

117TH CONGRESS
1ST SESSION

H. R. 3

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 22, 2021

Mr. PALLONE (for himself, Mr. NEAL, and Mr. SCOTT of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, Oversight and Reform, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

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

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

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

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

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE
 NEGOTIATION

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

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

Sec. 103. Fair Price Negotiation Implementation Fund.

TITLE II—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 drug 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—NIH, FDA, AND OVERDOSE EPIDEMIC FUNDING

Subtitle A—Biomedical Innovation Expansion

Sec. 501. NIH Innovation Initiatives.

Sec. 502. NIH clinical trial.

Sec. 503. Innovation Network.

Subtitle B—Investing in Safety and Innovation

Sec. 511. Food and Drug Administration.

Sec. 512. Study on high-risk, high-reward drugs.

Subtitle C—Overdose Epidemic Response

Sec. 521. Overdose Epidemic Response Fund.

Sec. 522. Substance Abuse and Mental Health Services Administration.

Sec. 523. Centers for Disease Control and Prevention.

Sec. 524. Food and Drug Administration.

Sec. 525. National Institutes of Health.

Sec. 526. Health Resources and Services Administration.

Sec. 527. Administration for Children and Families.

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

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

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

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

13 **“SEC. 1191. ESTABLISHMENT OF PROGRAM.**

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

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

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

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

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

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

8 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
9 term ‘initial price applicability year’ means a plan
10 year (beginning with plan year 2024) or, if agreed
11 to in an agreement under section 1193 by the Sec-
12 retary and manufacturer involved, a period of more
13 than one plan year (beginning on or after January
14 1, 2024).

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

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

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

5 “(A) beginning on the sooner of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(B) APPLICABLE COUNTRIES.—

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

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

20 “(I) Australia.

21 “(II) Canada.

22 “(III) France.

23 “(IV) Germany.

24 “(V) Japan.

25 “(VI) The United Kingdom.

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

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

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

11 “(1)(A) with respect to an initial price applica-
12 bility year during 2024, at least 25 negotiation-eligible
13 drugs described in subparagraphs (A) and (B),
14 but not subparagraph (C), of subsection (d)(1) (or,
15 with respect to an initial price applicability year dur-
16 ing such period beginning after 2024, the maximum
17 number (if such number is less than 25) of such ne-
18 gotiation-eligible drugs for the year) with respect to
19 such year; and

20 “(B) with respect to an initial price applica-
21 bility year during 2025 or a subsequent year, at
22 least 50 negotiation-eligible drugs described in sub-
23 paragraphs (A) and (B), but not subparagraph (C),
24 of subsection (d)(1) (or, with respect to an initial
25 price applicability year during such period, the max-

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

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

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

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

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

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

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

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

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

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

4 “(2) continue to be marketed.

5 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

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

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

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

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

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

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

22 “(1) DRUG PRODUCTS.—A drug that—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(h) CONFLICT OF INTEREST.—

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

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

21 “(A) a financial interest (as described in
22 section 2635.402 of title 5, Code of Federal
23 Regulations, as in effect on the date of the en-
24 actment of this section, (except for an interest
25 described in subsection (b)(2)(iv) of such sec-

1 tion)) on the date of the selected drug publica-
2 tion date, with respect the price applicability
3 year (as applicable);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(2) AMOUNTS DESCRIBED.—

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

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

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

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

25 “(e) REGULATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(3) REQUIREMENT.—

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

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

5 “(B) TARGET PRICE.—

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

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

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

1 “(c) LIMITATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(b) UPDATES.—

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

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

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

21 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

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

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

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

6 “(a) ADMINISTRATIVE DUTIES.—

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

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

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

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

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

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

“(i) the lesser of—

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

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

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

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

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

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

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

4 “(ii) any other discounts.

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

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

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

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

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

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

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

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

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

6 “(2) MONITORING COMPLIANCE.—

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

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

20 “(b) COLLECTION OF DATA.—

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

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

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

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

15 “(c) CONTRACT WITH THIRD PARTIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(b) NATIONAL ACADEMY OF MEDICINE STUDY.—
 11 Not later than December 31, 2027, the National Academy
 12 of Medicine shall conduct a study, and submit to Congress
 13 a report, on recommendations for improvements to the
 14 program under this part, including the determination of
 15 the limits applied under section 1194(c).

16 “(c) MEDPAC STUDY.—Not later than December 31,
 17 2027, the Medicare Payment Advisory Commission shall
 18 conduct a study, and submit to Congress a report, on the
 19 program under this part with respect to the Medicare pro-
 20 gram under title XVIII, including with respect to the ef-
 21 fect of the program on individuals entitled to benefits or
 22 enrolled under such title.

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

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

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

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

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

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

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

19 “(g) GAO STUDY.—Not later than December 31,
20 2027, the Comptroller General of the United States shall
21 conduct a study of, and submit to Congress a report on,
22 the implementation of the Fair Price Negotiation Program
23 under this part.”.

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

1 (1) UNDER MEDICARE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (A) PHSA.—Part D of title XXVII of the
 14 Public Health Service Act (42 U.S.C. 300gg–
 15 111 et seq.) is amended by adding at the end
 16 the following new section:

17 **“SEC. 2799A–11. FAIR PRICE NEGOTIATION PROGRAM AND**
 18 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

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

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

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

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

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

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

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

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

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

11 (B) ERISA.—

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

18 **“SEC. 726. FAIR PRICE NEGOTIATION PROGRAM AND APPLI-**
 19 **CATION OF MAXIMUM FAIR PRICES.**

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

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

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

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

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

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

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

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

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

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

10 (ii) APPLICATION TO RETIREE AND
 11 CERTAIN SMALL GROUP HEALTH PLANS.—
 12 Section 732(a) of the Employee Retire-
 13 ment Income Security Act of 1974 (29
 14 U.S.C. 1191a(a)) is amended by striking
 15 “section 711” and inserting “sections 711
 16 and 726”.

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

“Sec. 726. Fair Price Negotiation Program and application of maximum fair
 prices.”.

23 (C) IRC.—

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

5 **“SEC. 9826. FAIR PRICE NEGOTIATION PROGRAM AND AP-**
 6 **PLICATION OF MAXIMUM FAIR PRICES.**

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

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

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

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

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

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

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

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

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

17 (ii) APPLICATION TO RETIREE AND
 18 CERTAIN SMALL GROUP HEALTH PLANS.—
 19 Section 9831(a)(2) of the Internal Revenue
 20 Code of 1986 is amended by inserting
 21 “other than with respect to section 9826,”
 22 before “any group health plan”.

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

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

“Sec. 9826. Fair Price Negotiation Program and application of maximum fair
 prices.”.

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

7 (A) in subsection (c)(1)(C)(ii)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 “(2) For purposes of this subsection:

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

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

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

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

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

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

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

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

14 “(1) such tax, divided by

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 (c) CONFORMING AMENDMENTS.—

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

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

23 (d) CLERICAL AMENDMENTS.—

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

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

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

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

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

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

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

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

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

5 (2) \$600,000,000 shall become available on Oc-
6 tober 1, 2022;

7 (3) \$600,000,000 shall become available on Oc-
8 tober 1, 2023;

9 (4) \$600,000,000 shall become available on Oc-
10 tober 1, 2024; and

11 (5) \$600,000,000 shall become available on Oc-
12 tober 1, 2025.

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

17 **TITLE II—PRESCRIPTION DRUG** 18 **INFLATION REBATES**

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

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

23 “(z) REBATE BY MANUFACTURERS FOR SINGLE
24 SOURCE DRUGS WITH PRICES INCREASING FASTER
25 THAN INFLATION.—

1 “(1) REQUIREMENTS.—

2 “(A) SECRETARIAL PROVISION OF INFOR-
3 MATION.—Not later than 6 months after the
4 end of each calendar quarter beginning on or
5 after July 1, 2023, the Secretary shall, for each
6 part B rebatable drug, report to each manufac-
7 turer of such part B rebatable drug the fol-
8 lowing for such calendar quarter:

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

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

19 “(iii) The rebate amount specified
20 under such paragraph for such part B
21 rebatable drug and calendar quarter.

22 “(B) MANUFACTURER REQUIREMENT.—
23 For each calendar quarter beginning on or after
24 July 1, 2023, the manufacturer of a part B
25 rebatable drug shall, for such drug, not later

1 than 30 days after the date of receipt from the
2 Secretary of the information described in sub-
3 paragraph (A) for such calendar quarter, pro-
4 vide to the Secretary a rebate that is equal to
5 the amount specified in paragraph (3) for such
6 drug for such calendar quarter.

7 “(2) PART B REBATABLE DRUG DEFINED.—

8 “(A) IN GENERAL.—In this subsection, the
9 term ‘part B rebatable drug’ means a single
10 source drug or biological (as defined in sub-
11 paragraph (D) of section 1847A(c)(6)), includ-
12 ing a biosimilar biological product (as defined
13 in subparagraph (H) of such section), paid for
14 under this part, except such term shall not in-
15 clude such a drug or biological—

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

21 “(ii) that is a vaccine described in
22 subparagraph (A) or (B) of section
23 1861(s)(10).

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

1 “(i) for 2024, shall be the dollar
2 amount specified under such subparagraph
3 for 2023, increased by the percentage in-
4 crease in the consumer price index for all
5 urban consumers (United States city aver-
6 age) for the 12-month period ending with
7 June of the previous year; and

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

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

19 “(3) REBATE AMOUNT.—

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

1 “(i) subject to subparagraphs (B) and
2 (G), the total number of units of the bill-
3 ing and payment code for such part B
4 rebatable drug furnished under this part
5 during the calendar quarter; and

6 “(ii) the amount (if any) by which—

7 “(I) the payment amount under
8 subparagraph (B) or (C) of section
9 1847A(b)(1), as applicable, for such
10 part B rebatable drug during the cal-
11 endar quarter; exceeds

12 “(II) the inflation-adjusted pay-
13 ment amount determined under sub-
14 paragraph (C) for such part B
15 rebatable drug during the calendar
16 quarter.

17 “(B) EXCLUDED UNITS.—For purposes of
18 subparagraph (A)(i), the total number of units
19 of the billing and payment code for each part
20 B rebatable drug furnished during a calendar
21 quarter shall not include—

22 “(i) units packaged into the payment
23 for a procedure or service under section
24 1833(t) or under section 1833(i) (instead

1 of separately payable under such respective
2 section);

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

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

13 “(C) DETERMINATION OF INFLATION-AD-
14 JUSTED PAYMENT AMOUNT.—The inflation-ad-
15 justed payment amount determined under this
16 subparagraph for a part B rebatable drug for
17 a calendar quarter is—

18 “(i) the payment amount for the bill-
19 ing and payment code for such drug in the
20 payment amount benchmark quarter (as
21 defined in subparagraph (D)); increased by

22 “(ii) the percentage by which the re-
23 bate period CPI–U (as defined in subpara-
24 graph (F)) for the calendar quarter ex-

1 ceeds the benchmark period CPI–U (as de-
2 fined in subparagraph (E)).

3 “(D) PAYMENT AMOUNT BENCHMARK
4 QUARTER.—The term ‘payment amount bench-
5 mark quarter’ means the calendar quarter be-
6 ginning January 1, 2016.

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

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

20 “(G) COUNTING UNITS.—

21 “(i) CUT-OFF PERIOD TO COUNT
22 UNITS.—For purposes of subparagraph
23 (A)(i), subject to clause (ii), to count the
24 total number of billing units for a part B
25 rebatable drug for a quarter, the Secretary

1 may use a cut-off period in order to ex-
2 clude from such total number of billing
3 units for such quarter claims for services
4 furnished during such quarter that were
5 not processed at an appropriate time prior
6 to the end of the cut-off period.

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

21 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
22 AND EXEMPTION.—

23 “(A) SUBSEQUENTLY APPROVED DRUGS.—
24 Subject to subparagraph (B), in the case of a
25 part B rebatable drug first approved or licensed

1 by the Food and Drug Administration after
2 July 1, 2015, clause (i) of paragraph (3)(C)
3 shall be applied as if the term ‘payment amount
4 benchmark quarter’ were defined under para-
5 graph (3)(D) as the third full calendar quarter
6 after the day on which the drug was first mar-
7 keted and clause (ii) of paragraph (3)(C) shall
8 be applied as if the term ‘benchmark period
9 CPI-U’ were defined under paragraph (3)(E)
10 as if the reference to ‘July 2015’ under such
11 paragraph were a reference to ‘the first month
12 of the first full calendar quarter after the day
13 on which the drug was first marketed’.

14 “(B) TIMELINE FOR PROVISION OF RE-
15 BATES FOR SUBSEQUENTLY APPROVED
16 DRUGS.—In the case of a part B rebatable drug
17 first approved or licensed by the Food and
18 Drug Administration after July 1, 2015, para-
19 graph (1)(B) shall be applied as if the reference
20 to ‘July 1, 2023’ under such paragraph were a
21 reference to the later of the 6th full calendar
22 quarter after the day on which the drug was
23 first marketed or July 1, 2023.

24 “(C) EXEMPTION FOR SHORTAGES.—The
25 Secretary may reduce or waive the rebate

1 amount under paragraph (1)(B) with respect to
2 a part B rebatable drug that is described as
3 currently in shortage on the shortage list in ef-
4 fect under section 506E of the Federal Food,
5 Drug, and Cosmetic Act or in the case of other
6 exigent circumstances, as determined by the
7 Secretary.

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

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

20 “(ii) in the case such drug is deter-
21 mined (pursuant to such section 1192(c))
22 to no longer be a selected drug, for each
23 applicable year beginning after the price
24 applicability period with respect to such
25 drug, clause (i) of paragraph (3)(C) shall

1 be applied as if the term ‘payment amount
2 benchmark quarter’ were defined under
3 paragraph (3)(D) as the calendar quarter
4 beginning January 1 of the last year be-
5 ginning during such price applicability pe-
6 riod with respect to such selected drug and
7 clause (ii) of paragraph (3)(C) shall be ap-
8 plied as if the term ‘benchmark period
9 CPI-U’ were defined under paragraph
10 (3)(E) as if the reference to ‘July 2015’
11 under such paragraph were a reference to
12 the July of the year preceding such last
13 year.

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

18 “(A) in computing the amount of any coin-
19 surance applicable under this title to an indi-
20 vidual with respect to such drug, the computa-
21 tion of such coinsurance shall be based on the
22 inflation-adjusted payment amount determined
23 under paragraph (3)(C) for such part B
24 rebatable drug; and

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

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

8 “(7) CIVIL MONEY PENALTY.—If a manufac-
9 turer of a part B rebatable drug has failed to com-
10 ply with the requirements under paragraph (1)(B)
11 for such drug for a calendar quarter, the manufac-
12 turer shall be subject to, in accordance with a proc-
13 ess established by the Secretary pursuant to regula-
14 tions, a civil money penalty in an amount equal to
15 at least 125 percent of the amount specified in para-
16 graph (3) for such drug for such calendar quarter.
17 The provisions of section 1128A (other than sub-
18 sections (a) (with respect to amounts of penalties or
19 additional assessments) and (b)) shall apply to a
20 civil money penalty under this paragraph in the
21 same manner as such provisions apply to a penalty
22 or proceeding under section 1128A(a).

23 “(8) STUDY AND REPORT.—

1 “(A) STUDY.—The Secretary shall conduct
2 a study of the feasibility of and operational
3 issues involved with the following:

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

7 “(ii) Including drugs and biologicals
8 paid for under MA plans under part C in
9 the rebate system under this subsection.

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

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

20 “(9) APPLICATION TO MULTIPLE SOURCE
21 DRUGS.—The Secretary may, based on the report
22 submitted under paragraph (8) and pursuant to
23 rulemaking, apply the provisions of this subsection
24 to multiple source drugs (as defined in section
25 1847A(c)(6)(C)), including, for purposes of deter-

1 mining the rebate amount under paragraph (3), by
 2 calculating manufacturer-specific average sales
 3 prices for the benchmark period and the rebate pe-
 4 riod.”.

5 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
 6 1833 of the Social Security Act (42 U.S.C. 1395l) is
 7 amended—

8 (1) in subsection (a)—

9 (A) in paragraph (1)—

10 (i) in subparagraph (S), by striking
 11 “with respect to” and inserting “subject to
 12 subparagraph (DD), with respect to”;

13 (ii) by striking “and (DD)” and in-
 14 serting “(EE)”; and

15 (iii) by inserting before the semicolon
 16 at the end the following: “, and (EE) with
 17 respect to a part B rebatable drug (as de-
 18 fined in paragraph (2) of section 1834(z))
 19 for which the payment amount for a cal-
 20 endar quarter under paragraph
 21 (3)(A)(ii)(I) of such section for such quar-
 22 ter exceeds the inflation-adjusted payment
 23 under paragraph (3)(A)(ii)(II) of such sec-
 24 tion for such quarter, the amounts paid
 25 shall be the difference between (i) the pay-

1 ment amount under paragraph
 2 (3)(A)(ii)(I) of such section for such drug,
 3 and (ii) 20 percent of the inflation-ad-
 4 justed payment amount under paragraph
 5 (3)(A)(ii)(II) of such section for such
 6 drug”; and

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

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

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

17 “(9) In the case of a part B rebatable drug (as de-
 18 fined in paragraph (2) of section 1834(z)) for which pay-
 19 ment under this subsection is not packaged into a payment
 20 for a covered OPD service (as defined in subsection
 21 (t)(1)(B)) (or group of services) furnished on or after July
 22 1, 2023, under the system under this subsection, in lieu
 23 of calculation of coinsurance and the amount of payment
 24 otherwise applicable under this subsection, the provisions
 25 of section 1834(z)(5), paragraph (1)(EE) of subsection

1 (a), and the flush left matter following paragraph (9) of
 2 subsection (a), shall, as determined appropriate by the
 3 Secretary, apply under this subsection in the same manner
 4 as such provisions of section 1834(z)(5) and subsection
 5 (a) apply under such section and subsection.”; and

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

8 “(F) PART B REBATABLE DRUGS.—In the
 9 case of a part B rebatable drug (as defined in
 10 paragraph (2) of section 1834(z)) for which
 11 payment under this part is not packaged into a
 12 payment for a service furnished on or after July
 13 1, 2023, under the system under this sub-
 14 section, in lieu of calculation of coinsurance and
 15 the amount of payment otherwise applicable
 16 under this subsection, the provisions of section
 17 1834(z)(5), paragraph (1)(EE) of subsection
 18 (a), and the flush left matter following para-
 19 graph (9) of subsection (a), shall, as determined
 20 appropriate by the Secretary, apply under this
 21 subsection in the same manner as such provi-
 22 sions of section 1834(z)(5) and subsection (a)
 23 apply under such section and subsection.”.

24 (c) CONFORMING AMENDMENTS.—

1 (1) TO PART B ASP CALCULATION.—Section
 2 1847A(c)(3) of the Social Security Act (42 U.S.C.
 3 1395w–3a(c)(3)) is amended by inserting “or section
 4 1834(z)” after “section 1927”.

5 (2) EXCLUDING PARTS B DRUG INFLATION RE-
 6 BATE FROM BEST PRICE.—Section
 7 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
 8 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-
 9 serting “or section 1834(z)” after “this section”.

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

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

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

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

23 “(a) IN GENERAL.—

24 “(1) IN GENERAL.—Subject to the provisions of
 25 this section, in order for coverage to be available

under this part for a part D rebatable drug (as defined in subsection (h)(1)) of a manufacturer (as defined in section 1927(k)(5)) dispensed during an applicable year, the manufacturer must have entered into and have in effect an agreement described in subsection (b).

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

“(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

“(B) the Secretary determines that in the period beginning on January 1, 2023, and ending on December 31, 2023, there were extenuating circumstances.

“(3) APPLICABLE YEAR.—For purposes of this section the term ‘applicable year’ means a year beginning with 2023.

“(b) AGREEMENTS.—

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

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

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

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

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

23 “(B) MANUFACTURER REQUIREMENTS.—
24 For each applicable year with respect to which
25 the agreement is in effect, the manufacturer of

the part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such year, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (c) for such dosage form and strength with respect to such drug for such year.

“(2) LENGTH OF AGREEMENT.—

“(A) IN GENERAL.—An agreement under this section, with respect to a part D rebatable drug, shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

“(B) TERMINATION.—

“(i) BY SECRETARY.—The Secretary may provide for termination of an agreement under this section for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice of such termination. The

1 Secretary shall provide, upon request, a
2 manufacturer with a hearing concerning
3 such a termination, but such hearing shall
4 not delay the effective date of the termi-
5 nation.

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

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

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

19 “(C) EFFECTIVENESS OF TERMINATION.—
20 Any termination under this paragraph shall not
21 affect rebates due under the agreement under
22 this section before the effective date of its ter-
23 mination.

24 “(D) DELAY BEFORE REENTRY.—In the
25 case of any agreement under this section with

1 a manufacturer that is terminated in a plan
2 year, the Secretary may not enter into another
3 such agreement with the manufacturer (or a
4 successor manufacturer) before the subsequent
5 plan year, unless the Secretary finds good cause
6 for an earlier reinstatement of such an agree-
7 ment.

8 “(c) REBATE AMOUNT.—

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

15 “(A) the total number of units of such dos-
16 age form and strength with respect to such part
17 D rebatable drug and year; and

18 “(B) the amount (if any) by which—

19 “(i) the annual manufacturer price
20 (as determined in paragraph (2)) paid for
21 such dosage form and strength with re-
22 spect to such part D rebatable drug for the
23 year; exceeds

24 “(ii) the inflation-adjusted payment
25 amount determined under paragraph (3)

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

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

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

15 “(B) the ratio of—

16 “(i) the total number of units of such
17 dosage form and strength dispensed during
18 each such calendar quarter of such year; to

19 “(ii) the total number of units of such
20 dosage form and strength dispensed during
21 such year.

22 “(3) DETERMINATION OF INFLATION-ADJUSTED
23 PAYMENT AMOUNT.—The inflation-adjusted payment
24 amount determined under this paragraph for a dos-
25 age form and strength with respect to a part D

1 rebatable drug for an applicable year, subject to sub-
 2 paragraphs (A) and (D) of paragraph (5), is—

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

7 “(B) the percentage by which the applica-
 8 ble year CPI–U (as defined in subsection
 9 (h)(5)) for the applicable year exceeds the
 10 benchmark period CPI–U (as defined in sub-
 11 section (h)(4)).

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

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

24 “(B) the ratio of—

1 “(i) the total number of units of such
 2 dosage form and strength dispensed during
 3 each such calendar quarter of such pay-
 4 ment amount benchmark year; to

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

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

10 “(A) SUBSEQUENTLY APPROVED DRUGS.—

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

1 date on which the drug was first marketed by
2 any manufacturer’.

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

11 “(C) TREATMENT OF NEW FORMULA-
12 TIONS.—

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

22 “(ii) LINE EXTENSION DEFINED.—In
23 this subparagraph, the term ‘line exten-
24 sion’ means, with respect to a part D
25 rebatable drug, a new formulation of the

1 drug (as determined by the Secretary),
2 such as an extended release formulation,
3 but does not include an abuse-deterrent
4 formulation of the drug (as determined by
5 the Secretary), regardless of whether such
6 abuse-deterrent formulation is an extended
7 release formulation.

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

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

19 “(ii) in the case such drug is deter-
20 mined (pursuant to such section 1192(c))
21 to no longer be a selected drug, for each
22 applicable year beginning after the price
23 applicability period with respect to such
24 drug, subparagraphs (A) and (B) of para-
25 graph (4) shall be applied as if the term

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

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

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

21 “(f) CIVIL MONEY PENALTY.—In the case of a man-
22 ufacturer of a part D rebatable drug with an agreement
23 in effect under this section who has failed to comply with
24 the terms of the agreement under subsection (b)(1)(B)
25 with respect to such drug for an applicable year, the Sec-

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

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

12 “(1) The determination of units under this sec-
 13 tion.

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

16 “(3) The calculation of the rebate amount
 17 under this section.

18 “(h) DEFINITIONS.—In this section:

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

20 “(A) IN GENERAL.—The term ‘part D
 21 rebatable drug’ means a drug or biological that
 22 would (without application of this section) be a
 23 covered part D drug, except such term shall,
 24 with respect to an applicable year, not include
 25 such a drug or biological if the average annual

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

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

10 “(i) for 2024, shall be the dollar
11 amount specified under such subparagraph
12 for 2023, increased by the percentage in-
13 crease in the consumer price index for all
14 urban consumers (United States city aver-
15 age) for the 12-month period beginning
16 with January of 2023; and

17 “(ii) for a subsequent year, shall be
18 the dollar amount specified in this sub-
19 paragraph for the previous year, increased
20 by the percentage increase in the consumer
21 price index for all urban consumers
22 (United States city average) for the 12-
23 month period beginning with January of
24 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 “(2) UNIT DEFINED.—The term ‘unit’ means,
5 with respect to a part D rebatable drug, the lowest
6 identifiable quantity (such as a capsule or tablet,
7 milligram of molecules, or grams) of the part D
8 rebatable drug that is dispensed to individuals under
9 this part.

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

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

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

22 “(6) AVERAGE MANUFACTURER PRICE.—The
23 term ‘average manufacturer price’ has the meaning,
24 with respect to a part D rebatable drug of a manu-
25 facturer, given such term in section 1927(k)(1), with

1 respect to a covered outpatient drug of a manufac-
2 turer for a rebate period under section 1927.”.

3 (b) CONFORMING AMENDMENTS.—

4 (1) TO PART B ASP CALCULATION.—Section
5 1847A(c)(3) of the Social Security Act (42 U.S.C.
6 1395w-3a(c)(3)), as amended by section 201(c)(1),
7 is further amended by striking “section 1927 or sec-
8 tion 1834(z)” and inserting “section 1927, section
9 1834(z), or section 1860D-14B”.

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

17 (3) COORDINATION WITH MEDICAID REBATE IN-
18 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
19 of the Social Security Act (42 U.S.C. 1396r-
20 8(b)(3)(D)(i)), as amended by section 201(c)(3), is
21 further amended by striking “or section 1834(z)”
22 and inserting “, section 1834(z), or section 1860D-
23 14B”.

1 **SEC. 203. PROVISION REGARDING INFLATION REBATES**
2 **FOR GROUP HEALTH PLANS AND GROUP**
3 **HEALTH INSURANCE COVERAGE.**

4 (a) IN GENERAL.—Not later than December 31,
5 2023, the Secretary of Labor, in consultation with the
6 Secretary of Health and Human Services and the Sec-
7 retary of the Treasury, shall submit to Congress a report
8 on—

9 (1) potential models for an agreement process
10 with manufacturers of prescription drugs under
11 which such manufacturers provide for inflation re-
12 bates with respect to such drugs that are furnished
13 or dispensed to participants and beneficiaries of
14 group health plans and health insurance coverage of-
15 fered in the group market in a manner similar to
16 how manufacturers provide for rebates under section
17 1834(z) of the Social Security Act, as added by sec-
18 tion 201, and section 1860D–14B of such Act, as
19 added by section 202, with respect to prescription
20 drugs that are furnished or dispensed under part B
21 of title XVIII of such Act and part D of such title,
22 respectively; and

23 (2) potential models for enforcement mecha-
24 nisms with respect to such an agreement process
25 that ensure that such inflation rebates are propor-
26 tionally distributed, with respect to costs, to group

1 health plans and health insurance issuers offering
2 health insurance coverage in the group market, to
3 participants and beneficiaries of such plans and cov-
4 erage, or to both.

5 (b) REGULATIONS.—Not later than December 31,
6 2024, the Secretary of Labor shall, in consultation with
7 the Secretary of Health and Human Services and the Sec-
8 retary of the Treasury, promulgate regulations to imple-
9 ment a model described in subsection (a)(1) and a model
10 described in subsection (a)(2), if the Secretary determines
11 that—

12 (1) the prices of a sufficient number (as deter-
13 mined by the Secretary) of drugs described in sub-
14 section (a)(1) have increased over a period of time
15 (as determined by the Secretary) at a percentage
16 that exceeds the percentage by which the consumer
17 price index for all urban consumers (United States
18 city average) has increased over such period; and

19 (2) such model described in subsection (a)(1)
20 and such model described in subsection (a)(2) are
21 feasible.

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 2023, 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(z) 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 2023, 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, the Secretary
19 of Labor, and the Secretary of the Treasury appropriate
20 data 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, the Secretary of Labor,
 3 and the Secretary of the Treasury appropriate data as
 4 necessary for the Secretaries to obtain information needed
 5 to 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 2024 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 2024 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 2024,” after “paragraph
2 (4),”; and

3 (ii) in clause (ii)(III), by striking
4 “and each subsequent year” and inserting
5 “through 2023”; 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 2024,” 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 2023”; 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 2023”;

20 (2) in paragraph (3)(A)—

21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2024,” 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 2023”; 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 2024,
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 2024 and each suc-
25 ceeding year, \$0.”; and

(ii) in clause (ii), by striking “clause (i)(I)” and inserting “clause (i)(I)(aa)”;
(B) in subparagraph (B)—

(i) in clause (i)—

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

(II) in subclause (VI)—

(aa) by striking “for a subsequent year” and inserting “for each of years 2021 through 2023”; and

(bb) by striking the period at the end and inserting a semicolon; and

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

“(VII) for 2024, is equal to \$2,000; or

“(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.”; and

1 (ii) in clause (ii), by striking “clause
2 (i)(II)” and inserting “clause (i)”;

3 (C) in subparagraph (C)(i), by striking
4 “and for amounts” and inserting “and, for a
5 year preceding 2024, for amounts”; and

6 (D) in subparagraph (E), by striking “In
7 applying” and inserting “For each of years
8 2011 through 2023, in applying”.

9 (b) DECREASING REINSURANCE PAYMENT
10 AMOUNT.—Section 1860D–15(b)(1) of the Social Security
11 Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting
12 after “80 percent” the following: “(or, with respect to a
13 coverage year after 2023, 20 percent)”.

14 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

21 **“(a) ESTABLISHMENT.—**The Secretary shall estab-
22 lish a manufacturer discount program (in this section re-
23 ferred to as the ‘program’). Under the program, the Sec-
24 retary shall enter into agreements described in subsection
25 (b) with manufacturers and provide for the performance

1 of the duties described in subsection (c). The Secretary
2 shall establish a model agreement for use under the pro-
3 gram by not later than January 1, 2023, in consultation
4 with manufacturers, and allow for comment on such model
5 agreement.

6 “(b) TERMS OF AGREEMENT.—

7 “(1) IN GENERAL.—

8 “(A) AGREEMENT.—An agreement under
9 this section shall require the manufacturer to
10 provide applicable beneficiaries access to dis-
11 counted prices for applicable drugs of the man-
12 ufacturer that are dispensed on or after Janu-
13 ary 1, 2024.

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

20 “(C) TIMING OF AGREEMENT.—

21 “(i) SPECIAL RULE FOR 2024.—In
22 order for an agreement with a manufac-
23 turer to be in effect under this section with
24 respect to the period beginning on January
25 1, 2024, and ending on December 31,

1 2024, the manufacturer shall enter into
2 such agreement not later than 30 days
3 after the date of the establishment of a
4 model agreement under subsection (a).

5 “(ii) 2025 AND SUBSEQUENT
6 YEARS.—In order for an agreement with a
7 manufacturer to be in effect under this
8 section with respect to plan year 2025 or
9 a subsequent plan year, the manufacturer
10 shall enter into such agreement (or such
11 agreement shall be renewed under para-
12 graph (4)(A)) not later than January 30 of
13 the preceding year.

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

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

1 istering the program, including any determination
2 under subparagraph (A) of subsection (c)(1) or pro-
3 cedures established under such subsection (c)(1).

4 “(4) LENGTH OF AGREEMENT.—

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

11 “(B) TERMINATION.—

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

1 effective date to be repealed if the Sec-
2 retary determines appropriate.

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

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

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

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

22 “(iv) NOTICE TO THIRD PARTY.—The
23 Secretary shall provide notice of such ter-
24 mination to a third party with a contract
25 under subsection (d)(3) within not less

1 than 30 days before the effective date of
2 such termination.

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines
2 appropriate;

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

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

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

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

24 “(5) IMPLEMENTATION.—Notwithstanding any
25 other provision of law, the Secretary may implement

1 the program under this section by program instruc-
2 tion or otherwise.

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

6 “(e) ENFORCEMENT.—

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

10 “(2) CIVIL MONEY PENALTY.—

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

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

24 “(ii) 25 percent of such amount.

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

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

14 “(g) DEFINITIONS.—In this section:

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

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

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

22 “(C) has incurred costs, as determined in
 23 accordance with section 1860D-2(b)(4)(C), for
 24 covered part D drugs in the year that exceed
 25 the annual deductible with respect to such indi-

1 vidual for such year, as specified in section
2 1860D–2(b)(1), section 1860D–14(a)(1)(B), or
3 section 1860D–14(a)(2)(B), as applicable.

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

6 “(A) means a covered part D drug—

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

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

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

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

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

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

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

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

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

16 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(h) SUNSET OF PROGRAM.—

4 “(1) IN GENERAL.—The program shall not
5 apply with respect to applicable drugs dispensed on
6 or after January 1, 2024, 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, 2024, 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 2024 and each subse-
 2 quent year, the manufacturer dis-
 3 counts provided under section 1860D–
 4 14C subtracted from the actuarial
 5 value to produce such bid; and”; and
 6 (B) in subsection (c)(1)(C)—

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

10 “(i) the reinsurance”;

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

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

16 “(ii) for 2024 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 2024, 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 2024 or the annual out-of-pocket threshold
7 specified in subsection (b)(4)(B) for the
8 year for 2024 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 2024, 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 2024, 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 2024, the continuation”;

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

4 (iii) in subparagraph (E), by striking
 5 “The elimination” and inserting “For a
 6 year preceding 2024, 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 2024, 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 2024, 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 2024 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 2024”
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 2023, the Medicare
22 coverage gap discount program under section
23 1860D–14A; and

1 “(B) for 2024 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 2023, an agreement
8 described in subsection (b) of section 1860D–
9 14A with the Secretary; and

10 “(B) for 2024 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 2023, 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 2024 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, 2024, 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, 2024.”.

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 2024 and
21 subsequent plan years.

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

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

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

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

13 “(E) ENROLLEE OPTION REGARDING
14 SPREADING COST-SHARING.—The Secretary
15 shall establish by regulation a process under
16 which, with respect to plan year 2024 and sub-
17 sequent plan years, a prescription drug plan or
18 an MA–PD plan shall, in the case of a part D
19 eligible individual enrolled with such plan for
20 such plan year who is not a subsidy eligible in-
21 dividual (as defined in section 1860D–14(a)(3))
22 and with respect to whom the plan projects that
23 the dispensing of the first fill of a covered part
24 D drug to such individual will result in the indi-
25 vidual incurring costs that are equal to or above
26 the annual out-of-pocket threshold specified in

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

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

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

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

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

“(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

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

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

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

“(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2024, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).”.

TITLE IV—DRUG PRICE TRANSPARENCY

SEC. 401. DRUG PRICE TRANSPARENCY.

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

“SEC. 1150D. REPORTING ON DRUG PRICES.

“(a) DEFINITIONS.—In this section:

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

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

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

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

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

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

25 “(ii) not a preventative vaccine; and

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

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

10 “(b) REPORT.—

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

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

18 “(i) 10 percent or more within a 12-
19 month period beginning on or after Janu-
20 ary 1, 2021; or

21 “(ii) 25 percent or more within a 36-
22 month period beginning on or after Janu-
23 ary 1, 2021;

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, 2023; 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 2023; 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 2023.

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, 2021, 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, 2023.

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
9 Health 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. 1150E. 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-

lie and written in plain language that consumers can readily understand, an annual report—

“(1) summarizing the information reported pursuant to section 1150D;

“(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

“(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 1150D; and

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

“(b) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.”.

TITLE V—NIH, FDA, AND OVERDOSE EPIDEMIC FUNDING Subtitle A—Biomedical Innovation Expansion

SEC. 501. NIH INNOVATION INITIATIVES.

(a) NIH INNOVATION ACCOUNT.—

1 (1) IN GENERAL.—Section 1001(b) of the 21st
2 Century Cures Act (Public Law 114–255) is amend-
3 ed by adding at the end the following:

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

6 “(A) IN GENERAL.—In addition to the
7 funds made available under paragraph (2),
8 there are authorized to be appropriated, and
9 are hereby appropriated, to the Account, out of
10 any monies in the Treasury not otherwise ap-
11 propriated, to be available until expended with-
12 out further appropriation, the following:

13 “(i) For fiscal year 2022,
14 \$255,400,000.

15 “(ii) For fiscal year 2023,
16 \$160,400,000.

17 “(iii) For fiscal year 2024,
18 \$414,600,000.

19 “(iv) For fiscal year 2025,
20 \$547,000,000.

21 “(v) For fiscal year 2026,
22 \$948,000,000.

23 “(vi) For fiscal year 2027,
24 \$842,400,000.

1 “(vii) For fiscal year 2028,
2 \$1,089,600,000.

3 “(viii) For fiscal year 2029,
4 \$1,115,600,000.

5 “(ix) For fiscal year 2030,
6 \$1,170,600,000.

7 “(x) For fiscal year 2031,
8 \$956,400,000.

9 “(B) SUPPLEMENTAL FUNDING FOR CER-
10 TAIN PROJECTS.—Of the total amounts made
11 available under subparagraph (A) for each of
12 fiscal years 2022 through 2031, a total amount
13 not to exceed the following shall be made avail-
14 able for the following categories of NIH Innova-
15 tion Projects:

16 “(i) For projects described in para-
17 graph (4)(A), an amount not to exceed a
18 total of \$2,070,600,000 as follows:

19 “(I) For each of fiscal years
20 2022 and 2024, \$50,000,000.

21 “(II) For fiscal year 2025,
22 \$100,000,000.

23 “(III) For each of fiscal years
24 2026 and 2027, \$300,000,000.

1 “(IV) For each of fiscal years
2 2028 through 2030, \$317,000,000.

3 “(V) For fiscal year 2031,
4 \$319,600,000.

5 “(ii) For projects described in para-
6 graph (4)(B), an amount not to exceed a
7 total of \$2,041,900,000 as follows:

8 “(I) For each of fiscal years
9 2022 and 2024, \$50,000,000.

10 “(II) For fiscal year 2025,
11 \$128,000,000.

12 “(III) For fiscal year 2026,
13 \$209,000,000.

14 “(IV) For fiscal year 2027,
15 \$100,000,000.

16 “(V) For fiscal year 2028,
17 \$325,000,000.

18 “(VI) For fiscal year 2029,
19 \$350,000,000.

20 “(VII) For fiscal year 2030,
21 \$400,000,000.

22 “(VIII) For fiscal year 2031,
23 \$429,900,000.

1 “(iii) For projects described in para-
2 graph (4)(C), an amount not to exceed a
3 total of \$1,558,400,000 as follows:

4 “(I) For each of fiscal years
5 2024 and 2025, \$151,200,000.

6 “(II) For each of fiscal years
7 2026 through 2030, \$251,200,000.

8 “(iv) For projects described in para-
9 graph (4)(D), an amount not to exceed
10 \$15,400,000 for each of fiscal years 2022
11 through 2031.

12 “(C) ADDITIONAL NIH INNOVATION
13 PROJECTS.—In addition to funding NIH Inno-
14 vation Projects pursuant to subparagraph (B),
15 of the total amounts made available under sub-
16 paragraph (A), a total amount not to exceed
17 the following shall be made available for the fol-
18 lowing categories of NIH Innovation Projects:

19 “(i) To support research related to
20 combating antimicrobial resistance and an-
21 tibiotic resistant bacteria, including re-
22 search into new treatments, diagnostics,
23 and vaccines, research, in consultation with
24 the Centers for Disease Control and Pre-
25 vention, into stewardship, and the develop-

1 ment of strategies, in coordination with the
2 Biomedical Advanced Research and Devel-
3 opment Authority under section 319L of
4 the Public Health Service Act, to support
5 commercialization of new antibiotics, not
6 to exceed a total of \$1,144,500,000, as fol-
7 lows:

8 “(I) For each of fiscal years
9 2022 through 2025, \$100,000,000.

10 “(II) For each of fiscal years
11 2026 and 2027, \$120,000,000.

12 “(III) For each of fiscal years
13 2028 through 2030, \$125,000,000.

14 “(IV) For fiscal year 2031,
15 \$129,500,000.

16 “(ii) To support research and re-
17 search activities related to rare diseases or
18 conditions, including studies or analyses
19 that help to better understand the natural
20 history of a rare disease or condition and
21 translational studies related to rare dis-
22 eases or conditions, not to exceed a total of
23 \$530,600,000, as follows:

24 “(I) For fiscal year 2022,
25 \$40,000,000.

1 “(II) For fiscal year 2023,
2 \$45,000,000.

3 “(III) For fiscal year 2024,
4 \$48,000,000.

5 “(IV) For each of fiscal years
6 2025 and 2026, \$52,400,000.

7 “(V) For fiscal year 2027,
8 \$55,800,000.

9 “(VI) For fiscal year 2028,
10 \$56,000,000.

11 “(VII) For fiscal year 2029,
12 \$57,000,000.

13 “(VIII) For each of fiscal years
14 2030 and 2031, \$62,000,000.”.

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

18 (A) in subsection (a), by striking “sub-
19 section (b)(4)” and inserting “subsections
20 (b)(4) and (b)(5)”;

21 (B) in subsection (b)(1), by striking “para-
22 graph (4)” and inserting “paragraphs (4) and
23 (5)”;

1 (C) in subsection (c)(2)(A)(ii), by inserting
2 “or pursuant to subsection (b)(5)” after “sub-
3 section (b)(3)”; and

4 (D) in subsection (d), by inserting “or pur-
5 suant to subsection (b)(5)” after “subsection
6 (b)(3)”.

7 (b) WORKPLAN.—Section 1001(c)(1) of the 21st
8 Century Cures Act (Public Law 114–255) is amended by
9 adding at the end the following:

10 “(D) UPDATES.—The Director of NIH
11 shall, after seeking recommendations in accord-
12 ance with the process described in subpara-
13 graph (C), update the work plan submitted
14 under this subsection for each of fiscal years
15 2022 through 2031 to reflect the amendments
16 made to this section by the Elijah E. Cum-
17 mings Lower Drug Costs Now Act.”.

18 (c) ANNUAL REPORTS.—Section 1001(c)(2)(A) of the
19 21st Century Cures Act (Public Law 114–255) is amend-
20 ed by striking “2027” and inserting “2031”.

21 (d) SUNSET.—Section 1001(e) of the 21st Century
22 Cures Act (Public Law 114–255) is amended by striking
23 “September 30, 2026” and inserting “September 30,
24 2031”.

1 **SEC. 502. NIH CLINICAL TRIAL.**

2 Part A of title IV of the Public Health Service Act
3 (42 U.S.C. 281 et seq.) is amended by adding at the end
4 the following:

5 **“SEC. 4040. CLINICAL TRIAL ACCELERATION PILOT INITIA-**
6 **TIVE.**

7 “(a) ESTABLISHMENT OF PILOT PROGRAM.—The
8 Secretary, acting through the Director of the National In-
9 stitutes of Health, shall, not later than 2 years after the
10 date of enactment of this Act, establish and implement
11 a pilot program to award multi-year contracts to eligible
12 entities to support phase II clinical trials and phase III
13 clinical trials—

14 “(1) to promote innovation in treatments and
15 technologies supporting the advanced research and
16 development and production of high need cures; and

17 “(2) to provide support for the development of
18 medical products and therapies.

19 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
20 assistance under the pilot program established under sub-
21 section (a), an entity shall—

22 “(1) be seeking to market a medical product or
23 therapy that is the subject of clinical trial or trials
24 to be supported using such assistance;

25 “(2) be a public or private entity, which may
26 include a private or public research institution, a

1 contract research organization, an institution of
2 higher education (as defined in section 101 of the
3 Higher Education Act of 1965 (20 U.S.C. 1001)), a
4 medical center, a biotechnology company, or an aca-
5 demic research institution; and

6 “(3) comply with requirements of the Federal
7 Food, Drug, and Cosmetic Act and section 351 of
8 this Act, as applicable, at all stages of development,
9 manufacturing, review, approval, and safety surveil-
10 lance of a medical product.

11 “(c) DUTIES.—The Secretary, acting through the Di-
12 rector of National Institutes of Health, shall—

13 “(1) in establishing the pilot program under
14 subsection (a), consult with—

15 “(A) the Director of the National Center
16 for Advancing Translational Sciences and the
17 other national research institutes in considering
18 their requests for new or expanded clinical trial
19 support efforts; and

20 “(B) the Commissioner of Food and Drugs
21 and any other head of a Federal agency as the
22 Secretary determines to be appropriate to en-
23 sure coordination and efficiently advance clin-
24 ical trial activities;

1 “(2) in implementing the pilot program under
2 subsection (a), consider consulting with patients and
3 patient advocates; and

4 “(3) in awarding contracts under the pilot pro-
5 gram under subsection (a), consider—

6 “(A) the expected health impacts of the
7 clinical trial or trials to be supported under the
8 contract; and

9 “(B) the degree to which the medical prod-
10 uct or therapy that is the subject of such clin-
11 ical trial or trials is a high need cure.

12 “(d) EXCLUSION.—A contract may not be awarded
13 under the pilot program under subsection (a) if the drug
14 that is the subject of the clinical trial or trials to be sup-
15 ported under the contract is a drug designated under sec-
16 tion 526 of the Federal Food, Drug, and Cosmetic Act
17 as a drug for a rare disease or condition.

18 “(e) NIH CLINICAL TRIAL ACCELERATOR AC-
19 COUNT.—

20 “(1) ESTABLISHMENT.—There is established in
21 the Treasury an account, to be known as the ‘NIH
22 Clinical Trial Accelerator Account’ (referred to in
23 this section as the ‘Account’), for purposes of car-
24 rying out this section.

1 “(2) TRANSFER OF DIRECT SPENDING SAV-
2 INGS.—There shall be transferred to the Account
3 from the general fund of the Treasury,
4 \$400,000,000 for each of fiscal years 2022 through
5 2026, to be available until expended without further
6 appropriation.

7 “(3) WORK PLAN.—Not later than 180 days
8 after the date of enactment of this Act, the Sec-
9 retary shall submit to the Committee on Energy and
10 Commerce of the House of Representatives and the
11 Committee on Health, Education, Labor, and Pen-
12 sions of the Senate a work plan that includes the
13 proposed implementation of this section and the pro-
14 posed allocation of funds in the Account.

15 “(f) REPORTS TO CONGRESS.—Not later than Octo-
16 ber 1 of each fiscal year, the Secretary shall submit to
17 the Committee on Energy and Commerce of the House
18 of Representatives and the Committee on Health, Edu-
19 cation, Labor, and Pensions of the Senate a report on—

20 “(1) the implementation of this section;

21 “(2) any available results on phase II clinical
22 trials and phase III clinical trials supported under
23 this section during such fiscal year; and

24 “(3) the extent to which Federal funds are obli-
25 gated to support such clinical trials, including the

1 specific amount of such support and awards pursu-
2 ant to an allocation from the Account under sub-
3 section (e).

4 “(g) DEFINITIONS.—In this section:

5 “(1) PHASE II CLINICAL TRIAL.—The term
6 ‘phase II clinical trial’ means a phase II clinical in-
7 vestigation, as described in section 312.21 of title
8 21, Code of Federal Regulations (or any successor
9 regulations).

10 “(2) PHASE III CLINICAL TRIALS.—The term
11 ‘phase III clinical trial’ means a phase III clinical
12 investigation, as described in section 312.21 of title
13 21, Code of Federal Regulations (or any successor
14 regulations).

15 “(3) HIGH NEED CURE.—The term ‘high need
16 cure’ has the meaning given such term in section
17 480(a)(3).”.

18 **SEC. 503. INNOVATION NETWORK.**

19 Part A of title IV of the Public Health Service Act
20 (42 U.S.C. 281 et seq.), as amended by section 502, is
21 further amended by adding at the end the following:

22 **“SEC. 404P. INNOVATION NETWORK.**

23 “(a) FUNDS.—The Director of NIH shall award
24 grants or contracts to eligible entities to develop, expand,
25 and enhance the commercialization of biomedical products.

1 “(b) ELIGIBLE ENTITY.—In this section, the term
2 ‘eligible entity’ means an entity receiving funding under—

3 “(1) the Small Business Innovation Research
4 program of the National Institutes of Health; or

5 “(2) the Small Business Technology Transfer
6 program of the National Institutes of Health.

7 “(c) USE OF FUNDS.—An eligible entity shall use the
8 funds received through such grant or contract to sup-
9 port—

10 “(1) the Commercialization Readiness Pilot
11 program of the National Institutes of Health;

12 “(2) the Innovation Corps program of the Na-
13 tional Institutes of Health;

14 “(3) the Commercialization Accelerator pro-
15 gram of the National Institutes of Health;

16 “(4) the Commercialization Assistance program
17 of the National Institutes of Health; and

18 “(5) such other programs and activities as the
19 Director of NIH determines to be appropriate, to
20 support the commercialization stage of research,
21 later stage research and development, technology
22 transfer, and commercialization technical assistance.

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section

1 \$100,000,000 for each of fiscal years 2022 through 2026,
2 to be available until expended.”.

3 **Subtitle B—Investing in Safety and**
4 **Innovation**

5 **SEC. 511. FOOD AND DRUG ADMINISTRATION.**

6 (a) FDA INNOVATION ACCOUNT.—

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

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

13 (B) by adding at the end the following new
14 paragraph:

15 “(5) SUPPLEMENTAL FUNDING AND ADDI-
16 TIONAL ACTIVITIES.—

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

24 “(i) For fiscal year 2022,
25 \$417,500,000.

1 “(ii) For each of fiscal years 2023
2 and 2024, \$157,500,000.

3 “(iii) For each of fiscal years 2025
4 through 2027, \$152,500,000.

5 “(iv) For each of fiscal years 2028
6 through 2031, \$202,500,000.

7 “(B) SUPPLEMENTAL FUNDING FOR CER-
8 TAIN ACTIVITIES.—Of the total amounts made
9 available under subparagraph (A) for each of
10 fiscal years 2028 through 2031, a total amount
11 not to exceed \$50,000,000 for each such fiscal
12 year, shall be made available for the activities
13 under subtitles A through F (including the
14 amendments made by such subtitles) of title III
15 of this Act and section 1014 (relating to Inter-
16 center Institutes) of the Federal Food, Drug,
17 and Cosmetic Act.

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

1 “(i) For modernization of the tech-
2 nical infrastructure of the Food and Drug
3 Administration, including enhancements
4 such as interoperability across the agency,
5 and additional capabilities to develop an
6 advanced information technology infra-
7 structure to support the agency’s regu-
8 latory mission:

9 “(I) For fiscal year 2022,
10 \$180,000,000.

11 “(II) For each of fiscal years
12 2023 through 2031, \$60,000,000.

13 “(ii) For support for continuous man-
14 ufacturing of drugs and biological prod-
15 ucts, including complex biological products
16 such as regenerative medicine therapies,
17 through grants to institutions of higher
18 education and nonprofit organizations and
19 other appropriate mechanisms, for each of
20 fiscal years 2022 through 2031,
21 \$20,000,000.

22 “(iii) For support for the Commis-
23 sioner of Food and Drugs to engage ex-
24 perts, such as through the formation and
25 operation of public-private partnerships or

1 other appropriate collaborative efforts, to
2 advance the development and delivery of
3 individualized human gene therapy prod-
4 ucts:

5 “(I) For fiscal year 2022,
6 \$50,000,000.

7 “(II) For each of fiscal years
8 2023 through 2031, \$10,000,000.

9 “(iv) For support for inspections, en-
10 forcement, and quality surveillance activi-
11 ties across the Food and Drug Administra-
12 tion, including foreign and domestic in-
13 spections across products, for each of fiscal
14 years 2022 through 2031, \$20,000,000.

15 “(v) For support for activities of the
16 Food and Drug Administration related to
17 customs and border protection to provide
18 improvements to technologies, inspection
19 capacity, and sites of import (including
20 international mail facilities) in which the
21 Food and Drug Administration operates,
22 for each of fiscal years 2022 through
23 2031, \$10,000,000.

24 “(vi) To further advance the develop-
25 ment of a coordinated postmarket surveil-

1 lance system for all medical products, in-
2 cluding drugs, biological products, and de-
3 vices, linked to electronic health records in
4 furtherance of the Food and Drug Admin-
5 istration’s postmarket surveillance capabili-
6 ties:

7 “(I) For fiscal year 2022,
8 \$112,500,000.

9 “(II) For each of fiscal years
10 2023 through 2031, \$12,500,000.

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

16 “(I) For each of fiscal years
17 2022 through 2024, \$10,000,000.

18 “(II) For each of fiscal years
19 2025 through 2031, \$5,000,000.

20 “(viii) For carrying out section 714A
21 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 379d–3a; relating to hiring
23 authority for scientific, technical, and pro-
24 fessional personnel), for each of fiscal
25 years 2022 through 2031, \$2,500,000.

1 “(ix) For the Food and Drug Admin-
2 istration to support improvements to the
3 technological infrastructure for reporting
4 and analysis of adverse events associated
5 with the use of drugs and biological prod-
6 ucts, for each of fiscal years 2022 through
7 2031, \$12,500,000.”.

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

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

16 (B) in subsection (d)—

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

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

23 (b) ANNUAL REPORT.—Section 1002(c)(2)(A) of the
24 21st Century Cures Act (Public Law 114–255) is amend-

1 ed, in the matter preceding clause (i), by striking “2026”
2 and inserting “2032”.

3 (c) SUNSET.—Section 1002(e) of the 21st Century
4 Cures Act (Public Law 114–255) is amended by striking
5 “September 30, 2025” and inserting “September 30,
6 2030”.

7 **SEC. 512. STUDY ON HIGH-RISK, HIGH-REWARD DRUGS.**

8 (a) IN GENERAL.—Not later than 180 days after the
9 date of enactment of this Act, the Secretary of Health and
10 Human Services shall conduct a study to identify—

11 (1) diseases or conditions that lack a treatment
12 approved by the Food and Drug Administration and
13 instances in which development of a treatment for
14 such diseases or conditions could fill an unmet med-
15 ical need for the treatment of a serious or life-
16 threatening disease or condition or a rare disease or
17 condition; and

18 (2) appropriate incentives that would lead to
19 the development, approval, and marketing of such
20 treatments.

21 (b) REPORT TO CONGRESS; RECOMMENDATIONS.—
22 Not later than one year after the date of enactment of
23 this Act, the Secretary shall submit to the Congress a re-
24 port that includes—

1 (1) findings from the study under subsection
2 (a); and

3 (2) recommendations regarding legislation nec-
4 essary to create appropriate incentives identified
5 pursuant to subsection (a)(2).

6 **Subtitle C—Overdose Epidemic** 7 **Response**

8 **SEC. 521. OVERDOSE EPIDEMIC RESPONSE FUND.**

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

17 (b) OPIOID EPIDEMIC RESPONSE FUND.—

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

24 (2) FUNDING.—There is authorized to be ap-
25 propriated, and there is appropriated, to the Fund,

1 out of any monies in the Treasury not otherwise ap-
2 propriated \$2,000,000,000 for each of fiscal years
3 2022 through 2026.

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

10 (c) PROGRAMS AND ACTIVITIES.—Of the total
11 amount in the Fund for each of fiscal years 2022 through
12 2026, such amount shall be allocated as follows:

13 (1) SAMHSA.—For the Substance Abuse and
14 Mental Health Services Administration to carry out
15 programs and activities pursuant to section 522,
16 \$1,500,000,000 for each of fiscal years 2022
17 through 2026.

18 (2) CDC.—For the Centers for Disease Control
19 and Prevention to carry out programs and activities
20 pursuant to section 523, \$120,000,000 for each of
21 fiscal years 2022 through 2026.

22 (3) FDA.—For the Food and Drug Adminis-
23 tration to carry out programs and activities pursu-
24 ant to section 524, \$10,000,000 for each of fiscal
25 years 2022 through 2026.

1 (4) NIH.—For the National Institutes of
2 Health to carry out programs and activities pursu-
3 ant to section 525, \$240,000,000 for each of fiscal
4 years 2022 through 2026.

5 (5) HRSA.—For the Health Resources and
6 Services Administration to carry out programs and
7 activities pursuant to section 526, \$90,000,000 for
8 each of fiscal years 2022 through 2026.

9 (6) ACF.—For the Administration for Children
10 and Families to carry out programs and activities
11 pursuant to section 527, \$40,000,000 for each of
12 fiscal years 2022 through 2026.

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 2022
2 through 2026 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 2023 through 2027, 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. 522. SUBSTANCE ABUSE AND MENTAL HEALTH SERV-**
13 **ICES ADMINISTRATION.**

14 (a) IN GENERAL.—The entirety of the funds made
15 available pursuant to section 521(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—

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

6 (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).

14 (c) RESERVATIONS.—Of the amount made available pursuant to section 521(c)(1) for a fiscal year—

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

19 (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.

22 **SEC. 523. CENTERS FOR DISEASE CONTROL AND PREVENTION.**

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

1 521(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 521(c)(2) for carrying out this section,
14 not more than 20 percent may be used for intramural pur-
15 poses.

16 **SEC. 524. FOOD AND DRUG ADMINISTRATION.**

17 The entirety of the funds made available pursuant to
18 section 521(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. 525. NATIONAL INSTITUTES OF HEALTH.**

8 The entirety of the funds made available pursuant to
9 section 521(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. 526. HEALTH RESOURCES AND SERVICES ADMINIS-**
4 **TRATION.**

5 The entirety of the funds made available pursuant to
6 section 521(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. 527. ADMINISTRATION FOR CHILDREN AND FAMILIES.**

15 Of the funds made available pursuant to section
16 521(c)(6) for each of fiscal years 2022 through 2026,
17 \$40,000,000 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.).

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