

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.

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## 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

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## 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

and not based on the specific formulation or package size or package type), as computed (as of the date of publication of such drug as a selected drug under section 1192(a)) in all countries described in clause (ii) of subparagraph (B) that are applicable countries (as described in clause (i) of such subparagraph) with respect to such drug.

“(B) APPLICABLE COUNTRIES.—

“(i) IN GENERAL.—For purposes of subparagraph (A), a country described in clause (ii) is an applicable country described in this clause with respect to a drug if there is available an average price for any unit for the drug for sales of such drug in such country.

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

“(I) Australia.

“(II) Canada.

“(III) France.

“(IV) Germany.

“(V) Japan.

“(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-

tion)) on the date of the selected drug publication date, with respect the price applicability year (as applicable);

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

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

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

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

“(A) the highest-ranking officer or employee of the Department of Health and Human Services (as determined by the organizational chart of the Department) that does not have a conflict under this subsection; and

“(B) is nominated by the President and confirmed by the Senate with respect to the position.

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(e) 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



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

10 “(2) LENGTH OF AGREEMENT.—

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

18 “(B) TERMINATION.—

19 “(i) BY SECRETARY.—The Secretary  
20 may provide for termination of an agree-  
21 ment under this section for violation of the  
22 requirements of the agreement or other  
23 good cause shown. Such termination shall  
24 not be effective earlier than 30 days after  
25 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

(B) in clause (ii), by striking “for a subsequent year” and inserting “for each of years 2007 through 2023”; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

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

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

“(I) for a year preceding 2024, the greater of—”;

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

(IV) by adding at the end the following:

“(II) for 2024 and each succeeding year, \$0.”; and

1                   (ii) in clause (ii), by striking “clause  
2                   (i)(I)” and inserting “clause (i)(I)(aa)”;  
3                   (B) in subparagraph (B)—  
4                   (i) in clause (i)—  
5                   (I) in subclause (V), by striking  
6                   “or” at the end;  
7                   (II) in subclause (VI)—  
8                   (aa) by striking “for a sub-  
9                   sequent year” and inserting “for  
10                  each of years 2021 through  
11                  2023”; and  
12                  (bb) by striking the period  
13                  at the end and inserting a semi-  
14                  colon; and  
15                  (III) by adding at the end the  
16                  following new subclauses:  
17                  “(VII) for 2024, is equal to  
18                  \$2,000; or  
19                  “(VIII) for a subsequent year, is  
20                  equal to the amount specified in this  
21                  subparagraph for the previous year,  
22                  increased by the annual percentage in-  
23                  crease described in paragraph (6) for  
24                  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-

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

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

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

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

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

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

19 **TITLE V—NIH, FDA, AND**  
 20 **OVERDOSE EPIDEMIC FUNDING**  
 21 **Subtitle A—Biomedical Innovation**  
 22 **Expansion**

23 **SEC. 501. NIH INNOVATION INITIATIVES.**

24 (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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