection (a) to Indian Tribes or Tribal organizations; and

6 (2) not less than \$50,000,000 shall be reserved to make grants under subsection (a) to political subdivisions of States, such as counties, cities, or towns.

7 **SEC. 723. CENTERS FOR DISEASE CONTROL AND PREVENTION.**

8 (a) ADDRESSING OPIOID USE DISORDER.—The entirety of the funds made available pursuant to section

1 731(c)(2) shall be for the Director of the Centers for Dis-
2 ease Control and Prevention, pursuant to applicable au-
3 thorities in the Public Health Service Act (42 U.S.C. 201
4 et seq.), to continue and expand programs of the Centers
5 for Disease Control and Prevention to address opioid and
6 substance use disorder, including by—

7 (1) improving the timeliness and quality of data
8 on the opioid use disorder epidemic, including im-
9 provement of—

10 (A) data on fatal and nonfatal overdoses;

11 (B) syndromic surveillance;

12 (C) data on long-term sequelae (including
13 neonatal abstinence syndrome); and

14 (D) cause of death reporting related to
15 substance abuse or opioid overdose;

16 (2) expanding and strengthening evidence-based
17 prevention and education strategies;

18 (3) supporting responsible prescribing practices,
19 including through development and dissemination of
20 prescriber guidelines;

21 (4) improving access to and use of effective pre-
22 vention, treatment, and recovery support, including
23 through grants and the provision of technical assist-
24 ance to States and localities;

1 (5) strengthening partnerships with first re-
2 sponders, including to protect their safety;

3 (6) considering the needs of vulnerable popu-
4 lations;

5 (7) addressing infectious diseases linked to the
6 opioid crisis;

7 (8) strengthening prescription drug monitoring
8 programs; and

9 (9) providing financial and technical assistance
10 to State and local health department efforts to treat
11 and prevent substance use disorder.

12 (b) LIMITATION.—Of the funds made available pur-
13 suant to section 731(c)(2) for carrying out this section,
14 not more than 20 percent may be used for intramural pur-
15 poses.

16 **SEC. 724. FOOD AND DRUG ADMINISTRATION.**

17 The entirety of the funds made available pursuant to
18 section 731(c)(3) shall be for the Commissioner of Food
19 and Drugs, pursuant to applicable authorities in the Pub-
20 lic Health Service Act (42 U.S.C. 201 et seq.) or the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
22 seq.) and other applicable law, to support widespread inno-
23 vation in non-opioid and non-addictive medical products
24 for pain treatment, access to opioid addiction treatments,
25 appropriate use of approved opioids, and efforts to reduce

1 illicit importation of opioids. Such support may include the
2 following:

3 (1) Facilitating the development of non-opioid
4 and non-addictive pain treatments.

5 (2) Advancing guidance documents for sponsors
6 of non-opioid pain products.

7 (3) Developing evidence to inform the potential
8 for nonprescription overdose therapies.

9 (4) Examining expanded labeling indications for
10 medication-assisted treatment.

11 (5) Conducting public education and outreach,
12 including public workshops or public meetings, re-
13 garding the benefits of medication-assisted treat-
14 ment, including all drugs approved by the Food and
15 Drug Administration, and device treatment options
16 approved or cleared by the Food and Drug Adminis-
17 tration.

18 (6) Exploring the expansion and possible man-
19 datory nature of prescriber education regarding pain
20 management and appropriate opioid prescribing
21 through authorities under section 505–1 of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355–
23 1).

1 (7) Examining options to limit the duration of
2 opioid prescriptions for acute pain, including
3 through packaging options.

4 (8) Increasing staff and infrastructure capacity
5 to inspect and analyze packages at international
6 mail facilities and pursue criminal investigations.

7 **SEC. 725. NATIONAL INSTITUTES OF HEALTH.**

8 The entirety of the funds made available pursuant to
9 section 731(c)(4) shall be for the Director of the National
10 Institutes of Health, pursuant to applicable authorities in
11 the Public Health Service Act (42 U.S.C. 201 et seq.),
12 to carry out activities related to—

13 (1) accelerating research for addressing the
14 opioid use disorder epidemic, including developing
15 non-opioid medications and interventions, including
16 non-addictive medications, to manage pain, as well
17 as developing medications and interventions to treat
18 and to prevent substance use disorders;

19 (2) conducting and supporting research on
20 which treatments (in terms of pain management as
21 well as treating and preventing substance use dis-
22 orders) are optimal for which patients; and

23 (3) conducting and supporting research on cre-
24 ating longer-lasting or faster-acting antidotes for

1 opioid overdose, particularly in response to the prev-
2 alence of fentanyl and carfentanyl overdoses.

3 **SEC. 726. HEALTH RESOURCES AND SERVICES ADMINIS-**
4 **TRATION.**

5 The entirety of the funds made available pursuant to
6 section 731(c)(5) shall be for the Administrator of the
7 Health Resources and Services Administration, pursuant
8 to applicable authorities in titles III, VII, and VIII of the
9 Public Health Service Act (42 U.S.C. 241 et seq.), to
10 carry out activities that increase the availability and ca-
11 pacity of the behavioral health workforce. Such activities
12 shall include providing loan repayment assistance for sub-
13 stance use disorder treatment providers.

14 **SEC. 727. ADMINISTRATION FOR CHILDREN AND FAMILIES.**

15 Of the funds made available pursuant to section
16 731(c)(6) for each of fiscal years 2021 through 2025,
17 \$20,000,000 for each such fiscal year shall be for the Sec-
18 retary of Health and Human Services to carry out title
19 I of the Child Abuse Prevention and Treatment Act (42
20 U.S.C. 5101 et seq.).

21 **TITLE VIII—MISCELLANEOUS**

22 **SEC. 801. GUARANTEED ISSUE OF CERTAIN MEDIGAP POLI-**
23 **CIES.**

24 (a) GUARANTEED ISSUE OF MEDIGAP POLICIES TO
25 ALL MEDIGAP-ELIGIBLE MEDICARE BENEFICIARIES.—

1 (1) IN GENERAL.—Section 1882(s) of the So-
2 cial Security Act (42 U.S.C. 1395ss(s)) is amend-
3 ed—

4 (A) in paragraph (2)(A), by striking “65
5 years of age or older and is enrolled for benefits
6 under part B” and inserting “entitled to, or en-
7 rolled for, benefits under part A and enrolled
8 for benefits under part B”;

9 (B) in paragraph (2)(D), by striking “who
10 is 65 years of age or older as of the date of
11 issuance and”;

12 (C) in paragraph (3)(B)(ii), by striking “is
13 65 years of age or older and”; and

14 (D) in paragraph (3)(B)(vi), by striking
15 “at age 65”.

16 (2) ADDITIONAL ENROLLMENT PERIOD FOR
17 CERTAIN INDIVIDUALS.—

18 (A) ONE-TIME ENROLLMENT PERIOD.—

19 (i) IN GENERAL.—In the case of a
20 specified individual, the Secretary shall es-
21 tablish a one-time enrollment period de-
22 scribed in clause (iii) during which such an
23 individual may enroll in any medicare sup-
24 plemental policy of the individual’s choos-
25 ing.

1 (ii) APPLICATION.—The provisions
2 of—

3 (I) paragraph (2) of section
4 1882(s) of the Social Security Act (42
5 U.S.C. 1395ss(s)) shall apply with re-
6 spect to a specified individual who is
7 described in subclause (I) of subpara-
8 graph (B)(iii) as if references in such
9 paragraph (2) to the 6 month period
10 described in subparagraph (A) of such
11 paragraph were references to the one-
12 time enrollment period established
13 under clause (i); and

14 (II) paragraph (3) of such sec-
15 tion shall apply with respect to a spec-
16 ified individual who is described in
17 subclause (II) of subparagraph
18 (B)(iii) as if references in such para-
19 graph (3) to the period specified in
20 subparagraph (E) of such paragraph
21 were references to the one-time enroll-
22 ment period established under clause
23 (i).

24 (iii) PERIOD.—The enrollment period
25 established under clause (i) shall be the 6-

1 month period beginning on January 1,
2 2024.

3 (B) SPECIFIED INDIVIDUAL.—For pur-
4 poses of this paragraph, the term “specified in-
5 dividual” means an individual who—

6 (i) is entitled to hospital insurance
7 benefits under part A of title XVIII of the
8 Social Security Act (42 U.S.C. 1395c et
9 seq.) pursuant to section 226(b) or section
10 226A of such Act (42 U.S.C. 426(b); 426-
11 1);

12 (ii) is enrolled for benefits under part
13 B of such Act (42 U.S.C. 1395j et seq.);
14 and

15 (iii)(I) would not, but for the amend-
16 ments made by subparagraphs (A) and (B)
17 of paragraph (1) and the provisions of this
18 paragraph (if such provisions applied to
19 such individual), be eligible for the guaran-
20 teed issue of a medicare supplemental pol-
21 icy under paragraph (2) of section 1882(s)
22 of such Act (42 U.S.C. 1395ss(s)); or

23 (II) would not, but for the amend-
24 ments made by subparagraphs (C) and (D)
25 of paragraph (1) and the provisions of this

1 paragraph (if such provisions applied to
2 such individual), be eligible for the guaran-
3 teed issue of a medicare supplemental pol-
4 icy under paragraph (3) of such section.

5 (C) OUTREACH PLAN.—

6 (i) IN GENERAL.—The Secretary shall
7 develop an outreach plan to notify specified
8 individuals of the one-time enrollment pe-
9 riod established under subparagraph (A).

10 (ii) CONSULTATION.—In imple-
11 menting the outreach plan developed under
12 clause (i), the Secretary shall consult with
13 consumer advocates, brokers, insurers, the
14 National Association of Insurance Commis-
15 sioners, and State Health Insurance As-
16 sistance Programs.

17 (3) 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.

21 (b) GUARANTEED ISSUE OF MEDIGAP POLICIES FOR
22 MEDICARE ADVANTAGE ENROLLEES.—

23 (1) IN GENERAL.—Section 1882(s)(3) of the
24 Social Security Act (42 U.S.C. 1395ss(s)(3)), as
25 amended by subsection (a), is further amended—

1 (A) in subparagraph (B), by adding at the
2 end the following new clause:

3 “(vii) The individual—

4 “(I) was enrolled in a Medicare Advantage
5 plan under part C for not less than 12 months;

6 “(II) subsequently disenrolled from such
7 plan;

8 “(III) elects to receive benefits under this
9 title through the original Medicare fee-for-serv-
10 ice program under parts A and B; and

11 “(IV) has not previously elected to receive
12 benefits under this title through the original
13 Medicare fee-for-service program pursuant to
14 disenrollment from a Medicare Advantage plan
15 under part C.”;

16 (B) by striking subparagraph (C)(iii) and
17 inserting the following:

18 “(iii) Subject to subsection (v)(1), for purposes of an
19 individual described in clause (vi) or (vii) of subparagraph
20 (B), a medicare supplemental policy described in this sub-
21 paragraph shall include any medicare supplemental pol-
22 icy.”; and

23 (C) in subparagraph (E)—

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

1 (ii) in clause (v), by striking the pe-
2 riod at the end and inserting “; and”;

3 (iii) by adding at the end the fol-
4 lowing new clause—

5 “(vi) in the case of an individual described in
6 subparagraph (B)(vii), the annual, coordinated elec-
7 tion period (as defined in section 1851(e)(3)(B)) or
8 a continuous open enrollment period (as defined in
9 section 1851(e)(2)) during which the individual
10 disenrolls from a Medicare Advantage plan under
11 part C.”.

12 (2) EFFECTIVE DATE.—The amendments made
13 by paragraph (1) shall apply to medicare supple-
14 mental policies effective on or after January 1,
15 2024.

16 **SEC. 802. REPORTING REQUIREMENTS FOR PDP SPONSORS**
17 **REGARDING POINT-OF-SALE REJECTIONS**
18 **UNDER MEDICARE PART D.**

19 Section 1860D–4(g) of the Social Security Act (42
20 U.S.C. 1395w–104(g)) is amended by adding at the end
21 the following new paragraph:

22 “(3) REPORTING REQUIREMENTS REGARDING
23 POINT-OF-SALE REJECTIONS.—

24 “(A) IN GENERAL.—With respect to a plan
25 year beginning on or after January 1, 2020, a

1 PDP sponsor offering a prescription drug plan
2 shall submit to the Secretary, in a form and
3 manner specified by the Secretary, information
4 on point-of-sale rejections made during a period
5 of time occurring in such plan year (as specified
6 by the Secretary), including each of the fol-
7 lowing:

8 “(i) The reason for each point-of-sale
9 rejection.

10 “(ii) Identifying information for each
11 drug with respect to which a point-of-sale
12 rejection was made.

13 “(iii) With respect to applicable types
14 of point-of-sale rejections (as specified by
15 the Secretary), each of the following:

16 “(I) Whether such a rejection
17 was consistent with the formulary of
18 the plan (as approved by the Sec-
19 retary).

20 “(II) Whether a coverage deter-
21 mination or appeal of a coverage de-
22 termination was requested for the
23 drug with respect to which such a re-
24 jection was made.

1 “(III) The outcome of any such
2 coverage determination or appeal of a
3 coverage determination.

4 “(IV) The length of time between
5 when such a rejection was made and
6 when the drug with respect to which
7 such rejection was made is dispensed,
8 as applicable.

9 “(B) PUBLIC AVAILABILITY OF INFORMA-
10 TION.—The Secretary shall make publicly avail-
11 able on the public website of the Centers for
12 Medicare & Medicaid Services information sub-
13 mitted under subparagraph (A).

14 “(C) USE OF INFORMATION.—The Sec-
15 retary may use information submitted under
16 subparagraph (A), as determined appropriate,
17 in developing measures for the 5-star rating
18 system under section 1853(o)(4).

19 “(D) IMPLEMENTATION.—Notwithstanding
20 any other provision of law, the Secretary may
21 implement this paragraph through program in-
22 struction or otherwise.

23 “(E) FUNDING.—The are authorized to be
24 appropriated to the Secretary from the Federal
25 Supplementary Medical Insurance Trust Fund

1 under section 1841 such sums as may be nec-
2 essary to implement this paragraph.”.

3 **SEC. 803. PROVIDING ACCESS TO ANNUAL MEDICARE NOTI-**
4 **FICATIONS IN MULTIPLE LANGUAGES.**

5 (a) IN GENERAL.—Section 1804 of the Social Secu-
6 rity Act (42 U.S.C. 1395b–2) is amended by adding at
7 the end the following new subsection:

8 “(e) The notice provided under subsection (a) shall
9 be translated into languages in addition to English and
10 Spanish. In carrying out the previous sentence, the Sec-
11 retary shall prioritize translation of the notice into lan-
12 guages in which documents provided by the Commissioner
13 of Social Security are translated and language that are
14 the most frequently requested for translation for purposes
15 of applying for old-age insurance benefits under title II.”.

16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to notices distributed prior to
18 each Medicare open enrollment period beginning after
19 January 1, 2020.

20 **SEC. 804. TEMPORARY INCREASE IN MEDICARE PART B**
21 **PAYMENT FOR CERTAIN BIOSIMILAR BIO-**
22 **LOGICAL PRODUCTS.**

23 Section 1847A(b)(8) of the Social Security Act (42
24 U.S.C. 1395w–3a(b)(8)) is amended—

1 (1) by redesignating subparagraphs (A) and
2 (B) as clauses (i) and (ii), respectively, and moving
3 the margin of each such redesignated clause 2 ems
4 to the right;

5 (2) by striking “PRODUCT.—The amount” and
6 inserting the following: “PRODUCT.—

7 “(A) IN GENERAL.—Subject to subpara-
8 graph (B), the amount”; and

9 (3) by adding at the end the following new sub-
10 paragraph:

11 “(B) TEMPORARY PAYMENT INCREASE.—

12 “(i) IN GENERAL.—In the case of a
13 qualifying biosimilar biological product
14 that is furnished during the applicable 5-
15 year period for such product, the amount
16 specified in this paragraph for such prod-
17 uct with respect to such period is the sum
18 determined under subparagraph (A), ex-
19 cept that clause (ii) of such subparagraph
20 shall be applied by substituting ‘8 percent’
21 for ‘6 percent’.

22 “(ii) APPLICABLE 5-YEAR PERIOD.—
23 For purposes of clause (i), the applicable
24 5-year period for a biosimilar biological
25 product is—

1 “(I) in the case of such a product
2 for which payment was made under
3 this paragraph as of December 31,
4 2019, the 5-year period beginning on
5 January 1, 2020; and

6 “(II) in the case of such a prod-
7 uct for which payment is first made
8 under this paragraph during a cal-
9 endar quarter during the period be-
10 ginning January 1, 2020, and ending
11 December 31, 2024, the 5-year period
12 beginning on the first day of such cal-
13 endar quarter during which such pay-
14 ment is first made.

15 “(iii) QUALIFYING BIOSIMILAR BIO-
16 LOGICAL PRODUCT DEFINED.—For pur-
17 poses of this subparagraph, the term
18 ‘qualifying biosimilar biological product’
19 means a biosimilar biological product de-
20 scribed in paragraph (1)(C) with respect to
21 which—

22 “(I) in the case of a product de-
23 scribed in clause (ii)(I), the average
24 sales price is not more than the aver-

1 age sales price for the reference bio-
2 logical product; and

3 “(II) in the case of a product de-
4 scribed in clause (ii)(II), the wholesale
5 acquisition cost is not more than the
6 wholesale acquisition cost for the ref-
7 erence biological product.”.

8 **SEC. 805. WAIVING MEDICARE COINSURANCE FOR**
9 **COLORECTAL CANCER SCREENING TESTS.**

10 Section 1833(a) of the Social Security Act (42 U.S.C.
11 1395l(a)) is amended—

12 (1) in the second sentence, by striking “section
13 1834(0)” and inserting “section 1834(o)”;

14 (2) by moving such second sentence 2 ems to
15 the left; and

16 (3) by inserting the following third sentence fol-
17 lowing such second sentence: “For services furnished
18 on or after January 1, 2021, paragraph (1)(Y) shall
19 apply with respect to a colorectal cancer screening
20 test regardless of the code that is billed for the es-
21 tablishment of a diagnosis as a result of the test, or
22 for the removal of tissue or other matter or other
23 procedure that is furnished in connection with, as a
24 result of, and in the same clinical encounter as the
25 screening test.”.

1 **SEC. 806. MEDICARE COVERAGE OF CERTAIN**
2 **LYMPHEDEMA COMPRESSION TREATMENT**
3 **ITEMS.**

4 (a) COVERAGE.—

5 (1) IN GENERAL.—Section 1861 of the Social
6 Security Act (42 U.S.C. 1395x), as amended by sec-
7 tion 601 and section 603, is further amended—

8 (A) in subsection (s)(2)—

9 (i) in subparagraph (II), by striking
10 “and” after the semicolon at the end;

11 (ii) in subparagraph (JJ), by striking
12 the period at the end and inserting “;
13 and”; and

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

16 “(KK) lymphedema compression treatment
17 items (as defined in subsection (mmm));”; and

18 (B) by adding at the end the following new
19 subsection:

20 “(mmm) LYMPHEDEMA COMPRESSION TREATMENT
21 ITEMS.—The term ‘lymphedema compression treatment
22 items’ means compression garments, devices, bandaging
23 systems, components, and supplies, including multilayer
24 compression bandaging systems, standard fit gradient
25 compression garments, and other compression garments,

1 devices, bandaging systems, components, or supplies (as
2 determined by the Secretary), that are—

3 “(1) furnished on or after January 1, 2022, to
4 an individual with a diagnosis of lymphedema for the
5 treatment of such condition;

6 “(2) primarily and customarily used in the
7 medical treatment of lymphedema, as determined by
8 the Secretary; and

9 “(3) prescribed by a physician (or a physician
10 assistant, nurse practitioner, or a clinical nurse spe-
11 cialist (as those terms are defined in section
12 1861(aa)(5)) to the extent authorized under State
13 law).”.

14 (2) PAYMENT.—

15 (A) IN GENERAL.—Section 1833(a)(1) of
16 the Social Security Act (42 U.S.C.
17 1395l(a)(1)), as amended by section 601(c)(1),
18 is further amended—

19 (i) by striking “and” before “(DD)”;

20 and

21 (ii) by inserting before the semicolon
22 at the end the following: “, and (EE) with
23 respect to lymphedema compression treat-
24 ment items (as defined in section
25 1861(mmm)), the amount paid shall be

1 equal to 80 percent of the lesser of the ac-
2 tual charge or the amount determined
3 under the payment basis determined under
4 section 1834(z)”.

5 (B) PAYMENT BASIS AND LIMITATIONS.—

6 Section 1834 of the Social Security Act (42
7 U.S.C. 1395m), as amended by sections
8 601(c)(2) and 603(c), is further amended by
9 adding at the end the following new subsection:

10 “(z) PAYMENT FOR LYMPHEDEMA COMPRESSION
11 TREATMENT ITEMS.—

12 “(1) IN GENERAL.—The Secretary shall deter-
13 mine an appropriate payment basis for lymphedema
14 compression treatment items (as defined in section
15 1861(mmm)). In making such a determination, the
16 Secretary may take into account payment rates for
17 such items under State plans (or waivers of such
18 plans) under title XIX, the Veterans Health Admin-
19 istration, and group health plans and health insur-
20 ance coverage (as such terms are defined in section
21 2791 of the Public Health Service Act), and such
22 other information as the Secretary determines ap-
23 propriate.

24 “(2) FREQUENCY LIMITATION.—No payment
25 may be made under this part for lymphedema com-

1 pression treatment items furnished other than at
2 such frequency as the Secretary may establish.

3 “(3) APPLICATION OF COMPETITIVE ACQUISITION.—In the case of lymphedema compression
4 treatment items that are included in a competitive
5 acquisition program in a competitive acquisition area
6 under section 1847(a)—

7 “(A) the payment basis under this sub-
8 section for such items furnished in such area
9 shall be the payment basis determined under
10 such competitive acquisition program; and

11 “(B) the Secretary may use information on
12 the payment determined under such competitive
13 acquisition programs to adjust the payment
14 amount otherwise determined under this sub-
15 section for an area that is not a competitive ac-
16 quisition area under section 1847, and in the
17 case of such adjustment, paragraphs (8) and
18 (9) of section 1842(b) shall not be applied.”.

19 (3) CONFORMING AMENDMENTS.—

20 (A) EXCLUSIONS.—Section 1862(a)(1) of
21 the Social Security Act (42 U.S.C.
22 1395y(a)(1)), as amended by section 601(f) and
23 section 603(g), is further amended—
24

1 (i) in subparagraph (Q), by striking
2 “and” at the end;

3 (ii) in subparagraph (R), by striking
4 the semicolon and inserting “, and”; and

5 (iii) by adding at the end the fol-
6 lowing new subparagraph:

7 “(S) in the case of lymphedema compression
8 treatment items (as defined in section 1861(mmm)),
9 which are furnished more frequently than is estab-
10 lished pursuant to section 1834(z)(2);”.

11 (B) APPLICATION OF COMPETITIVE ACQUI-
12 SITION.—

13 (i) IN GENERAL.—Section 1847(a)(2)
14 of the Social Security Act (42 U.S.C.
15 1395w-3(a)(2)), as amended by sections
16 601(e)(2)(B)(ii), 602(b)(3)(B)(i), and
17 603(f)(2)(B), is further amended by add-
18 ing at the end the following new subpara-
19 graph:

20 “(G) LYMPHEDEMA COMPRESSION TREAT-
21 MENT ITEMS.—Lymphedema compression treat-
22 ment items (as defined in section 1861(mmm))
23 for which payment would otherwise be made
24 under section 1834(z).”.

1 (b) INCLUSION IN REQUIREMENTS FOR SUPPLIERS
2 OF MEDICAL EQUIPMENT AND SUPPLIES.—Section
3 1834(j)(5) of the Social Security Act (42 U.S.C.
4 1395m(j)(5)) is amended—

5 (1) by redesignating subparagraphs (E) and
6 (F) as subparagraphs (F) and (G), respectively; and

7 (2) by inserting after subparagraph (D) the fol-
8 lowing new subparagraph:

9 “(E) lymphedema compression treatment
10 items (as defined in section 1861(mmm));”.

11 (c) STUDY AND REPORT ON IMPLEMENTATION.—

12 (1) STUDY.—The Secretary of Health and
13 Human Services (in this section referred to as the
14 “Secretary”) shall conduct a study on the implemen-
15 tation of Medicare coverage of certain lymphedema
16 compression treatment items under the amendments
17 made by this Act. Such study shall include an eval-
18 uation of the following:

19 (A) Medicare beneficiary utilization of
20 items and services under parts A and B of title
21 XVIII of the Social Security Act as a result of
22 the implementation of such amendments.

23 (B) Whether the Secretary has determined,
24 pursuant to section 1861(mmm) of the Social
25 Security Act, as added by subsection (a)(1),

1 that lymphedema compression treatment items
2 other than compression bandaging systems and
3 standard fit gradient compression garments are
4 covered under such section.

5 (2) REPORT.—Not later than January 1, 2024,
6 the Secretary shall submit to Congress and make
7 available to the public a report on the study con-
8 ducted under paragraph (1).

9 **SEC. 807. PHYSICIAN FEE UPDATE.**

10 Section 1848(d)(19) of the Social Security Act (42
11 U.S.C. 1395w-4(d)(19)) is amended to read as follows:

12 “(19) UPDATE FOR 2020 THROUGH 2025.—The
13 update to the single conversion factor established in
14 paragraph (1)(C)—

15 “(A) for 2020 and 2021 shall be 0.5 per-
16 cent; and

17 “(B) for 2022 and each subsequent year
18 through 2025 shall be 0.0 percent.”.

19 **SEC. 808. ADDITIONAL COMMUNITY HEALTH CENTER**
20 **FUNDING.**

21 Section 10503 of the Patient Protection and Afford-
22 able Care Act (42 U.S.C. 254b-2) is amended by striking
23 subsection (e) and inserting the following:

24 “(e) ADDITIONAL ENHANCED FUNDING; CAPITAL
25 PROJECTS.—There is authorized to be appropriated, and

1 there is appropriated, out of any monies in the Treasury
2 not otherwise appropriated, to the CHC Fund—

3 “(1) to be transferred to the Secretary of
4 Health and Human Services to provide additional
5 enhanced funding for the community health center
6 program under section 330 of the Public Health
7 Service Act, \$1,000,000,000 for each of fiscal years
8 2021 through 2025; and

9 “(2) to be transferred to the Secretary of
10 Health and Human Services for capital projects of
11 the community health center program under section
12 330 of the Public Health Service Act,
13 \$5,000,000,000 for the period of fiscal years 2021
14 through 2025.”.

15 **SEC. 809. GRANTS TO IMPROVE TRAUMA SUPPORT SERV-**
16 **ICES AND MENTAL HEALTH CARE FOR CHIL-**
17 **DREN AND YOUTH IN EDUCATIONAL SET-**
18 **TINGS.**

19 (a) GRANTS, CONTRACTS, AND COOPERATIVE
20 AGREEMENTS AUTHORIZED.—The Secretary, in coordina-
21 tion with the Assistant Secretary for Mental Health and
22 Substance Use, is authorized to award grants to, or enter
23 into contracts or cooperative agreements with, State edu-
24 cational agencies, local educational agencies, Indian Tribes
25 (as defined in section 4 of the Indian Self-Determination

1 and Education Assistance Act) or their tribal educational
2 agencies, a school operated by the Bureau of Indian Edu-
3 cation, a Regional Corporation, or a Native Hawaiian edu-
4 cational organization, for the purpose of increasing stu-
5 dent access to evidence-based trauma support services and
6 mental health care by developing innovative initiatives, ac-
7 tivities, or programs to link local school systems with local
8 trauma-informed support and mental health systems, in-
9 cluding those under the Indian Health Service.

10 (b) DURATION.—With respect to a grant, contract,
11 or cooperative agreement awarded or entered into under
12 this section, the period during which payments under such
13 grant, contract, or agreement are made to the recipient
14 may not exceed 4 years.

15 (c) USE OF FUNDS.—An entity that receives a grant,
16 contract, or cooperative agreement under this section shall
17 use amounts made available through such grant, contract,
18 or cooperative agreement for evidence-based activities,
19 which shall include any of the following:

20 (1) Collaborative efforts between school-based
21 service systems and trauma-informed support and
22 mental health service systems to provide, develop, or
23 improve prevention, screening, referral, and treat-
24 ment and support services to students, such as pro-

1 viding trauma screenings to identify students in
2 need of specialized support.

3 (2) To implement schoolwide positive behavioral
4 interventions and supports, or other trauma-in-
5 formed models of support.

6 (3) To provide professional development to
7 teachers, teacher assistants, school leaders, special-
8 ized instructional support personnel, and mental
9 health professionals that—

10 (A) fosters safe and stable learning envi-
11 ronments that prevent and mitigate the effects
12 of trauma, including through social and emo-
13 tional learning;

14 (B) improves school capacity to identify,
15 refer, and provide services to students in need
16 of trauma support or behavioral health services;
17 or

18 (C) reflects the best practices for trauma-
19 informed identification, referral, and support
20 developed by the Interagency Task Force on
21 Trauma-Informed Care.

22 (4) Services at a full-service community school
23 that focuses on trauma-informed supports, which
24 may include a full-time site coordinator, or other ac-
25 tivities consistent with section 4625 of the Elemen-

1 tary and Secondary Education Act of 1965 (20
2 U.S.C. 7275).

3 (5) Engaging families and communities in ef-
4 forts to increase awareness of child and youth trau-
5 ma, which may include sharing best practices with
6 law enforcement regarding trauma-informed care
7 and working with mental health professionals to pro-
8 vide interventions, as well as longer term coordi-
9 nated care within the community for children and
10 youth who have experienced trauma and their fami-
11 lies.

12 (6) To provide technical assistance to school
13 systems and mental health agencies.

14 (7) To evaluate the effectiveness of the program
15 carried out under this section in increasing student
16 access to evidence-based trauma support services
17 and mental health care.

18 (8) To establish partnerships with or provide
19 subgrants to Head Start agencies (including Early
20 Head Start agencies), public and private preschool
21 programs, child care programs (including home-
22 based providers), or other entities described in sub-
23 section (a), to include such entities described in this
24 paragraph in the evidence-based trauma initiatives,
25 activities, support services, and mental health sys-

1 tems established under this section in order to pro-
2 vide, develop, or improve prevention, screening, re-
3 ferral, and treatment and support services to young
4 children and their families.

5 (d) APPLICATIONS.—To be eligible to receive a grant,
6 contract, or cooperative agreement under this section, an
7 entity described in subsection (a) shall submit an applica-
8 tion to the Secretary at such time, in such manner, and
9 containing such information as the Secretary may reason-
10 ably require, which shall include the following:

11 (1) A description of the innovative initiatives,
12 activities, or programs to be funded under the grant,
13 contract, or cooperative agreement, including how
14 such program will increase access to evidence-based
15 trauma support services and mental health care for
16 students, and, as applicable, the families of such stu-
17 dents.

18 (2) A description of how the program will pro-
19 vide linguistically appropriate and culturally com-
20 petent services.

21 (3) A description of how the program will sup-
22 port students and the school in improving the school
23 climate in order to support an environment condu-
24 cive to learning.

25 (4) An assurance that—

1 (A) persons providing services under the
2 grant, contract, or cooperative agreement are
3 adequately trained to provide such services; and

4 (B) teachers, school leaders, administra-
5 tors, specialized instructional support personnel,
6 representatives of local Indian Tribes or tribal
7 organizations as appropriate, other school per-
8 sonnel, and parents or guardians of students
9 participating in services under this section will
10 be engaged and involved in the design and im-
11 plementation of the services.

12 (5) A description of how the applicant will sup-
13 port and integrate existing school-based services
14 with the program in order to provide mental health
15 services for students, as appropriate.

16 (6) A description of the entities in the commu-
17 nity with which the applicant will partner or to
18 which the applicant will provide subgrants in accord-
19 ance with subsection (c)(8).

20 (e) INTERAGENCY AGREEMENTS.—

21 (1) LOCAL INTERAGENCY AGREEMENTS.—To
22 ensure the provision of the services described in sub-
23 section (c), a recipient of a grant, contract, or coop-
24 erative agreement under this section, or their des-
25 ignee, shall establish a local interagency agreement

1 among local educational agencies, agencies respon-
2 sible for early childhood education programs, Head
3 Start agencies (including Early Head Start agen-
4 cies), juvenile justice authorities, mental health
5 agencies, child welfare agencies, and other relevant
6 agencies, authorities, or entities in the community
7 that will be involved in the provision of such serv-
8 ices.

9 (2) CONTENTS.—In ensuring the provision of
10 the services described in subsection (c), the local
11 interagency agreement shall specify with respect to
12 each agency, authority, or entity that is a party to
13 such agreement—

14 (A) the financial responsibility for the serv-
15 ices;

16 (B) the conditions and terms of responsi-
17 bility for the services, including quality, ac-
18 countability, and coordination of the services;
19 and

20 (C) the conditions and terms of reimburse-
21 ment among such agencies, authorities, or enti-
22 ties, including procedures for dispute resolution.

23 (f) EVALUATION.—The Secretary shall reserve not
24 more than 3 percent of the funds made available under
25 subsection (l) for each fiscal year to—

1 (1) conduct a rigorous, independent evaluation
2 of the activities funded under this section; and

3 (2) disseminate and promote the utilization of
4 evidence-based practices regarding trauma support
5 services and mental health care.

6 (g) DISTRIBUTION OF AWARDS.—The Secretary shall
7 ensure that grants, contracts, and cooperative agreements
8 awarded or entered into under this section are equitably
9 distributed among the geographical regions of the United
10 States and among tribal, urban, suburban, and rural pop-
11 ulations.

12 (h) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed—

14 (1) to prohibit an entity involved with a pro-
15 gram carried out under this section from reporting
16 a crime that is committed by a student to appro-
17 priate authorities; or

18 (2) to prevent Federal, State, and tribal law en-
19 forcement and judicial authorities from exercising
20 their responsibilities with regard to the application
21 of Federal, tribal, and State law to crimes com-
22 mitted by a student.

23 (i) SUPPLEMENT, NOT SUPPLANT.—Any services
24 provided through programs carried out under this section
25 shall supplement, and not supplant, existing mental health

1 services, including any special education and related serv-
2 ices provided under the Individuals with Disabilities Edu-
3 cation Act (20 U.S.C. 1400 et seq.).

4 (j) CONSULTATION WITH INDIAN TRIBES.—In car-
5 rying out subsection (a), the Secretary shall, in a timely
6 manner, meaningfully consult with Indian Tribes and their
7 representatives to ensure notice of eligibility.

8 (k) DEFINITIONS.—In this section:

9 (1) ELEMENTARY SCHOOL.—The term “elemen-
10 tary school” has the meaning given such term in
11 section 8101 of the Elementary and Secondary Edu-
12 cation Act of 1965 (20 U.S.C. 7801).

13 (2) EVIDENCE-BASED.—The term “evidence-
14 based” has the meaning given such term in section
15 8101(21)(A)(i) of the Elementary and Secondary
16 Education Act of 1965 (20 U.S.C. 7801(21)(A)(i)).

17 (3) NATIVE HAWAIIAN EDUCATIONAL ORGANI-
18 ZATION.—The term “Native Hawaiian educational
19 organization” has the meaning given such term in
20 section 6207 of the Elementary and Secondary Edu-
21 cation Act of 1965 (20 U.S.C. 7517).

22 (4) LOCAL EDUCATIONAL AGENCY.—The term
23 “local educational agency” has the meaning given
24 such term in section 8101 of the Elementary and
25 Secondary Education Act of 1965 (20 U.S.C. 7801).

1 (5) REGIONAL CORPORATION.—The term “Re-
2 gional Corporation” has the meaning given the term
3 in section 3 of the Alaska Native Claims Settlement
4 Act (43 U.S.C. 1602).

5 (6) SCHOOL.—The term “school” means a pub-
6 lic elementary school or public secondary school.

7 (7) SCHOOL LEADER.—The term “school lead-
8 er” has the meaning given such term in section
9 8101 of the Elementary and Secondary Education
10 Act of 1965 (20 U.S.C. 7801).

11 (8) SECONDARY SCHOOL.—The term “sec-
12 ondary school” has the meaning given such term in
13 section 8101 of the Elementary and Secondary Edu-
14 cation Act of 1965 (20 U.S.C. 7801).

15 (9) SECRETARY.—The term “Secretary” means
16 the Secretary of Education.

17 (10) SPECIALIZED INSTRUCTIONAL SUPPORT
18 PERSONNEL.—The term “specialized instructional
19 support personnel” has the meaning given such term
20 in section 8101 of the Elementary and Secondary
21 Education Act of 1965 (20 U.S.C. 7801).

22 (11) STATE EDUCATIONAL AGENCY.—The term
23 “State educational agency” has the meaning given
24 such term in section 8101 of the Elementary and
25 Secondary Education Act of 1965 (20 U.S.C. 7801).

1 (l) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated, and there is appropriated,
3 out of any money in the Treasury not otherwise appro-
4 priated, to carry out this section, \$20,000,000 for each
5 of fiscal years 2021 through 2025.

6 **SEC. 810. PATHWAY TO HEALTH CAREERS ACT.**

7 (a) SHORT TITLE.—This section may be cited as the
8 “Pathways to Health Careers Act”.

9 (b) EXTENSION THROUGH FISCAL YEAR 2020 OF
10 FUNDING FOR DEMONSTRATION PROJECTS TO ADDRESS
11 HEALTH PROFESSIONS WORKFORCE NEEDS.—

12 (1) IN GENERAL.—Section 2008(c)(1) of the
13 Social Security Act (42 U.S.C. 1397g(c)(1)) is
14 amended by striking “2019.” and inserting “2020,
15 and to provide technical assistance and cover admin-
16 istrative costs associated with implementing the suc-
17 cessor to this section \$15,000,000 for fiscal year
18 2020.”.

19 (2) AVAILABILITY OF OTHER FUNDS.—Upon
20 the date of the enactment of this section—

21 (A) amounts expended pursuant to section
22 1501 of division B of Public Law 116–59, or
23 any other prior law making amounts available
24 for fiscal year 2020 for activities authorized by
25 section 2008 of the Social Security Act, shall be

1 charged to the appropriation made by sub-
2 section (c)(1) of such section 2008 for fiscal
3 year 2020 (not including the amount for tech-
4 nical assistance and administrative costs); and

5 (B) if such enactment occurs on or before
6 November 21, 2019, the availability of funds
7 appropriated in, and the authority provided
8 under, such section 1501 shall terminate.

9 (c) CAREER PATHWAYS THROUGH HEALTH PROFES-
10 SION OPPORTUNITY GRANTS.—Effective October 1, 2020,
11 section 2008 of the Social Security Act (42 U.S.C. 1397g)
12 is amended to read as follows:

13 **“SEC. 2008. CAREER PATHWAYS THROUGH HEALTH PRO-**
14 **FESSION OPPORTUNITY GRANTS.**

15 “(a) APPLICATION REQUIREMENTS.—An eligible en-
16 tity desiring a grant under this section for a project shall
17 submit to the Secretary an application for the grant, that
18 includes the following:

19 “(1) A description of how the applicant will use
20 a career pathways approach to train eligible individ-
21 uals for health professions that pay well or will put
22 eligible individuals on a career path to an occupation
23 that pays well, under the project.

24 “(2) A description of the adult basic education
25 and literacy activities, work readiness activities,

1 training activities, and case management and career
2 coaching services that the applicant will use to assist
3 eligible individuals to gain work experience, connec-
4 tion to employers, and job placement, and a descrip-
5 tion of the plan for recruiting, hiring, and training
6 staff to provide the case management, mentoring,
7 and career coaching services, under the project di-
8 rectly or through local governmental, apprenticeship,
9 educational, or charitable institutions.

10 “(3) In the case of an application for a grant
11 under this section for a demonstration project de-
12 scribed in subsection (c)(2)(B)(i)(I)—

13 “(A) a demonstration that the State in
14 which the demonstration project is to be con-
15 ducted has in effect policies or laws that permit
16 certain allied health and behavioral health care
17 credentials to be awarded to people with certain
18 arrest or conviction records (which policies or
19 laws shall include appeals processes, waivers,
20 certificates, and other opportunities to dem-
21 onstrate rehabilitation to obtain credentials, li-
22 censure, and approval to work in the proposed
23 health careers), and a plan described in the ap-
24 plication that will use a career pathway to as-
25 sist participants with such a record in acquiring

1 credentials, licensing, and employment in the
2 specified careers;

3 “(B) a discussion of how the project or fu-
4 ture strategic hiring decisions will demonstrate
5 the experience and expertise of the project in
6 working with job seekers who have arrest or
7 conviction records or employers with experience
8 working with people with arrest or conviction
9 records;

10 “(C) an identification of promising innova-
11 tions or best practices that can be used to pro-
12 vide the training;

13 “(D) a proof of concept or demonstration
14 that the applicant has done sufficient research
15 on workforce shortage or in-demand jobs for
16 which people with certain types of arrest or
17 conviction records can be hired;

18 “(E) a plan for recruiting students who
19 are eligible individuals into the project; and

20 “(F) a plan for providing post-employment
21 support and ongoing training as part of a ca-
22 reer pathway under the project.

23 “(4) 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)(II)—

1 “(A) a description of the partnerships,
2 strategic staff hiring decisions, tailored program
3 activities, or other programmatic elements of
4 the project, such as training plans for doulas
5 and other community health workers and train-
6 ing plans for midwives and other allied health
7 professions, that are designed to support a ca-
8 reer pathway in pregnancy, birth, or post-
9 partum services; and

10 “(B) a demonstration that the State in
11 which the demonstration project is to be con-
12 ducted recognizes doulas or midwives, as the
13 case may be.

14 “(5) A demonstration that the applicant has ex-
15 perience working with low-income populations, or a
16 description of the plan of the applicant to work with
17 a partner organization that has the experience.

18 “(6) A plan for providing post-employment sup-
19 port and ongoing training as part of a career path-
20 way under the project.

21 “(7) A description of the support services that
22 the applicant will provide under the project, includ-
23 ing a plan for how child care and transportation
24 support services will be guaranteed and, if the appli-
25 cant will provide a cash stipend or wage supplement,

1 how the stipend or supplement would be calculated
2 and distributed.

3 “(8) A certification by the applicant that the
4 project development included—

5 “(A) consultation with a local workforce
6 development board established under section
7 107 of the Workforce Innovation and Oppor-
8 tunity Act;

9 “(B) consideration of apprenticeship and
10 pre-apprenticeship models registered under the
11 Act of August 16, 1937 (also known as the
12 ‘National Apprenticeship Act’);

13 “(C) consideration of career pathway pro-
14 grams in the State in which the project is to be
15 conducted; and

16 “(D) a review of the State plan under sec-
17 tion 102 or 103 of the Workforce Innovation
18 and Opportunity Act.

19 “(9) A description of the availability and rel-
20 evance of recent labor market information and other
21 pertinent evidence of in-demand jobs or worker
22 shortages.

23 “(10) A certification that the applicant will di-
24 rectly provide or contract for the training services
25 described in the application.

1 “(11) A commitment by the applicant that, if
2 the grant is made to the applicant, the applicant
3 will—

4 “(A) during the planning period for the
5 project, provide the Secretary with any informa-
6 tion needed by the Secretary to establish ade-
7 quate data reporting and administrative struc-
8 ture for the project;

9 “(B) hire a person to direct the project not
10 later than the end of the planning period appli-
11 cable to the project;

12 “(C) accept all technical assistance offered
13 by the Secretary with respect to the grant;

14 “(D) participate in such in-person grantee
15 conferences as are regularly scheduled by the
16 Secretary;

17 “(E) provide all data required by the Sec-
18 retary under subsection (g); and

19 “(F) notify the local disabled veterans’
20 outreach program specialists under section
21 4103A of title 38, United States Code, and the
22 local veterans’ employment representatives
23 under section 4104 of such title, of the grant-
24 ee’s outreach plan for advertising training op-

1 portunities to potential participants in the
2 project.

3 “(b) PREFERENCES IN CONSIDERING APPLICA-
4 TIONS.—In considering applications for a grant under this
5 section, the Secretary shall give preference to—

6 “(1) applications submitted by applicants to
7 whom a grant was made under this section or any
8 predecessor to this section;

9 “(2) applications submitted by applicants who
10 have business and community partners in each of
11 the following categories:

12 “(A) State and local government agencies
13 and social service providers, including a State
14 or local entity that administers a State program
15 funded under part A of this title;

16 “(B) institutions of higher education, ap-
17 prenticeship programs, and local workforce de-
18 velopment boards established under section 107
19 of the Workforce Innovation and Opportunity
20 Act; and

21 “(C) health care employers, health care in-
22 dustry or sector partnerships, labor unions, and
23 labor-management partnerships;

1 “(3) applications that include opportunities for
2 mentoring or peer support, and make career coach-
3 ing available, as part of the case management plan;

4 “(4) applications which describe a project that
5 will serve a rural area in which—

6 “(A) the community in which the individ-
7 uals to be enrolled in the project reside is lo-
8 cated;

9 “(B) the project will be conducted; or

10 “(C) an employer partnership that has
11 committed to hiring individuals who successfully
12 complete all activities under the project is lo-
13 cated;

14 “(5) applications that include a commitment to
15 providing project participants with a cash stipend or
16 wage supplement; and

17 “(6) applications which have an emergency cash
18 fund to assist project participants financially in
19 emergency situations.

20 “(c) GRANTS.—

21 “(1) COMPETITIVE GRANTS.—

22 “(A) GRANT AUTHORITY.—

23 “(i) IN GENERAL.—The Secretary, in
24 consultation with the Secretary of Labor
25 and the Secretary of Education, may make

1 a grant in accordance with this paragraph
2 to an eligible entity whose application for
3 the grant is approved by the Secretary, to
4 conduct a project designed to train low-in-
5 come individuals for allied health profes-
6 sions, health information technology, physi-
7 cians assistants, nursing assistants, reg-
8 istered nurse, advanced practice nurse, and
9 other professions considered part of a
10 health care career pathway model.

11 “(ii) GUARANTEE OF GRANTEES IN
12 EACH STATE AND THE DISTRICT OF CO-
13 LUMBIA.—For each grant cycle, the Sec-
14 retary shall award a grant under this para-
15 graph to at least 2 eligible entities in each
16 State that is not a territory, to the extent
17 there are a sufficient number of applica-
18 tions submitted by the entities that meet
19 the requirements applicable with respect to
20 such a grant. If, for a grant cycle, there
21 are fewer than 2 such eligible entities in a
22 State, the Secretary shall include that in-
23 formation in the report required by sub-
24 section (g)(2) that covers the fiscal year.

1 “(B) GUARANTEE OF GRANTS FOR INDIAN
2 POPULATIONS.—From the amount reserved
3 under subsection (i)(2)(B) for each fiscal year,
4 the Secretary shall award a grant under this
5 paragraph to at least 10 eligible entities that
6 are an Indian tribe, a tribal organization, or a
7 tribal college or university, to the extent there
8 are a sufficient number of applications sub-
9 mitted by the entities that meet the require-
10 ments applicable with respect to such a grant.

11 “(C) GUARANTEE OF GRANTEEES IN THE
12 TERRITORIES.—From the amount reserved
13 under subsection (i)(2)(C) for each fiscal year,
14 the Secretary shall award a grant under this
15 paragraph to at least 2 eligible entities that are
16 located in a territory, to the extent there are a
17 sufficient number of applications submitted by
18 the entities that meet the requirements applica-
19 ble with respect to such a grant.

20 “(2) GRANTS FOR DEMONSTRATION
21 PROJECTS.—

22 “(A) GRANT AUTHORITY.—The Secretary,
23 in consultation with the Secretary of Labor and
24 the Secretary of Education (and, with respect
25 to demonstration projects of the type described

1 in subparagraph (B)(i)(I), the Attorney Gen-
2 eral) shall make a grant in accordance with this
3 subsection to an eligible entity whose applica-
4 tion for the grant is approved by the Secretary,
5 to conduct a demonstration project that meets
6 the requirements of subparagraph (B).

7 “(B) REQUIREMENTS.—The requirements
8 of this subparagraph are the following:

9 “(i) TYPE OF PROJECT.—The dem-
10 onstration project shall be of 1 of the fol-
11 lowing types:

12 “(I) INDIVIDUALS WITH ARREST
13 OR CONVICTION RECORDS DEM-
14 ONSTRATION.—The demonstration
15 project shall be of a type designed to
16 provide education and training for eli-
17 gible individuals with arrest or convic-
18 tion records to enter and follow a ca-
19 reer pathway in the health professions
20 through occupations that pay well and
21 are expected to experience a labor
22 shortage or be in high demand.

23 “(II) PREGNANCY AND CHILD-
24 BIRTH CAREER PATHWAY DEM-
25 ONSTRATION.—The demonstration

1 project shall be of a type designed to
2 provide education and training for eli-
3 gible individuals to enter and follow a
4 career pathway in the field of preg-
5 nancy, childbirth, or post-partum, in a
6 State that recognizes doulas or mid-
7 wives and that provides payment for
8 services provided by doulas or mid-
9 wives, as the case may be, under pri-
10 vate or public health insurance plans.

11 “(ii) DURATION.—The demonstration
12 project shall be conducted for not less than
13 5 years.

14 “(C) MINIMUM ALLOCATION OF FUNDS
15 FOR EACH TYPE OF DEMONSTRATION
16 PROJECT.—

17 “(i) INDIVIDUALS WITH ARREST OR
18 CONVICTION RECORDS DEMONSTRA-
19 TIONS.—Not less than 25 percent of the
20 amounts made available for grants under
21 this paragraph shall be used to make
22 grants for demonstration projects of the
23 type described in subparagraph (B)(i)(I).

24 “(ii) PREGNANCY AND CHILDBIRTH
25 CAREER PATHWAY DEMONSTRATIONS.—

1 Not less than 25 percent of the amounts
2 made available for grants under this para-
3 graph shall be used to make grants for
4 demonstration projects of the type de-
5 scribed in subparagraph (B)(i)(II).

6 “(3) GRANT CYCLE.—The grant cycle under
7 this section shall be not less than 5 years, with a
8 planning period of not more than the 1st 12 months
9 of the grant cycle. During the planning period, the
10 amount of the grant shall be in such lesser amount
11 as the Secretary determines appropriate.

12 “(d) USE OF GRANT.—

13 “(1) IN GENERAL.—An entity to which a grant
14 is made under this section shall use the grant in ac-
15 cordance with the approved application for the
16 grant.

17 “(2) SUPPORT TO BE PROVIDED.—

18 “(A) REQUIRED SUPPORT.—A project for
19 which a grant is made under this section shall
20 include the following:

21 “(i) An assessment for adult basic
22 skill competency, and provision of adult
23 basic skills education if necessary for
24 lower-skilled eligible individuals to enroll in
25 the project and go on to enter and com-

1 plete post-secondary training, through
2 means including the following:

3 “(I) Establishing a network of
4 partners that offer pre-training activi-
5 ties for project participants who need
6 to improve basic academic skills or
7 English language proficiency before
8 entering a health occupational train-
9 ing career pathway program.

10 “(II) Offering resources to enable
11 project participants to continue ad-
12 vancing adult basic skill proficiency
13 while enrolled in a career pathway
14 program.

15 “(III) Embedding adult basic
16 skill maintenance as part of ongoing
17 post-graduation career coaching and
18 mentoring.

19 “(ii) A guarantee that child care is an
20 available and affordable support service for
21 project participants through means such as
22 the following;

23 “(I) Referral to, and assistance
24 with, enrollment in a subsidized child
25 care program.

1 “(II) Direct payment to a child
2 care provider if a slot in a subsidized
3 child care program is not available or
4 reasonably accessible.

5 “(III) Payment of co-payments
6 or associated fees for child care.

7 “(iii) Case management plans that in-
8 clude career coaching (with the option to
9 offer appropriate peer support and men-
10 toring opportunities to help develop soft
11 skills and social capital), which may be of-
12 fered on an ongoing basis before, during,
13 and after initial training as part of a ca-
14 reer pathway model.

15 “(iv) A plan to provide project partici-
16 pants with transportation through means
17 such as the following:

18 “(I) Referral to, and assistance
19 with enrollment in, a subsidized trans-
20 portation program.

21 “(II) If a subsidized transpor-
22 tation program is not reasonably
23 available, direct payments to subsidize
24 transportation costs.

1 For purposes of this clause, the term
2 ‘transportation’ includes public transit, or
3 gasoline for a personal vehicle if public
4 transit is not reasonably accessible or
5 available.

6 “(v) In the case of a demonstration
7 project of the type described in subsection
8 (c)(2)(B)(i)(I), access to legal assistance
9 for project participants for the purpose of
10 addressing arrest or conviction records and
11 associated workforce barriers.

12 “(B) ALLOWED SUPPORT.—The goods and
13 services provided under a project for which a
14 grant is made under this section may include
15 the following:

16 “(i) A cash stipend that is at least
17 monthly.

18 “(ii) A reserve fund for financial as-
19 sistance to project participants in emer-
20 gency situations.

21 “(iii) Tuition, and training materials
22 such as books, software, uniforms, shoes,
23 and hair nets.

1 “(iv) In-kind resource donations such
2 as interview clothing and conference at-
3 tendance fees.

4 “(v) Assistance with accessing and
5 completing high school equivalency or adult
6 basic education courses as necessary to
7 achieve success in the project and make
8 progress toward career goals.

9 “(vi) Assistance with programs and
10 activities, including legal assistance,
11 deemed necessary to address arrest or con-
12 viction records as an employment barrier.

13 “(vii) Other support services as
14 deemed necessary for family well-being,
15 success in the project, and progress toward
16 career goals.

17 “(C) TREATMENT OF SUPPORT FOR PUR-
18 POSES OF MEANS-TESTED PROGRAMS.—Any
19 goods or services provided to an eligible indi-
20 vidual participating in a project for which a
21 grant is made under this section shall not be
22 considered income, and shall not be taken into
23 account for purposes of determining the eligi-
24 bility of the individual for, or amount of bene-

1 fits to be provided to the individual, under any
2 means-tested program.

3 “(3) TRAINING.—The number of hours of train-
4 ing provided to an eligible individual under a project
5 for which a grant is made under this section, for a
6 recognized postsecondary credential, including an in-
7 dustry-recognized credential, which is awarded in
8 recognition of attainment of measurable technical or
9 occupational skills necessary to gain employment or
10 advance within an occupation (including a certificate
11 awarded by a local workforce development board es-
12 tablished under section 107 of the Workforce Inno-
13 vation and Opportunity Act), shall be—

14 “(A) not less than the number of hours of
15 training required for certification in that level
16 of skill by the State in which the project is con-
17 ducted; or

18 “(B) if there is no such requirement, such
19 number of hours of training as the Secretary
20 finds is necessary to achieve that skill level.

21 “(4) INCOME LIMITATION.—An entity to which
22 a grant is made under this section shall not use the
23 grant to provide support to a person who is not an
24 eligible individual.

1 “(5) INCLUSION OF TANF RECIPIENTS.—In the
2 case of a project for which a grant is made under
3 this section that is conducted in a State that has a
4 program funded under part A of title IV, at least 10
5 percent of the eligible individuals to whom support
6 is provided under the project shall meet the income
7 eligibility requirements under that State program,
8 without regard to whether the individuals receive
9 benefits or services directly under that State pro-
10 gram.

11 “(6) PROHIBITION.—An entity to which a grant
12 is made under this section shall not use the grant
13 for purposes of entertainment, except that case man-
14 agement and career coaching services may include
15 celebrations of specific career-based milestones such
16 as completing a semester, graduation, or job place-
17 ment.

18 “(e) TECHNICAL ASSISTANCE.—

19 “(1) IN GENERAL.—The Secretary shall provide
20 technical assistance—

21 “(A) to assist eligible entities in applying
22 for grants under this section;

23 “(B) that is tailored to meet the needs of
24 grantees at each stage of the administration of

1 projects for which grants are made under this
2 section;

3 “(C) that is tailored to meet the specific
4 needs of Indian tribes, tribal organizations, and
5 tribal colleges and universities;

6 “(D) that is tailored to meet the specific
7 needs of the territories;

8 “(E) that is tailored to meet the specific
9 needs of eligible entities in carrying out dem-
10 onstration projects for which a grant is made
11 under this section; and

12 “(F) to facilitate the exchange of informa-
13 tion among eligible entities regarding best prac-
14 tices and promising practices used in the
15 projects.

16 “(2) CONTINUATION OF PEER TECHNICAL AS-
17 SISTANCE CONFERENCES.—The Secretary shall con-
18 tinue to hold peer technical assistance conferences
19 for entities to which a grant is made under this sec-
20 tion or was made under the immediate predecessor
21 of this section.

22 “(f) EVALUATION OF DEMONSTRATION PROJECTS.—

23 “(1) IN GENERAL.—The Secretary shall, by
24 grant, contract, or interagency agreement, conduct
25 rigorous and well-designed evaluations of the dem-

1 onstration projects for which a grant is made under
2 this section.

3 “(2) REQUIREMENT APPLICABLE TO INDIVID-
4 UALS WITH ARREST OR CONVICTION RECORDS DEM-
5 ONSTRATION.—In the case of a project of the type
6 described in subsection (c)(2)(B)(i)(I), the evalua-
7 tion shall include identification of successful activi-
8 ties for creating opportunities for developing and
9 sustaining, particularly with respect to low-income
10 individuals with arrest or conviction records, a
11 health professions workforce that has accessible
12 entry points, that meets high standards for edu-
13 cation, training, certification, and professional devel-
14 opment, and that provides increased wages and af-
15 fordable benefits, including health care coverage,
16 that are responsive to the needs of the workforce.

17 “(3) REQUIREMENT APPLICABLE TO PREG-
18 NANCY AND CHILDBIRTH CAREER PATHWAY DEM-
19 ONSTRATION.—In the case of a project of the type
20 described in subsection (c)(2)(B)(i)(II), 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 and other entry-level workers, a career
25 pathway that has accessible entry points, that meets

1 high standards for education, training, certification,
2 and professional development, and that provides in-
3 creased wages and affordable benefits, including
4 health care coverage, that are responsive to the
5 needs of the birth, pregnancy, and post-partum
6 workforce.

7 “(4) RULE OF INTERPRETATION.—Evaluations
8 conducted pursuant to this subsection may include a
9 randomized controlled trial, but this subsection shall
10 not be interpreted to require an evaluation to include
11 such a trial.

12 “(g) REPORTS.—

13 “(1) TO THE SECRETARY.—An eligible entity
14 awarded a grant to conduct a project under this sec-
15 tion shall submit interim reports to the Secretary on
16 the activities carried out under the project, and, on
17 the conclusion of the project, a final report on the
18 activities. Each such report shall include data on
19 participant outcomes related to earnings, employ-
20 ment in health professions, graduation rate, gradua-
21 tion timeliness, credential attainment, participant
22 demographics, and other data specified by the Sec-
23 retary.

24 “(2) TO THE CONGRESS.—During each Con-
25 gress, the Secretary shall submit to the Committee

1 on Ways and Means of the House of Representatives
2 and the Committee on Finance of the Senate a re-
3 port—

4 “(A) on the demographics of the partici-
5 pants in the projects for which a grant is made
6 under this section;

7 “(B) on the rate of which project partici-
8 pants completed all activities under the
9 projects;

10 “(C) on the employment credentials ac-
11 quired by project participants;

12 “(D) on the employment of project partici-
13 pants on completion of activities under the
14 projects, and the earnings of project partici-
15 pants at entry into employment;

16 “(E) on best practices and promising prac-
17 tices used in the projects;

18 “(F) on the nature of any technical assist-
19 ance provided to grantees under this section;

20 “(G) on, with respect to the period since
21 the period covered in the most recent prior re-
22 port submitted under this paragraph—

23 “(i) the number of applications sub-
24 mitted under this section, with a separate

1 statement of the number of applications re-
2 ferred to in subsection (b)(5);

3 “(ii) the number of applications that
4 were approved, with a separate statement
5 of the number of such applications referred
6 to in subsection (b)(5); and

7 “(iii) a description of how grants were
8 made in any case described in the last sen-
9 tence of subsection (c)(1)(A)(ii); and

10 “(H) that includes an assessment of the ef-
11 fectiveness of the projects with respect to ad-
12 dressing health professions workforce shortages
13 or in-demand jobs.

14 “(h) DEFINITIONS.—In this section:

15 “(1) ALLIED HEALTH PROFESSION.—The term
16 ‘allied health profession’ has the meaning given in
17 section 799B(5) of the Public Health Service Act.

18 “(2) CAREER PATHWAY.—The term ‘career
19 pathway’ has the meaning given that term in section
20 3(7) of the Workforce Innovation and Opportunity
21 Act.

22 “(3) DOULA.—The term ‘doula’ means an indi-
23 vidual who—

24 “(A) is certified by an organization that
25 has been established for not less than 5 years

1 and that requires the completion of continuing
2 education to maintain the certification, to pro-
3 vide non-medical advice, information, emotional
4 support, and physical comfort to an individual
5 during the individual's pregnancy, childbirth,
6 and post-partum period; and

7 “(B) maintains the certification by com-
8 pleting the required continuing education.

9 “(4) ELIGIBLE ENTITY.—The term ‘eligible en-
10 tity’ means any of the following entities that dem-
11 onstrates in an application submitted under this sec-
12 tion that the entity has the capacity to fully develop
13 and administer the project described in the applica-
14 tion:

15 “(A) A local workforce development board
16 established under section 107 of the Workforce
17 Innovation and Opportunity Act.

18 “(B) A State or territory, a political sub-
19 division of a State or territory, or an agency of
20 a State, territory, or such a political subdivi-
21 sion, including a State or local entity that ad-
22 ministers a State program funded under part A
23 of this title.

24 “(C) An Indian tribe, a tribal organization,
25 or a tribal college or university.

1 “(D) An institution of higher education (as
2 defined in the Higher Education Act of 1965).

3 “(E) A hospital (as defined in section
4 1861(e)).

5 “(F) A high-quality skilled nursing facility.

6 “(G) A Federally qualified health center
7 (as defined in section 1861(aa)(4)).

8 “(H) A nonprofit organization described in
9 section 501(c)(3) of the Internal Revenue Code
10 of 1986, a labor organization, or an entity with
11 shared labor-management oversight, that has a
12 demonstrated history of providing health profes-
13 sion training to eligible individuals.

14 “(I) In the case of a demonstration project
15 of the type provided for in subsection
16 (c)(2)(B)(i)(II) of this section, an entity recog-
17 nized by a State, Indian tribe, or tribal organi-
18 zation as qualified to train doulas or midwives,
19 if midwives or doulas, as the case may be, are
20 permitted to practice in the State involved.

21 “(J) An opioid treatment program (as de-
22 fined in section 1861(jjj)(2)), and other high
23 quality comprehensive addiction care providers.

24 “(5) ELIGIBLE INDIVIDUAL.—The term ‘eligible
25 individual’ means an individual whose family income

1 does not exceed 200 percent of the Federal poverty
2 level.

3 “(6) FEDERAL POVERTY LEVEL.—The term
4 ‘Federal poverty level’ means the poverty line (as de-
5 fined in section 673(2) of the Omnibus Budget Rec-
6 onciliation Act of 1981, including any revision re-
7 quired by such section applicable to a family of the
8 size involved).

9 “(7) INDIAN TRIBE; TRIBAL ORGANIZATION.—
10 The terms ‘Indian tribe’ and ‘tribal organization’
11 have the meaning given the terms in section 4 of the
12 Indian Self-Determination and Education Assistance
13 Act (25 U.S.C. 450b).

14 “(8) INSTITUTION OF HIGHER EDUCATION.—
15 The term ‘institution of higher education’ has the
16 meaning given the term in section 101 or
17 102(a)(1)(B) of the Higher Education Act of 1965.

18 “(9) TERRITORY.—The term ‘territory’ means
19 the Commonwealth of Puerto Rico, the United
20 States Virgin Islands, Guam, the Northern Mariana
21 Islands, and American Samoa.

22 “(10) TRIBAL COLLEGE OR UNIVERSITY.—The
23 term ‘tribal college or university’ has the meaning
24 given the term in section 316(b) of the Higher Edu-
25 cation Act of 1965.

1 “(i) FUNDING.—

2 “(1) IN GENERAL.—Out of any funds in the
3 Treasury of the United States not otherwise appro-
4 priated, there are appropriated to the Secretary to
5 carry out this section \$425,000,000 for each of fis-
6 cal years 2021 through 2025.

7 “(2) ALLOCATION OF FUNDS.—Of the amount
8 appropriated for a fiscal year under paragraph (1)
9 of this subsection—

10 “(A) 75 percent shall be available for
11 grants under subsection (c)(1)(A);

12 “(B) 4 percent shall be reserved for grants
13 under subsection (c)(1)(B);

14 “(C) 5 percent shall be reserved for grants
15 under subsection (c)(1)(C);

16 “(D) 6 percent shall be available for dem-
17 onstration project grants under subsection
18 (c)(2);

19 “(E) 6 percent, plus all amounts referred
20 to in subparagraphs (A) through (D) of this
21 paragraph that remain unused after all grant
22 awards are made for the fiscal year, shall be
23 available for the provision of technical assist-
24 ance and associated staffing; and

1 “(F) 4 percent shall be available for study-
2 ing the effects of the demonstration and non-
3 demonstration projects for which a grant is
4 made under this section, and for associated
5 staffing, for the purpose of supporting the rig-
6 orous evaluation of the demonstration projects,
7 and supporting the continued study of the
8 short-, medium-, and long-term effects of all
9 such projects, including the effectiveness of new
10 or added elements of the non-demonstration
11 projects.

12 “(j) NONAPPLICABILITY OF PRECEDING SECTIONS
13 OF THIS SUBTITLE.—

14 “(1) IN GENERAL.—Except as provided in para-
15 graph (2), the preceding sections of this subtitle
16 shall not apply to a grant awarded under this sec-
17 tion.

18 “(2) EXCEPTION FOR CERTAIN LIMITATIONS ON
19 USE OF GRANTS.—Section 2005(a) (other than para-
20 graphs (2), (3), (5), (6), and (8)) shall apply to a
21 grant awarded under this section to the same extent
22 and in the same manner as such section applies to
23 payments to States under this subtitle.”.

1 **SEC. 811. HOME VISITING TO REDUCE MATERNAL MOR-**
2 **TALITY AND MORBIDITY ACT.**

3 (a) **SHORT TITLE.**—This section may be cited as the
4 “Home Visiting to Reduce Maternal Mortality and Mor-
5 bidity Act”.

6 (b) **INCREASE IN TRIBAL SET-ASIDE PERCENT-**
7 **AGE.**—

8 (1) **IN GENERAL.**—Section 511(j)(2)(A) of the
9 Social Security Act (42 U.S.C. 711(j)(2)(A)) is
10 amended by striking “3” and inserting “6”.

11 (2) **EFFECTIVE DATE.**—The amendment made
12 by paragraph (1) shall take effect on October 1,
13 2020.

14 (c) **INCREASE IN FUNDING.**—Section 511(j)(1) of
15 such Act (42 U.S.C. 711(j)(1)) is amended—

16 (1) by striking “and” at the end of subpara-
17 graph (G); and

18 (2) by striking subparagraph (H) and inserting
19 the following:

20 “(H) \$400,000,000 for each of fiscal years
21 2017 through 2020;

22 “(I) \$600,000,000 for fiscal year 2021;
23 and

24 “(J) \$800,000,000 for fiscal year 2022.”.

1 (d) USE OF ADDITIONAL FUNDS.—Section 511(c) of
2 such Act (42 U.S.C. 711(c)) is amended by adding at the
3 end the following:

4 “(6) USE OF CERTAIN FUNDS TO PROVIDE AD-
5 DITIONAL RESOURCES TO ADDRESS HIGH RATES OF
6 MATERNAL MORTALITY AND MORBIDITY, SUPPORT
7 UNMET NEEDS IDENTIFIED BY THE NEEDS ASSESS-
8 MENT, OR INCREASE ALLOCATIONS TO STATES AND
9 TERRITORIES BASED ON RELATIVE POPULATION OR
10 POVERTY.—The Secretary shall ensure that any
11 amounts exceeding \$400,000,000 that are used for
12 grants under this subsection for a fiscal year are
13 used to—

14 “(A) provide additional funding priority to
15 States, tribes, and territories to address high
16 rates of maternal mortality and morbidity;

17 “(B) address unmet needs identified by a
18 needs assessment conducted under subsection
19 (b); or

20 “(C) increase the amounts allocated under
21 this section to States and to Puerto Rico,
22 Guam, the Virgin Islands, the Northern Mar-
23 iana Islands, and American Samoa, based on
24 the proportion of children who have not at-

1 tained 5 years of age and are living in pov-
2 erty.”.

