

116TH CONGRESS
1ST SESSION

H. R. 3

[Report No. 116-]

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

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

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, and Education and Labor, 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

NOVEMBER --, 2019

Reported from the Committee on Education and Labor with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on September 19, 2019]

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) *IN GENERAL.*—*This Act may be cited as the*
 5 *“Lower Drug Costs Now Act of 2019”.*

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

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

Sec. 201. Medicare part B rebate by manufacturers.

Sec. 202. Medicare part D rebate by manufacturers.

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

Sec. 301. Medicare part D benefit redesign.

8 **TITLE I—LOWERING PRICES**
 9 **THROUGH FAIR DRUG PRICE**
 10 **NEGOTIATION**

11 **SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN**
 12 **HIGH-PRICED SINGLE SOURCE DRUGS.**

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

1 **“PART E—FAIR PRICE NEGOTIATION PROGRAM**
2 **TO LOWER PRICES FOR CERTAIN HIGH-**
3 **PRICED SINGLE SOURCE DRUGS**

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

5 *“(a) IN GENERAL.—The Secretary shall establish a*
6 *Fair Price Negotiation Program (in this part referred to*
7 *as the ‘program’). Under the program, with respect to each*
8 *price applicability period, the Secretary shall—*

9 *“(1) publish a list of selected drugs in accord-*
10 *ance with section 1192;*

11 *“(2) enter into agreements with manufacturers of*
12 *selected drugs with respect to such period, in accord-*
13 *ance with section 1193;*

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

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

19 *“(b) DEFINITIONS RELATING TO TIMING.—For pur-*
20 *poses of this part:*

21 *“(1) INITIAL PRICE APPLICABILITY YEAR.—The*
22 *term ‘initial price applicability year’ means a plan*
23 *year (beginning with plan year 2023) or, if agreed to*
24 *in an agreement under section 1193 by the Secretary*
25 *and manufacturer involved, a period of more than*

1 *one plan year (beginning on or after January 1,*
2 *2023).*

3 *“(2) PRICE APPLICABILITY PERIOD.—The term*
4 *‘price applicability period’ means, with respect to a*
5 *drug, the period beginning with the initial price ap-*
6 *plicability year with respect to which such drug is a*
7 *selected drug and ending with the last plan year dur-*
8 *ing which the drug is a selected drug.*

9 *“(3) SELECTED DRUG PUBLICATION DATE.—The*
10 *term ‘selected drug publication date’ means, with re-*
11 *spect to each initial price applicability year, April 15*
12 *of the plan year that begins 2 years prior to such*
13 *year.*

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

18 *“(A) beginning on the sooner of—*

19 *“(i) the date on which the manufac-*
20 *turer of the drug and the Secretary enter*
21 *into an agreement under section 1193 with*
22 *respect to such drug; or*

23 *“(ii) June 15 following the selected*
24 *drug publication date with respect to such*
25 *selected drug; and*

1 “(B) ending on March 31 of the year that
2 begins one year prior to the initial price appli-
3 cability year.

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

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

8 “(A) in the case such drug is furnished or
9 dispensed to the individual at a pharmacy or by
10 a mail order service—

11 “(i) an individual who is enrolled
12 under a prescription drug plan under part
13 D of title XVIII or an MA–PD plan under
14 part C of such title under which coverage is
15 provided for such drug; and

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

1 “(B) in the case such drug is furnished or
2 administered to the individual by a hospital,
3 physician, or other provider of services or sup-
4 plier—

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

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

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

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

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

18 “(B) *APPLICABLE COUNTRIES.*—

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

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

4 “(I) *Australia.*

5 “(II) *Canada.*

6 “(III) *France.*

7 “(IV) *Germany.*

8 “(V) *Japan.*

9 “(VI) *The United Kingdom.*

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

14 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
15 **AS SELECTED DRUGS.**

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

20 “(1)(A) *with respect to an initial price applica-*
21 *bility year during the period beginning with 2023*
22 *and ending with 2027, at least 25 negotiation-eligible*
23 *drugs described in subparagraphs (A) and (B), but*
24 *not subparagraph (C), of subsection (d)(1) (or, with*
25 *respect to an initial price applicability year during*

1 *such period beginning after 2023, the maximum num-*
2 *ber (if such number is less than 25) of such negotia-*
3 *tion-eligible drugs for the year) with respect to such*
4 *year;*

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

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

22 *“(2) all negotiation-eligible drugs described in*
23 *subparagraph (C) of such subsection with respect to*
24 *such year; and*

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

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

16 “(b) *SELECTION OF DRUGS.—In carrying out sub-*
17 *section (a)(1) the Secretary shall select for inclusion on the*
18 *published list described in subsection (a) with respect to a*
19 *price applicability period, the negotiation-eligible drugs*
20 *that the Secretary projects will result in the greatest savings*
21 *to the Federal Government or fair price eligible individuals*
22 *during the price applicability period. In making this pro-*
23 *jection of savings for drugs for which there is an AIM price*
24 *for a price applicability period, the savings shall be pro-*
25 *jected across different dosage forms and strengths of the*

1 *drugs and not based on the specific formulation or package*
2 *size or package type of the drugs, taking into consideration*
3 *both the volume of drugs for which payment is made, to*
4 *the extent such data is available, and the amount by which*
5 *the net price for the drugs exceeds the AIM price for the*
6 *drugs.*

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

14 “(1) *are approved or licensed (as applicable)—*

15 “(A) *under section 505(j) of the Federal*
16 *Food, Drug, and Cosmetic Act using such drug*
17 *as the listed drug; or*

18 “(B) *under section 351(k) of the Public*
19 *Health Service Act using such drug as the ref-*
20 *erence product; and*

21 “(2) *continue to be marketed.*

22 “(d) *NEGOTIATION-ELIGIBLE DRUG.—*

23 “(1) *IN GENERAL.—For purposes of this part,*
24 *the term ‘negotiation-eligible drug’ means, with re-*
25 *spect to the selected drug publication date with re-*

1 *spect to an initial price applicability year, a quali-*
2 *fying single source drug, as defined in subsection (e),*
3 *that meets any of the following criteria:*

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

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

20 *“(C) INSULIN.—The drug is a qualifying*
21 *single source drug described in subsection (e)(3).*

22 *“(2) CLARIFICATION.—In determining whether a*
23 *qualifying single source drug satisfies any of the cri-*
24 *teria described in paragraph (1), the Secretary shall,*
25 *to the extent practicable, use data that is aggregated*

1 *across dosage forms and strengths of the drug and not*
2 *based on the specific formulation or package size or*
3 *package type of the drug.*

4 “(3) *PUBLICATION.*—*Not later than the selected*
5 *drug publication date with respect to an initial price*
6 *applicability year, the Secretary shall publish in the*
7 *Federal Register a list of negotiation-eligible drugs*
8 *with respect to such selected drug publication date.*

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

12 “(1) *DRUG PRODUCTS.*—*A drug that—*

13 “(A) *is approved under section 505(c) of the*
14 *Federal Food, Drug, and Cosmetic Act and con-*
15 *tinues to be marketed pursuant to such approval;*
16 *and*

17 “(B) *is not the listed drug for any drug*
18 *that is approved and continues to be marketed*
19 *under section 505(j) of such Act.*

20 “(2) *BIOLOGICAL PRODUCTS.*—*A biological prod-*
21 *uct that—*

22 “(A) *is licensed under section 351(a) of the*
23 *Public Health Service Act, including any prod-*
24 *uct that has been deemed to be licensed under*
25 *section 351 of such Act pursuant to section*

1 7002(e)(4) of the *Biologics Price Competition*
2 *and Innovation Act of 2009, and continues to be*
3 *marketed under section 351 of such Act; and*

4 “(B) is not the reference product for any bi-
5 *ological product that is licensed and continues to*
6 *be marketed under section 351(k) of such Act.*

7 “(3) *INSULIN PRODUCT.*—Notwithstanding para-
8 *graphs (1) and (2), any insulin product that is ap-*
9 *proved under subsection (c) or (j) of section 505 of the*
10 *Federal Food, Drug, and Cosmetic Act or licensed*
11 *under subsection (a) or (k) of section 351 of the Pub-*
12 *lic Health Service Act and continues to be marketed*
13 *under such section 505 or 351, including any insulin*
14 *product that has been deemed to be licensed under sec-*
15 *tion 351(a) of the Public Health Service Act pursuant*
16 *to section 7002(e)(4) of the Biologics Price Competi-*
17 *tion and Innovation Act of 2009 and continues to be*
18 *marketed pursuant to such licensure.*

19 *For purposes of applying paragraphs (1) and (2), a drug*
20 *or biological product that is marketed by the same sponsor*
21 *or manufacturer (or an affiliate thereof or a cross-licensed*
22 *producer or distributor) as the listed drug or reference prod-*
23 *uct described in such respective paragraph shall not be*
24 *taken into consideration.*

1 “(f) *INFORMATION ON INTERNATIONAL DRUG*
2 *PRICES.*—*For purposes of determining which negotiation-*
3 *eligible drugs to select under subsection (a) and, in the case*
4 *of such drugs that are selected drugs, to determine the max-*
5 *imum fair price for such a drug and whether such max-*
6 *imum fair price should be renegotiated under section 1194,*
7 *the Secretary shall use data relating to the AIM price with*
8 *respect to such drug as available or provided to the Sec-*
9 *retary and shall on an ongoing basis request from manufac-*
10 *turers of selected drugs information on the AIM price of*
11 *such a drug.*

12 “(g) *NEW-ENTRANT NEGOTIATION-ELIGIBLE DRUGS.*—

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

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

22 “(B) *that the Secretary determines under*
23 *paragraph (2) is likely to be a negotiation-eli-*
24 *gible drug with respect to the subsequent selected*
25 *drug publication date.*

1 “(2) *DETERMINATION.*—*In the case of a quali-*
2 *ifying single source drug that meets the criteria de-*
3 *scribed in subparagraphs (A) and (B) of paragraph*
4 *(1), with respect to an initial price applicability*
5 *year, if the wholesale acquisition cost at which such*
6 *drug is first marketed in the United States is equal*
7 *to or greater than the median household income (as*
8 *determined according to the most recent data collected*
9 *by the United States Census Bureau), the Secretary*
10 *shall determine before the selected drug publication*
11 *date with respect to the initial price applicability*
12 *year, if the drug is likely to be included as a negotia-*
13 *tion-eligible drug with respect to the subsequent se-*
14 *lected drug publication date, based on the projected*
15 *spending under title XVIII or in the United States on*
16 *such drug. For purposes of this paragraph the term*
17 *‘United States’ includes the 50 States, the District of*
18 *Columbia, and the territories of the United States.*

19 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

20 “(a) *IN GENERAL.*—*For purposes of section*
21 *1191(a)(2), the Secretary shall enter into agreements with*
22 *manufacturers of selected drugs with respect to a price ap-*
23 *plicability period, by not later than June 15 following the*
24 *selected drug publication date with respect to such selected*
25 *drug, under which—*

1 “(1) during the voluntary negotiation period for
2 the initial price applicability year for the selected
3 drug, the Secretary and manufacturer, in accordance
4 with section 1194, negotiate to determine (and, by not
5 later than the last date of such period and in accord-
6 ance with subsection (c), agree to) a maximum fair
7 price for such selected drug of the manufacturer in
8 order to provide access to such price—

9 “(A) to fair price eligible individuals who
10 with respect to such drug are described in sub-
11 paragraph (A) of section 1191(c)(1) and are fur-
12 nished or dispensed such drug during, subject to
13 subparagraph (2), the price applicability period;
14 and

15 “(B) to hospitals, physicians, and other
16 providers of services and suppliers with respect
17 to fair price eligible individuals who with respect
18 to such drug are described in subparagraph (B)
19 of such section and are furnished or adminis-
20 tered such drug during, subject to subparagraph
21 (2), the price applicability period;

22 “(2) the Secretary and the manufacturer shall,
23 in accordance with a process and during a period
24 specified by the Secretary pursuant to rulemaking, re-
25 negotiate (and, by not later than the last date of such

1 *period and in accordance with subsection (c), agree*
2 *to) the maximum fair price for such drug if the Sec-*
3 *retary determines that there is a material change in*
4 *any of the factors described in section 1194(d) relat-*
5 *ing to the drug, including changes in the AIM price*
6 *for such drug, in order to provide access to such max-*
7 *imum fair price (as so renegotiated)—*

8 *“(A) to fair price eligible individuals who*
9 *with respect to such drug are described in sub-*
10 *paragraph (A) of section 1191(c)(1) and are fur-*
11 *nished or dispensed such drug during any year*
12 *during the price applicability period (beginning*
13 *after such renegotiation) with respect to such se-*
14 *lected drug; and*

15 *“(B) to hospitals, physicians, and other*
16 *providers of services and suppliers with respect*
17 *to fair price eligible individuals who with respect*
18 *to such drug are described in subparagraph (B)*
19 *of such section and are furnished or adminis-*
20 *tered such drug during any year described in*
21 *subparagraph (A);*

22 *“(3) the maximum fair price (including as re-*
23 *negotiated pursuant to paragraph (2)), with respect*
24 *to such a selected drug, shall be provided to fair price*
25 *eligible individuals, who with respect to such drug are*

1 *described in subparagraph (A) of section 1191(c)(1),*
2 *at the pharmacy or by a mail order service at the*
3 *point-of-sale of such drug;*

4 *“(4) the manufacturer, subject to subsection (c),*
5 *submits to the Secretary, in a form and manner spec-*
6 *ified by the Secretary—*

7 *“(A) for the voluntary negotiation period*
8 *for the price applicability period (and, if appli-*
9 *cable, before any period of renegotiation specified*
10 *pursuant to paragraph (2)) with respect to such*
11 *drug all information that the Secretary requires*
12 *to carry out the negotiation (or renegotiation*
13 *process) under this part, including information*
14 *described in section 1192(f) and section*
15 *1194(d)(1); and*

16 *“(B) on an ongoing basis, information on*
17 *changes in prices for such drug that would affect*
18 *the AIM price for such drug or otherwise provide*
19 *a basis for renegotiation of the maximum fair*
20 *price for such drug pursuant to paragraph (2);*

21 *“(5) the manufacturer agrees that in the case the*
22 *selected drug of a manufacturer is a drug described*
23 *in subsection (c), the manufacturer will, in accord-*
24 *ance with such subsection, make any payment re-*

1 *quired under such subsection with respect to such*
2 *drug; and*

3 “(6) *the manufacturer complies with require-*
4 *ments imposed by the Secretary for purposes of ad-*
5 *ministering the program, including with respect to*
6 *the duties described in section 1196.*

7 “(b) *AGREEMENT IN EFFECT UNTIL DRUG IS NO*
8 *LONGER A SELECTED DRUG.—An agreement entered into*
9 *under this section shall be effective, with respect to a drug,*
10 *until such drug is no longer considered a selected drug*
11 *under section 1192(c).*

12 “(c) *SPECIAL RULE FOR CERTAIN SELECTED DRUGS*
13 *WITHOUT AIM PRICE.—*

14 “(1) *IN GENERAL.—In the case of a selected drug*
15 *for which there is no AIM price available with respect*
16 *to the initial price applicability year for such drug*
17 *and for which an AIM price becomes available begin-*
18 *ning with respect to a subsequent plan year during*
19 *the price applicability period for such drug, if the*
20 *Secretary determines that the amount described in*
21 *paragraph (2)(A) for a unit of such drug is greater*
22 *than the amount described in paragraph (2)(B) for a*
23 *unit of such drug, then by not later than one year*
24 *after the date of such determination, the manufac-*

1 *turer of such selected drug shall pay to the Treasury*
2 *an amount equal to the product of—*

3 *“(A) the difference between such amount de-*
4 *scribed in paragraph (2)(A) for a unit of such*
5 *drug and such amount described in paragraph*
6 *(2)(B) for a unit of such drug; and*

7 *“(B) the number of units of such drug sold*
8 *in the United States, including the 50 States, the*
9 *District of Columbia, and the territories of the*
10 *United States, during the period described in*
11 *paragraph (2)(B).*

12 *“(2) AMOUNTS DESCRIBED.—*

13 *“(A) WEIGHTED AVERAGE PRICE BEFORE*
14 *AIM PRICE AVAILABLE.—For purposes of para-*
15 *graph (1), the amount described in this subpara-*
16 *graph for a selected drug described in such para-*
17 *graph, is the amount equal to the weighted aver-*
18 *age manufacturer price (as defined in section*
19 *1927(k)(1)) for such dosage strength and form for*
20 *the drug during the period beginning with the*
21 *first plan year for which the drug is included on*
22 *the list of negotiation-eligible drugs published*
23 *under section 1192(d) and ending with the last*
24 *plan year during the price applicability period*

1 *for such drug with respect to which there is no*
2 *AIM price available for such drug.*

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

12 “(d) *CONFIDENTIALITY OF INFORMATION.—Informa-*
13 *tion submitted to the Secretary under this part by a manu-*
14 *facturer of a selected drug that is proprietary information*
15 *of such manufacturer (as determined by the Secretary) may*
16 *be used only by the Secretary or disclosed to and used by*
17 *the Comptroller General of the United States or the Medi-*
18 *care Payment Advisory Commission for purposes of car-*
19 *rying out this part.*

20 “(e) *REGULATIONS.—*

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

1 “(2) *INFORMATION SPECIFIED.*—*Information de-*
2 *scribed in paragraph (1), with respect to a selected*
3 *drug, shall include information on sales of the drug*
4 *(by the manufacturer of the drug or by another entity*
5 *under license or other agreement with the manufac-*
6 *turer, with respect to the sales of such drug, regardless*
7 *of the name under which the drug is sold) in any for-*
8 *foreign country that is part of the AIM price. The Sec-*
9 *retary shall verify, to the extent practicable, such*
10 *sales from appropriate officials of the government of*
11 *the foreign country involved.*

12 “(f) *COMPLIANCE WITH REQUIREMENTS FOR ADMIN-*
13 *ISTRATION OF PROGRAM.*—*Each manufacturer with an*
14 *agreement in effect under this section shall comply with re-*
15 *quirements imposed by the Secretary or a third party with*
16 *a contract under section 1196(c)(1), as applicable, for pur-*
17 *poses of administering the program.*

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

19 “(a) *IN GENERAL.*—*For purposes of this part, under*
20 *an agreement under section 1193 between the Secretary and*
21 *a manufacturer of a selected drug, with respect to the period*
22 *for which such agreement is in effect and in accordance*
23 *with subsections (b) and (c), the Secretary and the manu-*
24 *facturer—*

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

6 “(2) as applicable pursuant to section 1193(a)(2)
7 and in accordance with the process specified pursuant
8 to such section, renegotiate such maximum fair price
9 for such drug for the purpose described in such sec-
10 tion.

11 “(b) *NEGOTIATING METHODOLOGY AND OBJECTIVE.*—

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

18 “(2) *PRIORITIZING FACTORS.*—In considering
19 the factors described in subsection (d) in negotiating
20 (and, as applicable, renegotiating) the maximum fair
21 price for a selected drug, the Secretary shall, to the
22 extent practicable, consider all of the available factors
23 listed but shall prioritize the following factors:

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

4 “(B) *MARKET DATA.—The factor described*
5 *in paragraph (1)(B) of such subsection.*

6 “(C) *UNIT COSTS OF PRODUCTION AND DIS-*
7 *TRIBUTION.—The factor described in paragraph*
8 *(1)(C) of such subsection.*

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

12 “(3) *REQUIREMENT.—*

13 “(A) *IN GENERAL.—In negotiating the max-*
14 *imum fair price of a selected drug, with respect*
15 *to an initial price applicability year for the se-*
16 *lected drug, and, as applicable, in renegotiating*
17 *the maximum fair price for such drug, with re-*
18 *spect to a subsequent year during the price ap-*
19 *plicability period for such drug, in the case that*
20 *the manufacturer of the selected drug offers*
21 *under the negotiation or renegotiation, as appli-*
22 *cable, a price for such drug that is not more*
23 *than the target price described in subparagraph*
24 *(B) for such drug for the respective year, the Sec-*
25 *retary shall agree under such negotiation or re-*

1 *negotiation, respectively, to such offered price as*
2 *the maximum fair price.*

3 “(B) *TARGET PRICE.*—

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

23 “(ii) *SELECTED DRUGS WITHOUT AIM*
24 *PRICE.*—*In applying this paragraph in the*
25 *case of negotiating the maximum fair price*

1 of a selected drug for which there is no AIM
2 price available with respect to the initial
3 price applicability year for such drug, or,
4 as applicable, renegotiating the maximum
5 fair price for such drug with respect to a
6 subsequent year during the price applica-
7 bility period for such drug before the first
8 plan year for which there is an AIM price
9 available for such drug, the target price de-
10 scribed in this subparagraph for such drug
11 and respective year is the amount that is 80
12 percent of the average manufacturer price
13 (as defined in section 1927(k)(1)) for such
14 drug and year.

15 “(4) ANNUAL REPORT.—After the completion of
16 each voluntary negotiation period, the Secretary shall
17 submit to Congress a report on the maximum fair
18 prices negotiated (or, as applicable, renegotiated) for
19 such period. Such report shall include information on
20 how such prices so negotiated (or renegotiated) meet
21 the requirements of this part, including the require-
22 ments of this subsection.

23 “(c) LIMITATION.—

24 “(1) IN GENERAL.—Subject to paragraph (2), the
25 maximum fair price negotiated (including as renego-

1 *tiated) under this section for a selected drug, with re-*
2 *spect to each plan year during a price applicability*
3 *period for such drug, shall not exceed 120 percent of*
4 *the AIM price applicable to such drug with respect to*
5 *such year.*

6 *“(2) SELECTED DRUGS WITHOUT AIM PRICE.—*
7 *In the case of a selected drug for which there is no*
8 *AIM price available with respect to the initial price*
9 *applicability year for such drug, for each plan year*
10 *during the price applicability period before the first*
11 *plan year for which there is an AIM price available*
12 *for such drug, the maximum fair price negotiated (in-*
13 *cluding as renegotiated) under this section for the se-*
14 *lected drug shall not exceed the amount equal to 85*
15 *percent of the average manufacturer price for the*
16 *drug with respect to such year.*

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

23 *“(1) MANUFACTURER-SPECIFIC INFORMATION.—*
24 *The following information, including as submitted by*
25 *the manufacturer:*

1 “(A) *Research and development costs of the*
2 *manufacturer for the drug and the extent to*
3 *which the manufacturer has recouped research*
4 *and development costs.*

5 “(B) *Market data for the drug, including*
6 *the distribution of sales across different pro-*
7 *grams and purchasers and projected future reve-*
8 *nues for the drug.*

9 “(C) *Unit costs of production and distribu-*
10 *tion of the drug.*

11 “(D) *Prior Federal financial support for*
12 *novel therapeutic discovery and development*
13 *with respect to the drug.*

14 “(E) *Data on patents and on existing and*
15 *pending exclusivity for the drug.*

16 “(F) *National sales data for the drug.*

17 “(G) *Information on clinical trials for the*
18 *drug in the United States or in applicable coun-*
19 *tries described in section 1191(c)(3)(B).*

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

22 “(A) *The extent to which the drug rep-*
23 *resents a therapeutic advance as compared to ex-*
24 *isting therapeutic alternatives and, to the extent*

1 *such information is available, the costs of such*
2 *existing therapeutic alternatives.*

3 “(B) *Information on approval by the Food*
4 *and Drug Administration of alternative drug*
5 *products.*

6 “(C) *Information on comparative effective-*
7 *ness analysis for such products, taking into con-*
8 *sideration the effects of such products on specific*
9 *populations, such as individuals with disabil-*
10 *ities, the elderly, terminally ill, children, and*
11 *other patient populations.*

12 *In considering information described in subpara-*
13 *graph (C), the Secretary shall not use evidence or*
14 *findings from comparative clinical effectiveness re-*
15 *search in a manner that treats extending the life of*
16 *an elderly, disabled, or terminally ill individual as of*
17 *lower value than extending the life of an individual*
18 *who is younger, nondisabled, or not terminally ill.*
19 *Nothing in the previous sentence shall affect the ap-*
20 *plication or consideration of an AIM price for a se-*
21 *lected drug.*

22 “(3) *FOREIGN SALES INFORMATION.—To the ex-*
23 *tent available on a timely basis, including as pro-*
24 *vided by a manufacturer of the selected drug or other-*

1 *wise, information on sales of the selected drug in each*
2 *of the countries described in section 1191(c)(3)(B).*

3 *“(4) ADDITIONAL INFORMATION.—Information*
4 *submitted to the Secretary, in accordance with a*
5 *process specified by the Secretary, by other parties*
6 *that are affected by the establishment of a maximum*
7 *fair price for the selected drug.*

8 *“(e) REQUEST FOR INFORMATION.—For purposes of*
9 *negotiating and, as applicable, renegotiating (including for*
10 *purposes of determining whether to renegotiate) the max-*
11 *imum fair price of a selected drug under this part with*
12 *the manufacturer of the drug, with respect to a price appli-*
13 *cability period, and other relevant data for purposes of this*
14 *section—*

15 *“(1) the Secretary shall, not later than the se-*
16 *lected drug publication date with respect to the initial*
17 *price applicability year of such period, request drug*
18 *pricing information from the manufacturer of such*
19 *selected drug, including information described in sub-*
20 *section (d)(1); and*

21 *“(2) by not later than October 1 following the se-*
22 *lected drug publication date, the manufacturer of such*
23 *selected drug shall submit to the Secretary such re-*
24 *quested information in such form and manner as the*
25 *Secretary may require.*

1 *The Secretary shall request, from the manufacturer or oth-*
2 *ers, such additional information as may be needed to carry*
3 *out the negotiation and renegotiation process under this sec-*
4 *tion.*

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

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

13 “(b) *UPDATES.—*

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

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

1 *(all items; U.S. city average) as of September of*
2 *such previous year; or*

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

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

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

17 *“(a) ADMINISTRATIVE DUTIES.—*

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

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

1 *under section 1197 with group health plans and*
2 *health insurance issuers of health insurance cov-*
3 *erage offered in the individual or group market)*
4 *under which the maximum fair price for a se-*
5 *lected drug is provided to fair price eligible indi-*
6 *viduals, who with respect to such drug are de-*
7 *scribed in subparagraph (A) of section*
8 *1191(c)(1), at pharmacies or by mail order serv-*
9 *ice at the point-of-sale of the drug for the appli-*
10 *cable price period for such drug and providing*
11 *that such maximum fair price is used for deter-*
12 *mining cost-sharing under such plans or cov-*
13 *erage for the selected drug.*

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

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

10 *“(C) The establishment of procedures (in-*
11 *cluding through agreements and contracts de-*
12 *scribed in subparagraphs (A) and (B)) to ensure*
13 *that, not later than 90 days after the dispensing*
14 *of a selected drug to a fair price eligible indi-*
15 *vidual by a pharmacy or mail order service, the*
16 *pharmacy or mail order service is reimbursed for*
17 *an amount equal to the difference between—*

18 *“(i) the lesser of—*

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

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

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

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

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

5 *“(D) The establishment of procedures to en-*
6 *sure that the maximum fair price for a selected*
7 *drug is applied before—*

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

15 *“(ii) any other discounts.*

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

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

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

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

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

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

24 “(I) The establishment of a negotiation
25 process and renegotiation process in accordance

1 with section 1194, including a process for ac-
2 quiring information described in subsection (d)
3 of such section and determining amounts de-
4 scribed in subsection (b) of such section.

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

10 “(2) *MONITORING COMPLIANCE.—*

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

16 “(B) *NOTIFICATION.—If a third party with*
17 *a contract under subsection (c)(1) determines*
18 *that the manufacturer is not in compliance with*
19 *such agreement, the third party shall notify the*
20 *Secretary of such noncompliance for appropriate*
21 *enforcement under section 4192 of the Internal*
22 *Revenue Code of 1986 or section 1198, as appli-*
23 *cable.*

24 “(b) *COLLECTION OF DATA.—*

1 “(1) *FROM PRESCRIPTION DRUG PLANS AND MA-*
2 *PD PLANS.—The Secretary may collect appropriate*
3 *data from prescription drug plans under part D of*
4 *title XVIII and MA–PD plans under part C of such*
5 *title in a timeframe that allows for maximum fair*
6 *prices to be provided under this part for selected*
7 *drugs.*

8 “(2) *FROM HEALTH PLANS.—The Secretary may*
9 *collect appropriate data from group health plans or*
10 *health insurance issuers offering group or individual*
11 *health insurance coverage in a timeframe that allows*
12 *for maximum fair prices to be provided under this*
13 *part for selected drugs.*

14 “(3) *COORDINATION OF DATA COLLECTION.—To*
15 *the extent feasible, as determined by the Secretary, the*
16 *Secretary shall ensure that data collected pursuant to*
17 *this subsection is coordinated with, and not duplica-*
18 *tive of, other data collection efforts.*

19 “(c) *CONTRACT WITH THIRD PARTIES.—*

20 “(1) *IN GENERAL.—The Secretary may enter*
21 *into a contract with 1 or more third parties to ad-*
22 *minister the requirements established by the Secretary*
23 *in order to carry out this part. At a minimum, the*
24 *contract with a third party under the preceding sen-*
25 *tence shall require that the third party—*

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

5 “(B) receive, distribute, or facilitate the dis-
6 tribution of funds of manufacturers to appro-
7 priate individuals or entities in order to meet
8 the obligations of manufacturers under agree-
9 ments under this part;

10 “(C) provide adequate and timely informa-
11 tion to manufacturers, consistent with the agree-
12 ment with the manufacturer under this part, as
13 necessary for the manufacturer to fulfill its obli-
14 gations under this part; and

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

20 “(2) *PERFORMANCE REQUIREMENTS.*—The Sec-
21 retary shall establish performance requirements for a
22 third party with a contract under paragraph (1) and
23 safeguards to protect the independence and integrity
24 of the activities carried out by the third party under
25 the program under this part.

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

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

17 “(b) *PUBLICATION OF ELECTION.—With respect to*
18 *each price applicability period and each selected drug with*
19 *respect to such period, the Secretary and the Secretary of*
20 *Labor and the Secretary of the Treasury, as applicable,*
21 *shall make public a list of each group health plan and each*
22 *issuer of health insurance coverage, with respect to which*
23 *coverage is provided under such plan or coverage for such*
24 *drug, that has elected under subsection (a) not to partici-*

1 *pate under the program with respect to such period and*
2 *drug.*

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

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

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

15 *“(2) to a hospital, physician, or other provider*
16 *of services or supplier with respect to fair price eligi-*
17 *ble individuals who with respect to such drug is de-*
18 *scribed in subparagraph (B) of such section and is*
19 *furnished or administered such drug by such hospital,*
20 *physician, or provider or supplier during such year;*
21 *shall be subject to a civil monetary penalty equal to ten*
22 *times the amount equal to the difference between the price*
23 *for such drug made available for such year by such manu-*
24 *facturer with respect to such individual or hospital, physi-*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(h) *INFLATION REBATE FOR GROUP HEALTH*
9 *PLANS.*—

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

15 “(A) *establishing an agreement process with*
16 *manufacturers of prescription drugs under which*
17 *manufacturers provide for inflation rebates (in a*
18 *manner similar to rebates under section 1834(x)*
19 *and 1860D–14B with respect to part B and part*
20 *D drugs, respectively) with respect to drugs that*
21 *are furnished or dispensed to participants, en-*
22 *rollees, and beneficiaries of health insurance cov-*
23 *erage in connection with a group health plan;*
24 *and*

1 “(B) *establishing an enforcement mecha-*
2 *nism with respect to such agreement process that*
3 *ensures that such inflation rebates are, propor-*
4 *tionally distributed, with respect to costs, to—*

5 “(i) *participants, enrollees, and bene-*
6 *ficiaries of health insurance coverage offered*
7 *in the group market; and*

8 “(ii) *a health insurance issuer offering*
9 *health insurance coverage in the group mar-*
10 *ket.*

11 “(2) *REGULATIONS.—Not later than December*
12 *31, 2022, the Secretary of Labor shall, in consultation*
13 *with the Secretary of Health and Human Services*
14 *and the Secretary of the Treasury, promulgate regula-*
15 *tions consistent with the information contained in the*
16 *report submitted pursuant to paragraph (1) if—*

17 “(A) *the Secretary of Labor determines the*
18 *prices of a sufficient number (as determined by*
19 *the Secretary of Labor) of drugs described in*
20 *paragraph (1)(A) have increased at a percentage*
21 *that exceeds the percentage by which the con-*
22 *sumer price index for all urban consumers*
23 *(United States city average) for a period of time*
24 *(as determined by the Secretary of Labor); and*

1 “(B) the Secretary of Labor finds that the
2 agreement process identified pursuant to sub-
3 paragraph (A) of paragraph (1) and the enforce-
4 ment mechanism identified pursuant to subpara-
5 graph (B) of such paragraph are feasible.”.

6 (b) *APPLICATION OF MAXIMUM FAIR PRICES AND CON-*
7 *FORMING AMENDMENTS.—*

8 (1) *UNDER MEDICARE PRESCRIPTION DRUG PRO-*
9 *GRAM.—*

10 (A) *EXCEPTION TO NON-INTERFERENCE.—*
11 Section 1860D–11(i) of the Social Security Act
12 (42 U.S.C. 1395w–111(i)) is amended by insert-
13 ing “, except as provided under part E of title
14 XI,” after “the Secretary”.

15 (B) *APPLICATION AS NEGOTIATED PRICE.—*
16 Section 1860D–2(d)(1) of the Social Security Act
17 (42 U.S.C. 1395w–102(d)(1)) is amended—

18 (i) in subparagraph (B), by inserting
19 “, subject to subparagraph (D),” after “ne-
20 gotiated prices”; and

21 (ii) by adding at the end the following
22 new subparagraph:

23 “(D) *APPLICATION OF MAXIMUM FAIR PRICE*
24 *FOR SELECTED DRUGS.—In applying this sec-*
25 *tion, in the case of a covered part D drug that*

1 is a selected drug (as defined in section 1192(c)),
2 with respect to a price applicability period (as
3 defined in section 1191(b)(2)), the negotiated
4 price described in this subsection shall be the
5 maximum fair price (as defined in section
6 1191(c)(2)) for such drug and for each plan year
7 during such period.”.

8 (C) INFORMATION FROM PRESCRIPTION
9 DRUG PLANS AND MA–PD PLANS REQUIRED.—

10 (i) PRESCRIPTION DRUG PLANS.—Sec-
11 tion 1860D–12(b) of the Social Security Act
12 (42 U.S.C. 1395w–112(b)) is amended by
13 adding at the end the following new para-
14 graph:

15 “(8) PROVISION OF INFORMATION RELATED TO
16 MAXIMUM FAIR PRICES.—Each contract entered into
17 with a PDP sponsor under this part with respect to
18 a prescription drug plan offered by such sponsor shall
19 require the sponsor to provide information to the Sec-
20 retary as requested by the Secretary in accordance
21 with section 1196(b).”.

22 (ii) MA–PD PLANS.—Section
23 1857(f)(3) of the Social Security Act (42
24 U.S.C. 1395w–27(f)(3)) is amended by add-

1 *ing at the end the following new subpara-*
2 *graph:*

3 *“(E) PROVISION OF INFORMATION RELATED*
4 *TO MAXIMUM FAIR PRICES.—Section 1860D–*
5 *12(b)(8).”.*

6 *(2) UNDER GROUP HEALTH PLANS AND HEALTH*
7 *INSURANCE COVERAGE.—*

8 *(A) PHSA.—Part A of title XXVII of the*
9 *Public Health Service Act is amended by insert-*
10 *ing after section 2729 the following new section:*

11 **“SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM**
12 **AND APPLICATION OF MAXIMUM FAIR**
13 **PRICES.**

14 *“(a) IN GENERAL.—In the case of a group health plan*
15 *or health insurance issuer offering health insurance cov-*
16 *erage that is treated under section 1197 of the Social Secu-*
17 *rity Act as having in effect an agreement with the Secretary*
18 *under the Fair Price Drug Negotiation Program under part*
19 *E of title XI of such Act, with respect to a price applica-*
20 *bility period (as defined in section 1191(b) of such Act) and*
21 *a selected drug (as defined in section 1192(c) of such Act)*
22 *with respect to such period with respect to which coverage*
23 *is provided under such plan or coverage—*

24 *“(1) the provisions of such part shall apply to*
25 *the plans or coverage offered by such plan or issuer,*

1 *and to the individuals enrolled under such plans or*
2 *coverage, during such period, with respect to such se-*
3 *lected drug, in the same manner as such provisions*
4 *apply to prescription drug plans and MA–PD plans,*
5 *and to individuals enrolled under such prescription*
6 *drug plans and MA–PD plans;*

7 *“(2) the plan or issuer shall apply any cost-shar-*
8 *ing responsibilities under such plan or coverage, with*
9 *respect to such selected drug, by substituting the max-*
10 *imum fair price negotiated under such part for such*
11 *drug in lieu of the contracted rate under such plan*
12 *or coverage for such selected drug; and*

13 *“(3) the Secretary shall apply the provisions of*
14 *such part to such plan, issuer, and coverage, and such*
15 *individuals so enrolled in such plans.*

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

1 *coverage is provided under such plan or coverage before the*
2 *beginning of the plan year for which such election was*
3 *made.”.*

4 (B) *ERISA.*—

5 (i) *IN GENERAL.*—*Subpart B of part 7*
6 *of subtitle B of title I of the Employee Re-*
7 *tirement Income Security Act of 1974 (29*
8 *U.S.C. 1181 et. seq.) is amended by adding*
9 *at the end the following new section:*

10 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
11 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

22 “(1) *the provisions of such part shall apply, as*
23 *applicable—*

24 “(A) *if coverage of such selected drug is pro-*
25 *vided under such plan or coverage if the drug is*

1 *furnished or dispensed at a pharmacy or by a*
2 *mail order service, to the plans or coverage of-*
3 *fered by such plan or issuer, and to the individ-*
4 *uals enrolled under such plans or coverage, dur-*
5 *ing such period, with respect to such selected*
6 *drug, in the same manner as such provisions*
7 *apply to prescription drug plans and MA-PD*
8 *plans, and to individuals enrolled under such*
9 *prescription drug plans and MA-PD plans dur-*
10 *ing such period; and*

11 “(B) *if coverage of such selected drug is pro-*
12 *vided under such plan or coverage if the drug is*
13 *furnished or administered by a hospital, physi-*
14 *cian, or other provider of services or supplier, to*
15 *the plans or coverage offered by such plan or*
16 *issuers, to the individuals enrolled under such*
17 *plans or coverage, and to hospitals, physicians,*
18 *and other providers of services and suppliers*
19 *during such period, with respect to such drug in*
20 *the same manner as such provisions apply to the*
21 *Secretary, to individuals entitled to benefits*
22 *under part A of title XVIII or enrolled under*
23 *part B of such title, and to hospitals, physicians,*
24 *and other providers and suppliers participating*
25 *under title XVIII during such period;*

1 “(2) the plan or issuer shall apply any cost-shar-
2 ing responsibilities under such plan or coverage, with
3 respect to such selected drug, by substituting an
4 amount not more than the maximum fair price nego-
5 tiated under such part E of title XI for such drug in
6 lieu of the drug price upon which the cost-sharing
7 would have otherwise applied, and such cost-sharing
8 responsibilities with respect to such selected drug may
9 not exceed such amount; and

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

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

1 (ii) *APPLICATION TO RETIREE AND*
2 *CERTAIN SMALL GROUP HEALTH PLANS.—*
3 *Section 732(a) of the Employee Retirement*
4 *Income Security Act of 1974 (29 U.S.C.*
5 *1191a(a)) is amended by striking “section*
6 *711” and inserting “sections 711 and 716”.*

7 (iii) *CLERICAL AMENDMENT.—The*
8 *table of sections for subpart B of part 7 of*
9 *subtitle B of title I of the Employee Retire-*
10 *ment Income Security Act of 1974 is*
11 *amended by adding at the end the following:*

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

12 (C) *IRC.—*

13 (i) *IN GENERAL.—Subchapter B of*
14 *chapter 100 of the Internal Revenue Code of*
15 *1986 is amended by adding at the end the*
16 *following new section:*

17 **“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
18 **APPLICATION OF MAXIMUM FAIR PRICES.**

19 “(a) *IN GENERAL.—In the case of a group health plan*
20 *that is treated under section 1197 of the Social Security*
21 *Act as having in effect an agreement with the Secretary*
22 *under the Fair Price Drug Negotiation Program under part*
23 *E of title XI of such Act, with respect to a price applica-*
24 *bility period (as defined in section 1191(b) of such Act) and*

1 *a selected drug (as defined in section 1192(c) of such Act)*
2 *with respect to such period with respect to which coverage*
3 *is provided under such plan—*

4 “(1) *the provisions of such part shall apply to*
5 *the plans offered by such plan, and to the individuals*
6 *enrolled under such plans, during such period, with*
7 *respect to such selected drug, in the same manner as*
8 *such provisions apply to prescription drug plans and*
9 *MA–PD plans, and to individuals enrolled under*
10 *such prescription drug plans and MA–PD plans;*

11 “(2) *the plan shall apply any cost-sharing re-*
12 *sponsibilities under such plan, with respect to such*
13 *selected drug, by substituting the maximum fair price*
14 *negotiated under such part for such drug in lieu of*
15 *the contracted rate under such plan for such selected*
16 *drug; and*

17 “(3) *the Secretary shall apply the provisions of*
18 *such part to such plan and such individuals so en-*
19 *rolled in such plan.*

20 “(b) *NOTIFICATION REGARDING NONPARTICIPATION IN*
21 *FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group*
22 *health plan shall publicly disclose in a manner and in ac-*
23 *cordance with a process specified by the Secretary any elec-*
24 *tion made under section 1197 of the Social Security Act*
25 *by the plan to not participate in the Fair Drug Price Nego-*

1 *tiation Program under part E of title XI of such Act with*
2 *respect to a selected drug (as defined in section 1192(c) of*
3 *such Act) for which coverage is provided under such plan*
4 *before the beginning of the plan year for which such election*
5 *was made.”.*

6 *(ii) CLERICAL AMENDMENT.—The table*
7 *of sections for subchapter B of chapter 100*
8 *of such Code is amended by adding at the*
9 *end the following new item:*

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

10 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX IM-**
11 **POSED DURING NONCOMPLIANCE PERIODS.**

12 *(a) IN GENERAL.—Subchapter E of chapter 32 of the*
13 *Internal Revenue Code of 1986 is amended by adding at*
14 *the end the following new section:*

15 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
16 **PERIODS.**

17 *“(a) IN GENERAL.—There is hereby imposed on the*
18 *sale by the manufacturer, producer, or importer of any se-*
19 *lected drug during a day described in subsection (b) a tax*
20 *in an amount such that the applicable percentage is equal*
21 *to the ratio of—*

22 *“(1) such tax, divided by*

23 *“(2) the sum of such tax and the price for which*
24 *so sold.*

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

4 “(1) *The period beginning on the June 16th im-*
5 *mediately following the selected drug publication date*
6 *and ending on the first date during which the manu-*
7 *facturer of the drug has in place an agreement de-*
8 *scribed in subsection (a) of section 1193 of the Social*
9 *Security Act with respect to such drug.*

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

15 “(3) *In the case of a selected drug with respect*
16 *to which the Secretary of Health and Human Services*
17 *has specified a renegotiation period under such agree-*
18 *ment, the period beginning on the first date after the*
19 *last date of such renegotiation period and ending on*
20 *the first date during which the manufacturer of the*
21 *drug has agreed to a renegotiated maximum fair*
22 *price under such agreement.*

23 “(4) *With respect to information that is required*
24 *to be submitted to the Secretary of Health and*
25 *Human Services under such agreement, the period be-*

1 *ginning on the date on which such Secretary certifies*
2 *that such information is overdue and ending on the*
3 *date that such information is so submitted.*

4 *“(5) In the case of a selected drug with respect*
5 *to which a payment is due under subsection (c) of*
6 *such section 1193, the period beginning on the date*
7 *on which the Secretary of Health and Human Serv-*
8 *ices certifies that such payment is overdue and ending*
9 *on the date that such payment is made in full.*

10 *“(c) APPLICABLE PERCENTAGE.—The term ‘applicable*
11 *percentage’ means—*

12 *“(1) in the case of sales of a selected drug during*
13 *the first 90 days described in subsection (b) with re-*
14 *spect to such drug, 65 percent,*

15 *“(2) in the case of sales of such drug during the*
16 *91st day through the 180th day described in sub-*
17 *section (b) with respect to such drug, 75 percent,*

18 *“(3) in the case of sales of such drug during the*
19 *181st day through the 270th day described in sub-*
20 *section (b) with respect to such drug, 85 percent, and*

21 *“(4) in the case of sales of such drug during any*
22 *subsequent day, 95 percent.*

23 *“(d) DEFINITIONS.—The terms ‘selected drug publica-*
24 *tion date’ and ‘maximum fair price’ have the meaning*
25 *given such terms in section 1191 of the Social Security Act*

1 *and the term ‘selected drug’ has the meaning given such*
2 *term in section 1192 of such Act.*

3 “(e) *ANTI-ABUSE RULE.—In the case of a sale which*
4 *was timed for the purpose of avoiding the tax imposed by*
5 *this section, the Secretary may treat such sale as occurring*
6 *during a day described in subsection (b).”.*

7 (b) *NO DEDUCTION FOR EXCISE TAX PAYMENTS.—*
8 *Section 275 of the Internal Revenue Code of 1986 is amend-*
9 *ed by adding “or by section 4192” before the period at the*
10 *end of subsection (a)(6).*

11 (c) *CONFORMING AMENDMENTS.—*

12 (1) *Section 4221(a) of the Internal Revenue Code*
13 *of 1986 is amended by inserting “or 4192” after “sec-*
14 *tion 4191”.*

15 (2) *Section 6416(b)(2) of such Code is amended*
16 *by inserting “or 4192” after “section 4191”.*

17 (d) *CLERICAL AMENDMENTS.—*

18 (1) *The heading of subchapter E of chapter 32*
19 *of the Internal Revenue Code of 1986 is amended by*
20 *striking “**Medical Devices**” and inserting*
21 *“**Other Medical Products**”.*

22 (2) *The table of subchapters for chapter 32 of*
23 *such Code is amended by striking the item relating to*
24 *subchapter E and inserting the following new item:*

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

4 (e) *EFFECTIVE DATE.*—*The amendments made by this*
5 *section shall apply to sales after the date of the enactment*
6 *of this Act.*

7 **TITLE II—MEDICARE PARTS B**
8 **AND D PRESCRIPTION DRUG**
9 **INFLATION REBATES**

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

11 (a) *IN GENERAL.*—*Section 1834 of the Social Security*
12 *Act (42 U.S.C. 1395m) is amended by adding at the end*
13 *the following new subsection:*

14 “(x) *REBATE BY MANUFACTURERS FOR SINGLE*
15 *SOURCE DRUGS WITH PRICES INCREASING FASTER THAN*
16 *INFLATION.*—

17 “(1) *REQUIREMENTS.*—

18 “(A) *SECRETARIAL PROVISION OF INFORMA-*
19 *TION.*—*Not later than 6 months after the end of*
20 *each calendar quarter beginning on or after July*
21 *1, 2021, the Secretary shall, for each part B*
22 *rebtable drug, report to each manufacturer of*
23 *such part B rebatable drug the following for such*
24 *calendar quarter:*

1 “(i) Information on the total number
2 of billing units described in subparagraph
3 (A)(i) of paragraph (3) with respect to such
4 drug and calendar quarter.

5 “(ii) Information on the amount (if
6 any) of the excess average sales price in-
7 crease described in subparagraph (A)(ii) of
8 such paragraph for such drug and calendar
9 quarter.

10 “(iii) The rebate amount specified
11 under such paragraph for such part B
12 rebtable drug and calendar quarter.

13 “(B) MANUFACTURER REQUIREMENT.—For
14 each calendar quarter beginning on or after July
15 1, 2021, the manufacturer of a part B rebatable
16 drug shall, for such drug, not later than 30 days
17 after the date of receipt from the Secretary of the
18 information described in subparagraph (A) for
19 such calendar quarter, provide to the Secretary
20 a rebate that is equal to the amount specified in
21 paragraph (3) for such drug for such calendar
22 quarter.

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

24 “(A) IN GENERAL.—In this subsection, the
25 term ‘part B rebatable drug’ means a single

1 *source drug or biological (as defined in subpara-*
2 *graph (D) of section 1847A(c)(6)), including a*
3 *biosimilar biological product (as defined in sub-*
4 *paragraph (H) of such section), paid for under*
5 *this part, except such term shall not include such*
6 *a drug or biological—*

7 *“(i) if the average total allowed charges*
8 *for a year per individual that uses such a*
9 *drug or biological, as determined by the*
10 *Secretary, are less than, subject to subpara-*
11 *graph (B), \$100; or*

12 *“(ii) that is a vaccine described in sub-*
13 *paragraph (A) or (B) of section 1861(s)(10).*

14 *“(B) INCREASE.—The dollar amount ap-*
15 *plied under subparagraph (A)(i)—*

16 *“(i) for 2022, shall be the dollar*
17 *amount specified under such subparagraph*
18 *for 2021, increased by the percentage in-*
19 *crease in the consumer price index for all*
20 *urban consumers (United States city aver-*
21 *age) as of the first quarter of the previous*
22 *year; and*

23 *“(ii) for a subsequent year, shall be the*
24 *dollar amount specified in this clause (or*
25 *clause (i)) for the previous year, increased*

1 *by the percentage increase in the consumer*
2 *price index for all urban consumers (United*
3 *States city average) as of the first quarter*
4 *of the previous year.*

5 *Any dollar amount specified under this subpara-*
6 *graph that is not a multiple of \$10 shall be*
7 *rounded to the nearest multiple of \$10.*

8 “(3) *REBATE AMOUNT.—*

9 “(A) *IN GENERAL.—For purposes of para-*
10 *graph (1)(B), the amount specified in this para-*
11 *graph for a part B rebatable drug assigned to a*
12 *billing and payment code for a calendar quarter*
13 *is, subject to paragraph (4), the amount equal to*
14 *the product of—*

15 “(i) *subject to subparagraph (B), the*
16 *total number of billing units, as described*
17 *in section 1847A(b)(6)(B), for such part B*
18 *rebatable drug furnished under this part*
19 *during the calendar quarter; and*

20 “(ii) *the amount (if any) by which—*

21 “(I) *the payment amount under*
22 *subparagraph (B) or (C) of section*
23 *1847A(b)(1), as applicable, for such*
24 *part B rebatable drug during the cal-*
25 *endar quarter; exceeds*

1 “(II) the inflation-adjusted pay-
2 ment amount determined under sub-
3 paragraph (C) for such part B
4 rebtable drug during the calendar
5 quarter.

6 “(B) EXCLUDED UNITS.—For purposes of
7 subparagraph (A)(i), the total number of billing
8 units for part B rebtable drugs furnished dur-
9 ing a calendar quarter shall not include—

10 “(i) units packaged into the payment
11 for a related procedure or service under sec-
12 tion 1833(t) or under section 1833(i) (in-
13 stead of separately payable under such re-
14 spective section);

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

18 “(iii) units of a part B rebtable drug
19 of a manufacturer that is furnished to an
20 individual, if such manufacturer, with re-
21 spect to the furnishing of such units of such
22 drug, provides for discounts under section
23 340B of the Public Health Service Act or
24 for rebates under section 1927.

1 “(C) *DETERMINATION OF INFLATION-AD-*
2 *JUSTED PAYMENT AMOUNT.*—*The inflation-ad-*
3 *justed payment amount determined under this*
4 *subparagraph for a part B rebatable drug for a*
5 *calendar quarter is—*

6 “(i) *the payment amount for the bill-*
7 *ing and payment code for such drug in the*
8 *payment amount benchmark quarter (as de-*
9 *defined in subparagraph (D)); increased by*

10 “(ii) *the percentage by which the rebate*
11 *period CPI-U (as defined in subparagraph*
12 *(F)) for the calendar quarter exceeds the*
13 *benchmark period CPI-U (as defined in*
14 *subparagraph (E)).*

15 “(D) *PAYMENT AMOUNT BENCHMARK QUAR-*
16 *TER.*—*The term ‘payment amount benchmark*
17 *quarter’ means the calendar quarter beginning*
18 *January 1, 2016.*

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

23 “(F) *REBATE PERIOD CPI-U.*—*The term*
24 *‘rebate period CPI-U’ means, with respect to a*
25 *calendar quarter described in subparagraph (C),*

1 *the greater of the benchmark period CPI-U and*
2 *the consumer price index for all urban con-*
3 *sumers (United States city average) for the first*
4 *month of the calendar quarter that is two cal-*
5 *endar quarters prior to such described calendar*
6 *quarter.*

7 “(4) *SPECIAL TREATMENT OF CERTAIN DRUGS*
8 *AND EXEMPTION.—*

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

1 “(B) *TIMELINE FOR PROVISION OF REBATES*
2 *FOR NEW DRUGS.*—*In the case of a part B*
3 *rebtable drug first approved by the Food and*
4 *Drug Administration after July 1, 2015, clause*
5 *(i) of paragraph (1)(B) shall be applied as if the*
6 *reference to ‘July 1, 2021’ under such paragraph*
7 *were a reference to the later of the 6th full cal-*
8 *endar quarter after the day on which the drug*
9 *was first marketed or July 1, 2021.*

10 “(C) *EXEMPTION FOR SHORTAGES.*—*The*
11 *Secretary may reduce or waive the rebate under*
12 *paragraph (1)(B) with respect to a part B*
13 *rebtable drug that appears on the drug shortage*
14 *list in effect under section 506(e) of the Federal*
15 *Food, Drug, and Cosmetic Act or in the case of*
16 *other exigent circumstances, as determined by the*
17 *Secretary.*

18 “(D) *SELECTED DRUGS.*—*In the case of a*
19 *part B rebtable drug that is a selected drug (as*
20 *defined in section 1192(c)), for each applicable*
21 *year beginning after the price applicability pe-*
22 *riod (as defined in section 1191(b)(2) with re-*
23 *spect to such drug, clause (i) of paragraph (3)(C)*
24 *shall be applied as if the term ‘payment amount*
25 *benchmark quarter’ were defined under para-*

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

10 “(5) *APPLICATION TO BENEFICIARY COINSUR-*
11 *ANCE.—In the case of a part B rebatable drug for*
12 *which a rebate is payable under this subsection—*

13 “(A) *in computing the amount of any coin-*
14 *surance applicable under this title to an indi-*
15 *vidual with respect to such drug, the computa-*
16 *tion of such coinsurance shall be based on the in-*
17 *flation-adjusted payment amount determined*
18 *under paragraph (3)(C) for such part B*
19 *rebatable drug; and*

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

23 “(6) *REBATE DEPOSITS.—Amounts paid as re-*
24 *bates under paragraph (1)(B) shall be deposited into*

1 *the Federal Supplementary Medical Insurance Trust*
2 *Fund established under section 1841.*

3 “(7) *CIVIL MONEY PENALTY.—If a manufacturer*
4 *of a part B rebatable drug has failed to comply with*
5 *the requirements under paragraph (1)(B) for such*
6 *drug for a calendar quarter, the manufacturer shall*
7 *be subject to, in accordance with a process established*
8 *by the Secretary pursuant to regulations, a civil*
9 *money penalty in an amount equal to at least 125*
10 *percent of the amount specified in paragraph (3) for*
11 *such drug for such calendar quarter. The provisions*
12 *of section 1128A (other than subsections (a) (with re-*
13 *spect to amounts of penalties or additional assess-*
14 *ments) and (b)) shall apply to a civil money penalty*
15 *under this paragraph in the same manner as such*
16 *provisions apply to a penalty or proceeding under*
17 *section 1128A(a).*

18 “(8) *STUDY AND REPORT.—*

19 “(A) *STUDY.—The Secretary shall conduct*
20 *a study of the feasibility of and operational*
21 *issues involved with the following:*

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

1 “(ii) Including drugs and biologicals
2 paid for under MA plans under part C in
3 the rebate system under this subsection.

4 “(iii) Including drugs excluded under
5 paragraph (2)(A) and billing units of drugs
6 excluded under paragraph (3)(B) in the re-
7 bate system under this subsection.

8 “(B) REPORT.—Not later than 3 years after
9 the date of the enactment of this subsection, the
10 Secretary shall submit to Congress a report on
11 the study conducted under subparagraph (A).

12 “(9) APPLICATION TO MULTIPLE SOURCE
13 DRUGS.—The Secretary may, based on the report sub-
14 mitted under paragraph (8) and pursuant to rule-
15 making, apply the provisions of this subsection to
16 multiple source drugs (as defined in section
17 1847A(c)(6)(C)), including, for purposes of deter-
18 mining the rebate amount under paragraph (3), by
19 calculating manufacturer-specific average sales prices
20 for the benchmark period and the rebate period.”.

21 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
22 1833(a) of the Social Security Act is amended—

23 (1) in paragraph (1)—

1 (A) in subparagraph (S), by striking “with
2 respect to” and inserting “subject to subpara-
3 graph (DD), with respect to”;

4 (B) by striking “and (CC)” and inserting
5 “(CC)”; and

6 (C) by inserting before the semicolon at the
7 end the following: “, and (DD) with respect to
8 a part B rebatable drug (as defined in para-
9 graph (2) of section 1834(x)) for which a rebate
10 is payable under such section, the amounts paid
11 shall be the difference between (i) the payment
12 amount under paragraph (3)(A)(i)(I) of such
13 section for such drug, and (ii) 20 percent of the
14 inflation-adjusted payment amount under para-
15 graph (3)(A)(i)(II) of such section for such
16 drug”; and

17 (2) by adding at the end of the flush left matter
18 following paragraph (9), the following:

19 “*For purposes of applying paragraph (1)(DD) and section*
20 *1834(x)(5), the Secretary shall make such estimates and use*
21 *such data as the Secretary determines appropriate.*”.

22 (c) *CONFORMING AMENDMENT TO PART B ASP CAL-*
23 *CULATION.—Section 1847A(c)(3) of the Social Security Act*
24 *(42 U.S.C. 1395w-3a(c)(3)) is amended by inserting “or*
25 *section 1834(x)” after “section 1927”.*

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

2 *Part D of title XVIII of the Social Security Act is*
3 *amended by inserting after section 1860D–14A (42 U.S.C.*
4 *1395w–114a) the following new section:*

5 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
6 **DRUGS WITH PRICES INCREASING FASTER**
7 **THAN INFLATION.**

8 *“(a) IN GENERAL.—Subject to the provisions of this*
9 *section, in order for coverage to be available under this part*
10 *for a part D rebatable drug of a manufacturer dispensed*
11 *during an applicable year, the manufacturer must have en-*
12 *tered into and have in effect an agreement described in sub-*
13 *section (b). For purposes of this section the term ‘applicable*
14 *year’ means a year beginning with 2022.*

15 *“(b) AGREEMENTS.—*

16 *“(1) TERMS OF AGREEMENT.—An agreement de-*
17 *scribed in this subsection, with respect to a manufac-*
18 *turer of a part D rebatable drug, is an agreement*
19 *under which the following applies:*

20 *“(A) SECRETARIAL PROVISION OF INFORMA-*
21 *TION.—Not later than 9 months after the end of*
22 *each applicable year with respect to which the*
23 *agreement is in effect, the Secretary, for the part*
24 *D rebatable drug of the manufacturer, reports to*
25 *the manufacturer the following for such year:*

1 “(i) *Information on the total units (as*
2 *defined in subsection (g)(2)) dispensed for*
3 *each dosage form and strength with respect*
4 *to such part D rebatable drug and year.*

5 “(ii) *Information on the amount (if*
6 *any) of the excess average manufacturer*
7 *price increase described in subsection*
8 *(c)(1)(B) for each dosage form and strength*
9 *with respect to such drug and year.*

10 “(iii) *The rebate amount specified*
11 *under subsection (c) for each dosage form*
12 *and strength with respect to such drug and*
13 *year.*

14 “(B) *MANUFACTURER REQUIREMENTS.—*
15 *For each applicable year with respect to which*
16 *the agreement is in effect, the manufacturer of*
17 *the part D rebatable drug, for each dosage form*
18 *and strength with respect to such drug, not later*
19 *than 30 days after the date of receipt from the*
20 *Secretary of the information described in sub-*
21 *paragraph (A) for such year, provides to the Sec-*
22 *retary a rebate that is equal to the amount speci-*
23 *fied in subsection (c) for such dosage form and*
24 *strength with respect to such drug for such year.*

25 “(2) *LENGTH OF AGREEMENT.—*

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

7 “(B) *TERMINATION.*—

8 “(i) *BY SECRETARY.*—*The Secretary*
9 *may provide for termination of an agree-*
10 *ment under this section for violation of the*
11 *requirements of the agreement or other good*
12 *cause shown. Such termination shall not be*
13 *effective earlier than 60 days after the date*
14 *of notice of such termination. The Secretary*
15 *shall provide, upon request, a manufacturer*
16 *with a hearing concerning such a termi-*
17 *nation, but such hearing shall not delay the*
18 *effective date of the termination.*

19 “(ii) *BY A MANUFACTURER.*—*A manu-*
20 *facturer may terminate an agreement under*
21 *this section for any reason. Any such termi-*
22 *nation shall not be effective until the year*
23 *beginning at least 60 days after the date the*
24 *manufacturer provides notice to the Sec-*
25 *retary.*

1 “(C) *EFFECTIVENESS OF TERMINATION.*—
2 *Any termination under this paragraph shall not*
3 *affect rebates due under the agreement under this*
4 *section before the effective date of its termination.*

5 “(D) *DELAY BEFORE REENTRY.*—*In the*
6 *case of any agreement under this section with a*
7 *manufacturer which is terminated in a plan*
8 *year, another such agreement with the manufac-*
9 *turer (or a successor manufacturer) may not be*
10 *entered into before the subsequent plan year, un-*
11 *less the Secretary finds good cause for an earlier*
12 *reinstatement of such an agreement.*

13 “(3) *INFORMATION.*—*For purposes of carrying*
14 *out this section, the Secretary shall use information*
15 *submitted by manufacturers under section 1927(b)(3).*

16 “(c) *REBATE AMOUNT.*—

17 “(1) *IN GENERAL.*—*For purposes of this section,*
18 *the amount specified in this subsection for a dosage*
19 *form and strength with respect to a part D rebatable*
20 *drug and applicable year is, subject to subparagraphs*
21 *(B) and (C) of paragraph (3), the amount equal to*
22 *the product of—*

23 “(A) *the total average number of units*
24 *weighted by, and dispensed for, such dosage form*

1 *and strength with respect to such part D*
2 *rebtable drug and year; and*

3 “(B) *the amount (if any) by which—*

4 “(i) *the average manufacturer price (as*
5 *defined in subsection (g)) paid for such dos-*
6 *age form and strength with respect to such*
7 *part D rebtable drug during the year; ex-*
8 *ceeds*

9 “(ii) *the inflation-adjusted payment*
10 *amount determined under paragraph (2) for*
11 *such dosage form and strength with respect*
12 *to such part D rebtable drug during the*
13 *year.*

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

20 “(A) *the average manufacturer price paid*
21 *for such dosage form and strength with respect to*
22 *such drug in the payment amount benchmark*
23 *year (as defined in subsection (g)(3)); increased*
24 *by*

1 “(B) *the percentage by which the rebate pe-*
2 *riod CPI-U (as defined in subsection (g)(5)) for*
3 *the applicable year exceeds the benchmark period*
4 *CPI-U (as defined in subsection (g)(4)).*

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

7 “(A) *SUBSEQUENTLY APPROVED DRUGS.—*
8 *In the case of a part D rebatable drug first ap-*
9 *proved by the Food and Drug Administration*
10 *after January 1, 2016, subparagraph (A) of*
11 *paragraph (2) shall be applied as if the term*
12 *‘payment amount benchmark year’ were defined*
13 *under subsection (g)(3) as the first year begin-*
14 *ning after the day on which the drug was first*
15 *marketed and subparagraph (B) of paragraph*
16 *(2) shall be applied as if the term ‘benchmark*
17 *period CPI-U’ were defined under subsection*
18 *(g)(4) as if the reference to ‘January 2016’ under*
19 *such subsection were a reference to ‘January of*
20 *the first year beginning after the date on which*
21 *the drug was first marketed by any manufac-*
22 *turer’.*

23 “(B) *EXEMPTION FOR SHORTAGES.—The*
24 *Secretary may reduce or waive the rebate under*
25 *paragraph (1) with respect to a part D rebatable*

1 *drug in the case of a shortage of such drug or*
2 *other exigent circumstances, as determined by the*
3 *Secretary.*

4 “(C) *TREATMENT OF NEW FORMULA-*
5 *TIONS.—*

6 “(i) *IN GENERAL.—In the case of a*
7 *part D rebatable drug that is a line exten-*
8 *sion of a single source drug or an innovator*
9 *multiple source drug that is an oral solid*
10 *dosage form, the Secretary shall establish a*
11 *formula for determining the amount speci-*
12 *fied in this subsection with respect to such*
13 *part D rebatable drug and an applicable*
14 *year with consideration of the single source*
15 *drug or an innovator multiple source drug.*

16 “(ii) *LINE EXTENSION DEFINED.—In*
17 *this subparagraph, the term ‘line extension’*
18 *means, with respect to a part D rebatable*
19 *drug, a new formulation of the drug (as de-*
20 *termined by the Secretary), such as an ex-*
21 *tended release formulation, but does not in-*
22 *clude an abuse-deterrent formulation of the*
23 *drug (as determined by the Secretary), re-*
24 *gardless of whether such abuse-deterrent for-*

1 *mulation is an extended release formula-*
2 *tion.*

3 “(D) *SELECTED DRUGS.*—*In the case of a*
4 *part D rebatable drug that is a selected drug (as*
5 *defined in section 1192(c)), for each applicable*
6 *year beginning after the price applicability pe-*
7 *riod (as defined in section 1191(b)(2) with re-*
8 *spect to such drug, subparagraph (A) of para-*
9 *graph (2) shall be applied as if the term ‘pay-*
10 *ment amount benchmark year’ were defined*
11 *under subsection (g)(3) as the last year begin-*
12 *ning during such price applicability period with*
13 *respect to such selected drug and subparagraph*
14 *(B) of paragraph (2) shall be applied as if the*
15 *term ‘benchmark period CPI-U’ were defined*
16 *under subsection (g)(4) as if the reference to*
17 *‘January 2016’ under such subsection were a ref-*
18 *erence to January of the last year beginning*
19 *during such price applicability period with re-*
20 *spect to such drug.*

21 “(d) *REBATE DEPOSITS.*—*Amounts paid as rebates*
22 *under subsection (c) shall be deposited into the Medicare*
23 *Prescription Drug Account in the Federal Supplementary*
24 *Medical Insurance Trust Fund established under section*
25 *1841.*

1 “(e) *CIVIL MONEY PENALTY.*—*In the case of a manu-*
2 *facturer of a part D rebatable drug with an agreement in*
3 *effect under this section who has failed to comply with the*
4 *terms of the agreement under subsection (b)(1)(B) with re-*
5 *spect to such drug for an applicable year, the Secretary may*
6 *impose a civil money penalty on such manufacturer in an*
7 *amount equal to 125 percent of the amount specified in sub-*
8 *section (c) for such drug for such year. The provisions of*
9 *section 1128A (other than subsections (a) (with respect to*
10 *amounts of penalties or additional assessments) and (b))*
11 *shall apply to a civil money penalty under this subsection*
12 *in the same manner as such provisions apply to a penalty*
13 *or proceeding under section 1128A(a).*

14 “(f) *JUDICIAL REVIEW.*—*There shall be no judicial re-*
15 *view of the following:*

16 “(1) *The determination of units under this sec-*
17 *tion.*

18 “(2) *The determination of whether a drug is a*
19 *part D rebatable drug under this section.*

20 “(3) *The calculation of the rebate amount under*
21 *this section.*

22 “(g) *DEFINITIONS.*—*In this section:*

23 “(1) *PART D REBATABLE DRUG DEFINED.*—

24 “(A) *IN GENERAL.*—*The term ‘part D*
25 *rebatable drug’ means a drug or biological that*

1 *would (without application of this section) be a*
2 *covered part D drug, except such term shall, with*
3 *respect to an applicable year, not include such a*
4 *drug or biological if the average total cost under*
5 *a prescription drug plan under this part or MA–*
6 *PD plan under part C for such year per indi-*
7 *vidual who uses such a drug or biological, as de-*
8 *termined by the Secretary, are less than, subject*
9 *to subparagraph (B), \$100, as determined by the*
10 *Secretary using the most recent data available*
11 *or, if data is not available, as estimated by the*
12 *Secretary.*

13 “(B) INCREASE.—*The dollar amount ap-*
14 *plied under subparagraph (A)—*

15 “(i) *for 2023, shall be the dollar*
16 *amount specified under such subparagraph*
17 *for 2022, increased by the percentage in-*
18 *crease in the consumer price index for all*
19 *urban consumers (United States city aver-*
20 *age) as of January of 2022; and*

21 “(ii) *for a subsequent year, shall be the*
22 *dollar amount specified in this subpara-*
23 *graph (or subparagraph (A)) for the pre-*
24 *vious year, increased by the percentage in-*
25 *crease in the consumer price index for all*

1 *urban consumers (United States city aver-*
2 *age) as of January of the previous year.*

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

6 “(2) *UNIT DEFINED.*—*The term ‘unit’ means,*
7 *with respect to a part D rebatable drug, the lowest*
8 *identifiable quantity (such as a capsule or tablet, mil-*
9 *ligram of molecules, or grams) of the part D rebatable*
10 *drug that is dispensed to individuals enrolled under*
11 *a prescription drug plan under this part or an MA-*
12 *PD plan under part C.*

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

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

20 “(5) *REBATE PERIOD CPI-U.*—*The term ‘rebate*
21 *period CPI-U’ means, with respect to an applicable*
22 *year, the consumer price index for all urban con-*
23 *sumers (United States city average) for January of*
24 *such year.*

1 “(6) *AVERAGE MANUFACTURER PRICE.—The*
2 *term ‘average manufacturer price’ has the meaning,*
3 *with respect to a part D rebatable drug of a manufac-*
4 *turer for an applicable year, given such term in sec-*
5 *tion 1927(k)(1), with respect to a covered outpatient*
6 *drug of a manufacturer for a rebate period under sec-*
7 *tion 1927. For purposes of applying the previous sen-*
8 *tence, with respect to a part D rebatable drug of a*
9 *manufacturer and an applicable year, the Secretary*
10 *shall use the information with respect to the average*
11 *manufacturer price for such drug reported by the*
12 *manufacturer under section 1927(b)(3) with respect to*
13 *each of the quarters in the applicable year and cal-*
14 *culate an annual average manufacturer price for such*
15 *applicable year as the average of such average manu-*
16 *facturer prices for each such quarter, weighted by*
17 *units of such drug sold or dispensed with respect to*
18 *such applicable year.”.*

1 **TITLE III—PART D IMPROVE-**
2 **MENTS AND MAXIMUM OUT-**
3 **OF-POCKET CAP FOR MEDI-**
4 **CARE BENEFICIARIES**

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

6 (a) *BENEFIT STRUCTURE REDESIGN.*—Section
7 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
8 102(b)) is amended—

9 (1) in paragraph (2)—

10 (A) in subparagraph (A), in the matter pre-
11 ceding clause (i), by inserting “for a year pre-
12 ceding 2022 and for costs above the annual de-
13 ductible specified in paragraph (1) and up to the
14 annual out-of-pocket threshold specified in para-
15 graph (4)(B) for 2022 and each subsequent year”
16 after “paragraph (3)”;

17 (B) in subparagraph (C)—

18 (i) in clause (i), in the matter pre-
19 ceding subclause (I), by inserting “for a
20 year preceding 2022,” after “paragraph
21 (4),”; and

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

25 (C) in subparagraph (D)—

1 (i) in clause (i)—

2 (I) in the matter preceding sub-
3 clause (I), by inserting “for a year pre-
4 ceding 2022,” after “paragraph (4),”;
5 and

6 (II) in subclause (I)(bb), by strik-
7 ing “a year after 2018” and inserting
8 “each of years 2018 through 2021”;
9 and

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

13 (2) in paragraph (3)(A)—

14 (A) in the matter preceding clause (i), by
15 inserting “for a year preceding 2022,” after
16 “and (4),”; and

17 (B) in clause (ii), by striking “for a subse-
18 quent year” and inserting “for each of years
19 2007 through 2021”; and

20 (3) in paragraph (4)—

21 (A) in subparagraph (A)—

22 (i) in clause (i)—

23 (I) by redesignating subclauses (I)
24 and (II) as items (aa) and (bb), re-
25 spectively, and moving the margin of

1 *each such redesignated item 2 ems to*
2 *the right;*

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

7 *“(I) for a year preceding 2022,*
8 *the greater of—”;*

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

13 *(IV) by adding at the end the fol-*
14 *lowing:*

15 *“(II) for 2022 and each suc-*
16 *ceeding year, \$0.”; and*
17 *(ii) in clause (ii)—*

18 *(I) by striking “clause (i)(I)” and*
19 *inserting “clause (i)(I)(aa)”;* and

20 *(II) by adding at the end the fol-*
21 *lowing new sentence: “The Secretary*
22 *shall continue to calculate the dollar*
23 *amounts specified in clause (i)(I)(aa),*
24 *including with the adjustment under*

1 *this clause, after 2021 for purposes of*
2 *section 1860D–14(a)(1)(D)(iii).”;*

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 subse-*
9 *quent year” and inserting “for*
10 *2021”;* and

11 *(bb) by striking the period at*
12 *the end and inserting a semicolon;*
13 *and*

14 *(III) by adding at the end the fol-*
15 *lowing new subclauses:*

16 *“(VII) for 2022, is equal to*
17 *\$2,000; or*

18 *“(VIII) for a subsequent year, is*
19 *equal to the amount specified in this*
20 *subparagraph for the previous year,*
21 *increased by the annual percentage in-*
22 *crease described in paragraph (6) for*
23 *the year involved.”;* and

24 *(ii) in clause (ii), by striking “clause*
25 *(i)(II)” and inserting “clause (i)”;*

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

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

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

12 (c) *MANUFACTURER DISCOUNT PROGRAM.*—

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

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

19 “(a) *ESTABLISHMENT.*—The Secretary shall establish
20 a manufacturer discount program (in this section referred
21 to as the ‘program’). Under the program, the Secretary shall
22 enter into agreements described in subsection (b) with man-
23 ufacturers and provide for the performance of the duties de-
24 scribed in subsection (c). The Secretary shall establish a
25 model agreement for use under the program by not later

1 *than January 1, 2021, in consultation with manufacturers,*
2 *and allow for comment on such model agreement.*

3 “(b) *TERMS OF AGREEMENT.—*

4 “(1) *IN GENERAL.—*

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

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

17 “(C) *TIMING OF AGREEMENT.—*

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

1 *date of the establishment of a model agree-*
2 *ment under subsection (a).*

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

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

17 “(3) COMPLIANCE WITH REQUIREMENTS FOR AD-
18 *MINISTRATION OF PROGRAM.—Each manufacturer*
19 *with an agreement in effect under this section shall*
20 *comply with requirements imposed by the Secretary*
21 *or a third party with a contract under subsection*
22 *(d)(3), as applicable, for purposes of administering*
23 *the program, including any determination under sub-*
24 *paragraph (A) of subsection (c)(1) or procedures es-*
25 *tablished under such subsection (c)(1).*

1 “(4) *LENGTH OF AGREEMENT.*—

2 “(A) *IN GENERAL.*—*An agreement under*
3 *this section shall be effective for an initial period*
4 *of not less than 12 months and shall be auto-*
5 *matically renewed for a period of not less than*
6 *1 year unless terminated under subparagraph*
7 *(B).*

8 “(B) *TERMINATION.*—

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

24 “(ii) *BY A MANUFACTURER.*—*A manu-*
25 *facturer may terminate an agreement under*

1 *this section for any reason. Any such termi-*
2 *nation shall be effective, with respect to a*
3 *plan year—*

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

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

12 *“(iii) EFFECTIVENESS OF TERMI-*
13 *NATION.—Any termination under this sub-*
14 *paragraph shall not affect discounts for ap-*
15 *plicable drugs of the manufacturer that are*
16 *due under the agreement before the effective*
17 *date of its termination.*

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

24 *“(c) DUTIES DESCRIBED.—The duties described in*
25 *this subsection are the following:*

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

3 “(A) *the determination of the amount of the*
4 *discounted price of an applicable drug of a man-*
5 *ufacturer;*

6 “(B) *the establishment of procedures under*
7 *which discounted prices are provided to applica-*
8 *ble beneficiaries at pharmacies or by mail order*
9 *service at the point-of-sale of an applicable drug;*

10 “(C) *the establishment of procedures to en-*
11 *sure that, not later than the applicable number*
12 *of calendar days after the dispensing of an ap-*
13 *plicable drug by a pharmacy or mail order serv-*
14 *ice, the pharmacy or mail order service is reim-*
15 *bursed for an amount equal to the difference be-*
16 *tween—*

17 “(i) *the negotiated price of the applica-*
18 *ble drug; and*

19 “(ii) *the discounted price of the appli-*
20 *cable drug;*

21 “(D) *the establishment of procedures to en-*
22 *sure that the discounted price for an applicable*
23 *drug under this section is applied before any*
24 *coverage or financial assistance under other*
25 *health benefit plans or programs that provide*

1 *coverage or financial assistance for the purchase*
2 *or provision of prescription drug coverage on be-*
3 *half of applicable beneficiaries as the Secretary*
4 *may specify; and*

5 *“(E) providing a reasonable dispute resolu-*
6 *tion mechanism to resolve disagreements between*
7 *manufacturers, applicable beneficiaries, and the*
8 *third party with a contract under subsection*
9 *(d)(3).*

10 “(2) *MONITORING COMPLIANCE.—*

11 *“(A) IN GENERAL.—The Secretary shall*
12 *monitor compliance by a manufacturer with the*
13 *terms of an agreement under this section.*

14 *“(B) NOTIFICATION.—If a third party with*
15 *a contract under subsection (d)(3) determines*
16 *that the manufacturer is not in compliance with*
17 *such agreement, the third party shall notify the*
18 *Secretary of such noncompliance for appropriate*
19 *enforcement under subsection (e).*

20 “(3) *COLLECTION OF DATA FROM PRESCRIPTION*
21 *DRUG PLANS AND MA–PD PLANS.—The Secretary may*
22 *collect appropriate data from prescription drug plans*
23 *and MA–PD plans in a timeframe that allows for*
24 *discounted prices to be provided for applicable drugs*
25 *under this section.*

1 “(d) *ADMINISTRATION.*—

2 “(1) *IN GENERAL.*—*Subject to paragraph (2), the*
3 *Secretary shall provide for the implementation of this*
4 *section, including the performance of the duties de-*
5 *scribed in subsection (c).*

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

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

17 “(A) *receive and transmit information be-*
18 *tween the Secretary, manufacturers, and other*
19 *individuals or entities the Secretary determines*
20 *appropriate;*

21 “(B) *receive, distribute, or facilitate the dis-*
22 *tribution of funds of manufacturers to appro-*
23 *priate individuals or entities in order to meet*
24 *the obligations of manufacturers under agree-*
25 *ments under this section;*

1 “(C) provide adequate and timely informa-
2 tion to manufacturers, consistent with the agree-
3 ment with the manufacturer under this section,
4 as necessary for the manufacturer to fulfill its
5 obligations under this section; and

6 “(D) permit manufacturers to conduct peri-
7 odic audits, directly or through contracts, of the
8 data and information used by the third party to
9 determine discounts for applicable drugs of the
10 manufacturer under the program.

11 “(4) *PERFORMANCE REQUIREMENTS.*—The Sec-
12 retary shall establish performance requirements for a
13 third party with a contract under paragraph (3) and
14 safeguards to protect the independence and integrity
15 of the activities carried out by the third party under
16 the program under this section.

17 “(5) *IMPLEMENTATION.*—The Secretary may im-
18 plement the program under this section by program
19 instruction or otherwise.

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

23 “(e) *ENFORCEMENT.*—

1 “(1) *AUDITS.*—*Each manufacturer with an*
2 *agreement in effect under this section shall be subject*
3 *to periodic audit by the Secretary.*

4 “(2) *CIVIL MONEY PENALTY.*—

5 “(A) *IN GENERAL.*—*The Secretary may im-*
6 *pose a civil money penalty on a manufacturer*
7 *that fails to provide applicable beneficiaries dis-*
8 *counts for applicable drugs of the manufacturer*
9 *in accordance with such agreement for each such*
10 *failure in an amount the Secretary determines is*
11 *commensurate with the sum of—*

12 “(i) *the amount that the manufacturer*
13 *would have paid with respect to such dis-*
14 *counts under the agreement, which will then*
15 *be used to pay the discounts which the man-*
16 *ufacturer had failed to provide; and*

17 “(ii) *25 percent of such amount.*

18 “(B) *APPLICATION.*—*The provisions of sec-*
19 *tion 1128A (other than subsections (a) and (b))*
20 *shall apply to a civil money penalty under this*
21 *paragraph in the same manner as such provi-*
22 *sions apply to a penalty or proceeding under*
23 *section 1128A(a).*

24 “(f) *CLARIFICATION REGARDING AVAILABILITY OF*
25 *OTHER COVERED PART D DRUGS.*—*Nothing in this section*

1 *shall prevent an applicable beneficiary from purchasing a*
2 *covered part D drug that is not an applicable drug (includ-*
3 *ing a generic drug or a drug that is not on the formulary*
4 *of the prescription drug plan or MA–PD plan that the ap-*
5 *plicable beneficiary is enrolled in).*

6 “(g) *DEFINITIONS.—In this section:*

7 “(1) *APPLICABLE BENEFICIARY.—The term ‘ap-*
8 *plicable beneficiary’ means an individual who, on the*
9 *date of dispensing a covered part D drug—*

10 “(A) *is enrolled in a prescription drug plan*
11 *or an MA–PD plan;*

12 “(B) *is not enrolled in a qualified retiree*
13 *prescription drug plan; and*

14 “(C) *has incurred costs for covered part D*
15 *drugs in the year that are equal to or exceed the*
16 *annual deductible specified in section 1860D–*
17 *2(b)(1) for such year.*

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

20 “(A) *means a covered part D drug—*

21 “(i) *approved under a new drug appli-*
22 *cation under section 505(b) of the Federal*
23 *Food, Drug, and Cosmetic Act or, in the*
24 *case of a biologic product, licensed under*

1 *section 351 of the Public Health Service*
2 *Act; and*

3 *“(ii)(I) if the PDP sponsor of the pre-*
4 *scription drug plan or the MA organization*
5 *offering the MA–PD plan uses a formulary,*
6 *which is on the formulary of the prescrip-*
7 *tion drug plan or MA–PD plan that the ap-*
8 *plicable beneficiary is enrolled in;*

9 *“(II) if the PDP sponsor of the pre-*
10 *scription drug plan or the MA organization*
11 *offering the MA–PD plan does not use a for-*
12 *mulary, for which benefits are available*
13 *under the prescription drug plan or MA–*
14 *PD plan that the applicable beneficiary is*
15 *enrolled in; or*

16 *“(III) is provided through an exception*
17 *or appeal; and*

18 *“(B) does not include a selected drug (as de-*
19 *finied in section 1192(c)) during a price applica-*
20 *bility period (as defined in section 1191(b)(2))*
21 *with respect to such drug.*

22 *“(3) APPLICABLE NUMBER OF CALENDAR*
23 *DAYS.—The term ‘applicable number of calendar*
24 *days’ means—*

1 “(A) *with respect to claims for reimburse-*
2 *ment submitted electronically, 14 days; and*

3 “(B) *with respect to claims for reimburse-*
4 *ment submitted otherwise, 30 days.*

5 “(4) *DISCOUNTED PRICE.—*

6 “(A) *IN GENERAL.—The term ‘discounted*
7 *price’ means, with respect to an applicable drug*
8 *of a manufacturer furnished during a year to an*
9 *applicable beneficiary—*

10 “(i) *who has not incurred costs for cov-*
11 *ered part D drugs in the year that are*
12 *equal to or exceed the annual out-of-pocket*
13 *threshold specified in section 1860D-*
14 *2(b)(4)(B)(i) for the year, 90 percent of the*
15 *negotiated price of such drug; and*

16 “(ii) *who has incurred such costs in*
17 *the year that are equal to or exceed such*
18 *threshold for the year, 70 percent of the ne-*
19 *gotiated price of such drug.*

20 “(B) *CLARIFICATION.—Nothing in this sec-*
21 *tion shall be construed as affecting the responsi-*
22 *bility of an applicable beneficiary for payment*
23 *of a dispensing fee for an applicable drug.*

24 “(C) *SPECIAL CASE FOR CERTAIN*
25 *CLAIMS.—*

1 “(i) *CLAIMS SPANNING DEDUCTIBLE.—*

2 *In the case where the entire amount of the*
3 *negotiated price of an individual claim for*
4 *an applicable drug with respect to an ap-*
5 *plicable beneficiary does not fall at or above*
6 *the annual deductible specified in section*
7 *1860D–2(b)(1) for the year, the manufac-*
8 *turer of the applicable drug shall provide*
9 *the discounted price under this section on*
10 *only the portion of the negotiated price of*
11 *the applicable drug that falls at or above*
12 *such annual deductible.*

13 “(ii) *CLAIMS SPANNING OUT-OF-POCK-*
14 *ET THRESHOLD.—In the case where the en-*
15 *tire amount of the negotiated price of an in-*
16 *dividual claim for an applicable drug with*
17 *respect to an applicable beneficiary does not*
18 *fall entirely below or entirely above the an-*
19 *ual out-of-pocket threshold specified in sec-*
20 *tion 1860D–2(b)(4)(B)(i) for the year, the*
21 *manufacturer of the applicable drug shall*
22 *provide the discounted price—*

23 “(I) *in accordance with subpara-*
24 *graph (A)(i) on the portion of the ne-*

1 *gotiated price of the applicable drug*
2 *that falls below such threshold; and*

3 “*(II) in accordance with subpara-*
4 *graph (A)(ii) on the portion of such*
5 *price of such drug that falls at or*
6 *above such threshold.*

7 “(5) *MANUFACTURER.—The term ‘manufacturer’*
8 *means any entity which is engaged in the production,*
9 *preparation, propagation, compounding, conversion,*
10 *or processing of prescription drug products, either di-*
11 *rectly or indirectly by extraction from substances of*
12 *natural origin, or independently by means of chem-*
13 *ical synthesis, or by a combination of extraction and*
14 *chemical synthesis. Such term does not include a*
15 *wholesale distributor of drugs or a retail pharmacy li-*
16 *censed under State law.*

17 “(6) *NEGOTIATED PRICE.—The term ‘negotiated*
18 *price’ has the meaning given such term in section*
19 *423.100 of title 42, Code of Federal Regulations (as*
20 *in effect on the date of enactment of section 1860D–*
21 *14A), except that such negotiated price shall not in-*
22 *clude any dispensing fee for the applicable drug.*

23 “(7) *QUALIFIED RETIREE PRESCRIPTION DRUG*
24 *PLAN.—The term ‘qualified retiree prescription drug*

1 *plan’ has the meaning given such term in section*
2 *1860D–22(a)(2).”.*

3 *(2) SUNSET OF MEDICARE COVERAGE GAP DIS-*
4 *COUNT PROGRAM.—Section 1860D–14A of the Social*
5 *Security Act (42 U.S.C. 1395–114a) is amended—*

6 *(A) in subsection (a), in the first sentence,*
7 *by striking “The Secretary” and inserting “Sub-*
8 *ject to subsection (h), the Secretary”;* and

9 *(B) by adding at the end the following new*
10 *subsection:*

11 *“(h) SUNSET OF PROGRAM.—*

12 *“(1) IN GENERAL.—The program shall not apply*
13 *with respect to applicable drugs dispensed on or after*
14 *January 1, 2022, and, subject to paragraph (2),*
15 *agreements under this section shall be terminated as*
16 *of such date.*

17 *“(2) CONTINUED APPLICATION FOR APPLICABLE*
18 *DRUGS DISPENSED PRIOR TO SUNSET.—The provi-*
19 *sions of this section (including all responsibilities and*
20 *duties) shall continue to apply after January 1, 2022,*
21 *with respect to applicable drugs dispensed prior to*
22 *such date.”.*

23 *(3) INCLUSION OF ACTUARIAL VALUE OF MANU-*
24 *FACTURER DISCOUNTS IN BIDS.—Section 1860D–11*

1 *of the Social Security Act (42 U.S.C. 1395w–111) is*
2 *amended—*

3 *(A) in subsection (b)(2)(C)(iii)—*

4 *(i) by striking “assumptions regarding*
5 *the reinsurance” an inserting “assumptions*
6 *regarding—*

7 *“(I) the reinsurance”; and*

8 *(ii) by adding at the end the following:*

9 *“(II) for 2022 and each subse-*
10 *quent year, the manufacturer discounts*
11 *provided under section 1860D–14C*
12 *subtracted from the actuarial value to*
13 *produce such bid; and”; and*

14 *(B) in subsection (c)(1)(C)—*

15 *(i) by striking “an actuarial valuation*
16 *of the reinsurance” and inserting “an actu-*
17 *arial valuation of—*

18 *“(i) the reinsurance”;*

19 *(ii) in clause (i), as inserted by clause*
20 *(i) of this subparagraph, by adding “and”*
21 *at the end; and*

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

1 “(i) for 2022 and each subsequent
2 year, the manufacturer discounts provided
3 under section 1860D–14C;”.

4 (d) *CONFORMING AMENDMENTS.*—

5 (1) *Section 1860D–2 of the Social Security Act*
6 *(42 U.S.C. 1395w–102) is amended—*

7 (A) *in subsection (a)(2)(A)(i)(I), by striking*
8 *“, or an increase in the initial” and inserting*
9 *“or, for a year preceding 2022, an increase in*
10 *the initial”;*

11 (B) *in subsection (c)(1)(C)—*

12 (i) *in the subparagraph heading, by*
13 *striking “AT INITIAL COVERAGE LIMIT”; and*

14 (ii) *by inserting “for a year preceding*
15 *2022 or the annual out-of-pocket threshold*
16 *specified in subsection (b)(4)(B) for the year*
17 *for 2022 and each subsequent year” after*
18 *“subsection (b)(3) for the year” each place*
19 *it appears; and*

20 (C) *in subsection (d)(1)(A), by striking “or*
21 *an initial” and inserting “or, for a year pre-*
22 *ceding 2022, an initial”.*

23 (2) *Section 1860D–4(a)(4)(B)(i) of the Social*
24 *Security Act (42 U.S.C. 1395w–104(a)(4)(B)) is*

1 *amended by striking “the initial” and inserting “for*
2 *a year preceding 2022, the initial”.*

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

5 *(A) in paragraph (1)—*

6 *(i) in subparagraph (C), by striking*
7 *“The continuation” and inserting “For a*
8 *year preceding 2022, the continuation”;*

9 *(ii) in subparagraph (D)(iii), by strik-*
10 *ing “1860D–2(b)(4)(A)(i)(I)” and inserting*
11 *“1860D–2(b)(4)(A)(i)(I)(aa)”;* and

12 *(iii) in subparagraph (E), by striking*
13 *“The elimination” and inserting “For a*
14 *year preceding 2022, the elimination”;* and

15 *(B) in paragraph (2)—*

16 *(i) in subparagraph (C), by striking*
17 *“The continuation” and inserting “For a*
18 *year preceding 2022, the continuation”;* and

19 *(ii) in subparagraph (E)—*

20 *(I) by inserting “for a year pre-*
21 *ceding 2022,” after “subsection (c)”;*
22 *and*

23 *(II) by striking “1860D–*
24 *2(b)(4)(A)(i)(I)” and inserting*
25 *“1860D–2(b)(4)(A)(i)(I)(aa)”.*

1 (4) *Section 1860D–21(d)(7) of the Social Secu-*
2 *rity Act (42 U.S.C. 1395w–131(d)(7)) is amended by*
3 *striking “section 1860D–2(b)(4)(B)(i)” and inserting*
4 *“section 1860D–2(b)(4)(C)(i)”.*

5 (5) *Section 1860D–22(a)(2)(A) of the Social Se-*
6 *curity Act (42 U.S.C. 1395w–132(a)(2)(A)) is amend-*
7 *ed—*

8 (A) *by striking “the value of any discount”*
9 *and inserting the following: “the value of—*

10 *“(i) for years prior to 2022, any dis-*
11 *count”.*

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

15 (C) *by adding at the end the following new*
16 *clause:*

17 *“(ii) for 2022 and each subsequent*
18 *year, any discount provided pursuant to*
19 *section 1860D–14C.”.*

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

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

24 (B) *by inserting “for such year” before the*
25 *period.*

1 (7) *Paragraph (1) of section 1860D–43(a) of the*
2 *Social Security Act (42 U.S.C. 1395w–153(a)) is*
3 *amended to read as follows:*

4 “(1) *participate in—*

5 “(A) *for 2011 through 2021, the Medicare*
6 *coverage gap discount program under section*
7 *1860D–14A; and*

8 “(B) *for 2022 and each subsequent year, the*
9 *manufacturer discount program under section*
10 *1860D–14C;”.*

11 *(e) EFFECTIVE DATE.—The amendments made by this*
12 *section shall apply with respect to plan year 2022 and sub-*
13 *sequent plan years.*