

116TH CONGRESS
1ST SESSION

H. R. 3

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

IN THE HOUSE OF REPRESENTATIVES

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

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”.

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

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE
NEGOTIATION

Sec. 101. Providing for lower prices for certain high-priced single source drugs.
Sec. 102. Selected drug manufacturer excise tax imposed during noncompliance
periods.

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.

3 **TITLE I—LOWERING PRICES**
4 **THROUGH FAIR DRUG PRICE**
5 **NEGOTIATION**

6 **SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN**
7 **HIGH-PRICED SINGLE SOURCE DRUGS.**

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

12 **“PART E—FAIR PRICE NEGOTIATION PROGRAM**
13 **TO LOWER PRICES FOR CERTAIN HIGH-**
14 **PRICED SINGLE SOURCE DRUGS**
15 **“SEC. 1191. ESTABLISHMENT OF PROGRAM.**

16 “(a) IN GENERAL.—The Secretary shall establish a
17 Fair Price Negotiation Program (in this part referred to

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

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

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

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

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

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

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

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

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

3 “(3) SELECTED DRUG PUBLICATION DATE.—

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

8 “(4) VOLUNTARY NEGOTIATION PERIOD.—The

9 term ‘voluntary negotiation period’ means, with re-
10 spect to an initial price applicability year with re-
11 spect to a selected drug, the period—

12 “(A) beginning on the sooner of—

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

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

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

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

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

4 “(A) enrolled under a prescription drug
5 plan under part D of title XVIII or an MA–PD
6 plan under part C of such title under which
7 coverage is provided for such drug;

8 “(B) enrolled under a group health plan or
9 health insurance coverage offered in the group
10 or individual market (as such terms are defined
11 in section 2791 of the Public Health Service
12 Act) with respect to which there is in effect an
13 agreement with the Secretary under section
14 1197 with respect to such selected drug; or

15 “(C) entitled to benefits under part A of
16 title XVIII or enrolled under part B of such
17 title.

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

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

3 “(A) IN GENERAL.—The terms ‘average
4 international market price’ and ‘AIM price’
5 mean, with respect to a drug, the average price
6 (which shall be the net average price, if prac-
7 ticable, and volume-weighted, if practicable) for
8 any dosage form and strength of a unit (as de-
9 fined in subparagraph (C)) for the drug for
10 sales of such drug, as computed (as of the date
11 of publication of such drug as a selected drug
12 under section 1192(a)) in all countries de-
13 scribed in clause (ii) of subparagraph (B) that
14 are applicable countries (as described in clause
15 (i) of such subparagraph) with respect to such
16 drug.

17 “(B) APPLICABLE COUNTRIES.—

18 “(i) IN GENERAL.—For purposes of
19 subparagraph (A), a country described in
20 clause (ii) is an applicable country de-
21 scribed in this clause with respect to a
22 drug if there is available an average price
23 for any unit for the drug for sales of such
24 drug 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 “(C) UNIT.—The term ‘unit’ means, with
11 respect to a drug, the lowest identifiable quan-
12 tity (such as a capsule or tablet, milligram of
13 molecules, or grams) of the drug that is dis-
14 pensed.

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

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

21 “(1) at least 25 negotiation-eligible drugs de-
22 scribed in subparagraphs (A) and (B), but not sub-
23 paragraph (C), of subsection (d)(1) (or, with respect
24 to an initial price applicability year beginning after
25 2023, the maximum number (if such number is less

1 than 25) of such negotiation-eligible drugs for the
2 year) with respect to such year; and

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

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

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

1 this projection of savings for drugs for which there is an
2 AIM price for a price applicability period, the savings shall
3 be projected taking into consideration both the volume of
4 drugs for which payment is made, to the extent such data
5 is available, and the amount by which the net price for
6 the drugs exceeds the AIM price for the 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
11 year and each subsequent plan year beginning before the
12 first plan year beginning after the date on which the Sec-
13 retary determines the drug is no longer a qualifying single
14 source drug.

15 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

22 “(A) COVERED PART D DRUGS.—The drug
23 is among the 125 covered part D drugs (as de-
24 fined in section 1860D–2(e)) for which there
25 was an estimated greatest net spending under

1 parts C and D of title XVIII, as determined by
2 the Secretary, during the most recent plan year
3 prior to such drug publication date for which
4 data are available.

5 “(B) OTHER DRUGS.—The drug is among
6 the 125 drugs for which there was an estimated
7 greatest net spending in the United States, as
8 determined by the Secretary, during the most
9 recent plan year prior to such drug publication
10 date for which data are available.

11 “(C) INSULIN.—The drug is a qualifying
12 single source drug described in subsection
13 (e)(3).

14 “(2) CLARIFICATION.—In determining whether
15 a qualifying single source drug satisfies any of the
16 criteria described in paragraph (1), the Secretary
17 shall, to the extent practicable, use data that is ag-
18 gregated across strengths and dosage forms and
19 routes of administration of the drug.

20 “(3) PUBLICATION.—Not later than the se-
21 lected drug publication date with respect to an ini-
22 tial price applicability year, the Secretary shall pub-
23 lish in the Federal Register a list of negotiation-eli-
24 gible drugs with respect to such selected drug publi-
25 cation date.

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

4 “(1) DRUG PRODUCTS.—A drug that—

5 “(A) is approved under section 505(c) of
6 the Federal Food, Drug, and Cosmetic Act and
7 continues to be marketed pursuant to such ap-
8 proval; and

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

12 “(2) BIOLOGICAL PRODUCTS.—A biological
13 product that—

14 “(A) is licensed under section 351(a) of
15 the Public Health Service Act, including any
16 product that has been deemed to be licensed
17 under section 351 of such Act pursuant to sec-
18 tion 7002(e)(4) of the Biologics Price Competi-
19 tion and Innovation Act of 2009, and continues
20 to be marketed under section 351 of such Act;
21 and

22 “(B) is not the reference product for any
23 biological product that is licensed and continues
24 to be marketed under section 351(k) of such
25 Act.

1 “(3) INSULIN PRODUCT.—Notwithstanding
2 paragraphs (1) and (2), any insulin product that is
3 approved under subsection (c) or (j) of section 505
4 of the Federal Food, Drug, and Cosmetic Act or li-
5 censed under subsection (a) or (k) of section 351 of
6 the Public Health Service Act and continues to be
7 marketed under such section 505 or 351.

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

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

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

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

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

16 “(A) to fair price eligible individuals de-
17 scribed in subparagraph (A) or (B) of section
18 1191(c)(1) furnished such drug during, subject
19 to subparagraph (2), the price applicability pe-
20 riod; and

21 “(B) to hospitals, physicians, and other
22 providers of services and suppliers with respect
23 to fair price eligible individuals described in
24 subparagraph (C) of such section administered
25 such drug during, subject to subparagraph (2),
26 the price applicability period;

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

12 “(A) to fair price eligible individuals de-
13 scribed in subparagraph (A) or (B) of section
14 1191(c)(1) furnished such drug during any year
15 during the price applicability period (beginning
16 after such renegotiation) with respect to such
17 selected drug; and

18 “(B) to hospitals, physicians, and other
19 providers of services and suppliers with respect
20 to fair price eligible individuals described in
21 subparagraph (C) of such section administered
22 such drug during any year described in sub-
23 paragraph (A);

24 “(3) the maximum fair price (including as re-
25 negotiated pursuant to paragraph (2)), with respect

1 to such a selected drug, shall be provided to fair
2 price eligible individuals described in subparagraph
3 (A) or (B) of section 1191(c)(1) at the pharmacy or
4 by the mail order service at the point-of-sale of such
5 drug;

6 “(4) the manufacturer, subject to subsection
7 (c), submits to the Secretary, in a form and manner
8 specified by the Secretary—

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

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

23 “(5) the manufacturer agrees that in the case
24 the selected drug of a manufacturer is a drug de-
25 scribed in subsection (c), the manufacturer will, in

1 accordance with such subsection, make any payment
2 required under such subsection with respect to such
3 drug; and

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

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

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

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

1 such selected drug shall pay to the Treasury an
2 amount equal to the difference between such amount
3 described in paragraph (2)(A) for such drug and
4 such amount described in paragraph (2)(B) for such
5 drug.

6 “(2) AMOUNTS DESCRIBED.—

7 “(A) WEIGHTED AVERAGE PRICE BEFORE
8 AIM PRICE AVAILABLE.—For purposes of para-
9 graph (1), the amount described in this sub-
10 paragraph for a selected drug described in such
11 paragraph, is the amount equal to the weighted
12 average manufacturer price for such dosage
13 strength and form for the drug during the pe-
14 riod beginning with the first plan year for
15 which the drug is included on the list of nego-
16 tiation-eligible drugs published under section
17 1192(d) and ending with the last plan year dur-
18 ing the price applicability period for such drug
19 with respect to which there is no AIM price
20 available for such drug.

21 “(B) AMOUNT MULTIPLIER AFTER AIM
22 PRICE AVAILABLE.—For purposes of paragraph
23 (1), the amount described in this subparagraph
24 for a selected drug described in such paragraph,
25 is the amount equal to 200 percent of the AIM

1 price for such drug with respect to the first
2 plan year during the price applicability period
3 for such drug with respect to which there is an
4 AIM price available for such drug.

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

13 “(e) REGULATIONS.—

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

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

1 The Secretary shall verify, to the extent practicable,
2 such sales from appropriate officials of the govern-
3 ment of the foreign country involved.

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

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

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

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

22 “(2) as applicable pursuant to section
23 1193(a)(2) and in accordance with the process speci-
24 fied pursuant to such section, renegotiate such max-

1 imum fair price for such drug for the purpose de-
2 scribed in such section.

3 “(b) NEGOTIATING METHODOLOGY AND OBJEC-
4 TIVE.—

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

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

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

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

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

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

4 “(3) REQUIREMENT.—

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

20 “(B) TARGET PRICE.—

21 “(i) IN GENERAL.—Subject to clause
22 (ii), the target price described in this sub-
23 paragraph for a selected drug with respect
24 to a year, is the average price (which shall
25 be the net average price, if practicable, and

1 volume-weighted, if practicable) for any
2 dosage form and strength of a unit for the
3 drug for sales of such drug, as computed
4 in the applicable country described in sec-
5 tion 1191(c)(3)(B) with respect to such
6 drug that, with respect to such year, has
7 the lowest average price for such drug as
8 compared to the average prices (as so com-
9 puted) for such drug with respect to such
10 year in the other applicable countries de-
11 scribed in such section with respect to such
12 drug.

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

1 such drug and respective year is the
2 amount that is 80 percent of the average
3 manufacturer price for such drug and
4 year.

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

13 “(c) LIMITATION.—

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

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

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

7 “(d) CONSIDERATIONS.—For purposes of negotiating
8 and, as applicable, renegotiating (including for purposes
9 of determining whether to renegotiate) the maximum fair
10 price of a selected drug under this part with the manufac-
11 turer of the drug, the Secretary shall, consistent with sub-
12 section (b)(2), take into consideration the following fac-
13 tors:

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

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

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

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

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

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

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

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

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

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

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

22 “(C) Information on comparative effective-
23 ness analysis for such products.

24 “(3) FOREIGN SALES INFORMATION.—To the
25 extent available on a timely basis, including as pro-

1 vided by a manufacturer of the selected drug or oth-
2 erwise, information on sales of the selected drug in
3 each of the countries described in section
4 1191(e)(3)(B).

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

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

17 “(1) the Secretary shall, not later than the se-
18 lected drug publication date with respect to the ini-
19 tial price applicability year of such period, request
20 drug pricing information from the manufacturer of
21 such selected drug, including information described
22 in subsection (d)(1); and

23 “(2) by not later than October 1 following the
24 selected drug publication date, the manufacturer of
25 such selected drug shall submit to the Secretary

1 such requested information in such form and man-
2 ner as the Secretary may require.

3 The Secretary shall request, from the manufacturer or
4 others, such additional information as may be needed to
5 carry out the negotiation and renegotiation process under
6 this section.

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

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

14 “(b) UPDATES.—

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

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

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

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

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

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

17 “(a) ADMINISTRATIVE DUTIES.—

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

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

1 agreements under section 1197 with group
2 health plans and health insurance issuers of
3 health insurance coverage offered in the indi-
4 vidual or group market) under which the max-
5 imum fair price for a selected drug is provided
6 to fair price eligible individuals described in
7 subparagraph (A) or (B) of section 1191(c)(1)
8 at pharmacies or by mail order service at the
9 point-of-sale of the drug for the applicable price
10 period for such drug and providing that such
11 maximum fair price is used for determining
12 cost-sharing under such plans or coverage for
13 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) under which, in the case of a selected
19 drug administered by such a hospital, physician,
20 or other provider of services or supplier to fair
21 price eligible individuals described in subpara-
22 graph (C) of section 1191(c)(1) and if payment
23 for such drug may be made under part A of
24 title XVIII or part B of such title, the max-
25 imum fair price for the selected drug is pro-

1 vided to such hospitals, physicians, and other
2 providers of services and suppliers (as applica-
3 ble) and providing that such maximum fair
4 price is used for determining cost-sharing under
5 the respective part, for the selected drug.

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

15 “(i) the lesser of—

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

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

20 “(III) any other similar deter-
21 mination of pharmacy acquisition
22 costs of the drug, as determined by
23 the Secretary; and

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

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

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

11 “(ii) any other discounts.

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

22 “(F) The establishment of procedures to
23 compute and apply the maximum fair price
24 across different strengths and dosage forms of
25 a selected drug that are not based on the spe-

1 cific formulation, dosage or strength, pack-
2 aging, or form of administration.

3 “(G) The establishment of procedures to
4 negotiate and apply the maximum fair price in
5 a manner that does not include any dispensing
6 or similar fee.

7 “(H) The establishment of procedures to
8 carry out the provisions of this part with re-
9 spect to—

10 “(i) fair price eligible individuals who
11 are enrolled under a prescription drug plan
12 under part D of title XVIII or an MA-PD
13 plan under part C of such title; and

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

21 “(I) The establishment of a negotiation
22 process and renegotiation process in accordance
23 with section 1194, including a process for ac-
24 quiring information described in subsection (d)

1 of such section and determining amounts de-
2 scribed in subsection (b) of such section.

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

8 “(2) MONITORING COMPLIANCE.—

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

14 “(B) NOTIFICATION.—If a third party
15 with a contract under subsection (c)(1) deter-
16 mines that the manufacturer is not in compli-
17 ance with such agreement, the third party shall
18 notify the Secretary of such noncompliance for
19 appropriate enforcement under section 4192 of
20 the Internal Revenue Code of 1986 or section
21 1198, as applicable.

22 “(b) COLLECTION OF DATA.—

23 “(1) FROM PRESCRIPTION DRUG PLANS AND
24 MA-PD PLANS.—The Secretary may collect appro-
25 priate data from prescription drug plans under part

1 D of title XVIII and MA–PD plans under part C of
2 such title in a timeframe that allows for maximum
3 fair prices to be provided under this part for selected
4 drugs.

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

11 “(c) CONTRACT WITH THIRD PARTIES.—

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

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

22 “(B) receive, distribute, or facilitate the
23 distribution of funds of manufacturers to ap-
24 propriate individuals or entities in order to

1 meet the obligations of manufacturers under
2 agreements under this part;

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

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

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

19 “(d) COORDINATION WITH 340B PROGRAM.—In the
20 case of a manufacturer of a selected drug, with respect
21 to an initial price applicability year, for each year with
22 respect to which a maximum fair price is applied under
23 this part for such drug, such drug shall not be considered
24 a covered outpatient drug subject to an agreement under
25 section 340B of the Public Health Service Act.

1 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
2 **HEALTH PLANS.**

3 “(a) IN GENERAL.—Under the program under this
4 part the Secretary shall be treated as having in effect an
5 agreement with a group health plan or health insurance
6 issuer offering health insurance coverage (as such terms
7 are defined in section 2791 of the Public Health Service
8 Act), except in the case that such a plan or issuer affirma-
9 tively elects not to participate under the program, through
10 a process specified by the Secretary, with respect to a
11 price applicability period and a selected drug with respect
12 to such period with respect to which coverage is provided
13 under such plan or coverage.

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

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

25 “(a) VIOLATIONS RELATING TO OFFERING OF MAX-
26 IMUM FAIR PRICE.—Any manufacturer of a selected drug

1 that has entered into an agreement under section 1193,
2 with respect to a plan year during the price applicability
3 period for such drug, that does not provide access to a
4 price that is not more than the maximum fair price (or
5 a lesser price) for such drug for such year—

6 “(1) to a fair price eligible individual described
7 in subparagraph (A) or (B) of section 1191(e)(1)
8 furnished such drug during such year; or

9 “(2) to a hospital, physician, or other provider
10 of services or supplier with respect to fair price eligi-
11 ble individuals described in subparagraph (C) of
12 such section administered such drug during such
13 year;

14 shall be subject to a civil monetary penalty equal to ten
15 times the amount equal to the difference between the price
16 for such drug made available by such manufacturer with
17 respect to such individual or hospital, physician, provider,
18 or supplier and the maximum fair price for such drug for
19 such year.

20 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
21 MENT.—Any manufacturer of a selected drug that has en-
22 tered into an agreement under section 1193, with respect
23 to a plan year during the price applicability period for
24 such drug, that is in violation of a requirement imposed
25 pursuant to section 1193(a)(6) shall be subject to a civil

1 monetary penalty of not more than \$1,000,000 for each
2 such violation.

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

8 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

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

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

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

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

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

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

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

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

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

21 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
22 CONFORMING AMENDMENTS.—

23 (1) UNDER MEDICARE PRESCRIPTION DRUG
24 PROGRAM.—

1 (A) EXCEPTION TO NON-INTER-
2 FERENCE.—Section 1860D–11(i) of the Social
3 Security Act (42 U.S.C. 1395w–111(i)) is
4 amended by inserting “, except as provided
5 under part E of title XI,” after “the Sec-
6 retary”.

7 (B) APPLICATION AS NEGOTIATED
8 PRICE.—Section 1860D–2(d)(1) of the Social
9 Security Act (42 U.S.C. 1395w–102(d)(1)) is
10 amended—

11 (i) in subparagraph (B), by inserting
12 “, subject to subparagraph (D),” after
13 “negotiated prices”; and

14 (ii) by adding at the end the following
15 new subparagraph:

16 “(D) APPLICATION OF MAXIMUM FAIR
17 PRICE FOR SELECTED DRUGS.—In applying this
18 section, in the case of a covered part D drug
19 that is a selected drug (as defined in section
20 1192(c)), with respect to a price applicability
21 period (as defined in section 1191(b)(2)), the
22 negotiated price described in this subsection
23 shall be the maximum fair price (as defined in
24 section 1191(c)(2)) for such drug and for each
25 plan year during such period.”.

1 (C) INFORMATION FROM PRESCRIPTION
2 DRUG PLANS AND MA-PD PLANS REQUIRED.—

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

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

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

20 “(E) PROVISION OF INFORMATION RE-
21 LATED TO MAXIMUM FAIR PRICES.—Section
22 1860D-12(b)(8).”.

23 (2) UNDER GROUP HEALTH PLANS AND
24 HEALTH INSURANCE COVERAGE.—

1 (A) PHSA.—Part A of title XXVII of the
2 Public Health Service Act is amended by insert-
3 ing after section 2729 the following new sec-
4 tion:

5 **“SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM**
6 **AND APPLICATION OF MAXIMUM FAIR**
7 **PRICES.**

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

19 “(1) the provisions of such part shall apply to
20 the plans or coverage offered by such plan or issuer,
21 and to the individuals enrolled under such plans or
22 coverage, during such period, with respect to such
23 selected drug, in the same manner as such provi-
24 sions apply to prescription drug plans and MA–PD

1 plans, and to individuals enrolled under such pre-
2 scription drug plans and MA–PD plans;

3 “(2) the plan or issuer shall apply any cost-
4 sharing responsibilities under such plan or coverage,
5 with respect to such selected drug, by substituting
6 the maximum fair price negotiated under such part
7 for such drug in lieu of the contracted rate under
8 such plan or coverage for such selected drug; and

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

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

25 (B) ERISA.—

1 (i) IN GENERAL.—Subpart B of part
2 7 of subtitle B of title I of the Employee
3 Retirement Income Security Act of 1974
4 (29 U.S.C. 1181 et. seq.) is amended by
5 adding at the end the following new sec-
6 tion:

7 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
8 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

20 “(1) the provisions of such part shall apply to
21 the plans or coverage offered by such plan or issuer,
22 and to the individuals enrolled under such plans or
23 coverage, during such period, with respect to such
24 selected drug, in the same manner as such provi-
25 sions apply to prescription drug plans and MA–PD

1 plans, and to individuals enrolled under such pre-
2 scription drug plans and MA–PD plans;

3 “(2) the plan or issuer shall apply any cost-
4 sharing responsibilities under such plan or coverage,
5 with respect to such selected drug, by substituting
6 the maximum fair price negotiated under such part
7 for such drug in lieu of the contracted rate under
8 such plan or coverage for such selected drug; and

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

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

24 (ii) CLERICAL AMENDMENT.—The
25 table of sections for part 7 of subtitle B of

1 title I of the Employee Retirement Income
 2 Security Act of 1974 is amended by adding
 3 at the end the following:

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

4 (C) IRC.—

5 (i) IN GENERAL.—Subchapter B of
 6 chapter 100 of the Internal Revenue Code
 7 of 1986 is amended by adding at the end
 8 the following new section:

9 **“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM**
 10 **AND APPLICATION OF MAXIMUM FAIR**
 11 **PRICES.**

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

21 “(1) the provisions of such part shall apply to
 22 the plans offered by such plan, and to the individ-
 23 uals enrolled under such plans, during such period,
 24 with respect to such selected drug, in the same man-

1 ner as such provisions apply to prescription drug
2 plans and MA–PD plans, and to individuals enrolled
3 under such prescription drug plans and MA–PD
4 plans;

5 “(2) the plan shall apply any cost-sharing re-
6 sponsibilities under such plan, with respect to such
7 selected drug, by substituting the maximum fair
8 price negotiated under such part for such drug in
9 lieu of the contracted rate under such plan for such
10 selected drug; and

11 “(3) the Secretary shall apply the provisions of
12 such part to such plan and such individuals so en-
13 rolled in such plan.

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

1 (ii) CLERICAL AMENDMENT.—The
 2 table of sections for subchapter B of chap-
 3 ter 100 of such Code is amended by add-
 4 ing at the end the following new item:

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

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

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

11 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
 12 **PERIODS.**

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

18 “(1) such tax, divided by

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

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

1 “(1) The period beginning on the June 16th
2 immediately following the selected drug publication
3 date and ending on the first date during which the
4 manufacturer of the drug has in place an agreement
5 described in subsection (a) of section 1193 of the
6 Social Security Act with respect to such drug.

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

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

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

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

7 “(c) APPLICABLE PERCENTAGE.—The term ‘applica-
8 ble percentage’ means—

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

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

15 “(3) in the case of sales of such drug during
16 the 181st day through the 270th day described in
17 subsection (b) with respect to such drug, 85 percent,
18 and

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

21 “(d) DEFINITIONS.—The terms ‘selected drug publi-
22 cation date’ and ‘maximum fair price’ have the meaning
23 given such terms in section 1191 of the Social Security
24 Act and the term ‘selected drug’ has the meaning given
25 such term in section 1192 of such Act.

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

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

9 (c) CONFORMING AMENDMENTS.—

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

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

15 (d) CLERICAL AMENDMENTS.—

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

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

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

4 (e) EFFECTIVE DATE.—The amendments made by
5 this section shall apply to sales after the date of the enact-
6 ment 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 Secu-
12 rity Act (42 U.S.C. 1395m) is amended by adding at the
13 end the following new subsection:

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

17 “(1) REQUIREMENTS.—

18 “(A) SECRETARIAL PROVISION OF INFOR-
19 MATION.—Not later than 6 months after the
20 end of each calendar quarter beginning on or
21 after July 1, 2021, the Secretary shall, for each
22 part B rebatable drug, report to each manufac-
23 turer of such part B rebatable drug the fol-
24 lowing for such 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
4 such 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 rebatable drug and calendar quarter.

13 “(B) MANUFACTURER REQUIREMENT.—
14 For each calendar quarter beginning on or after
15 July 1, 2021, the manufacturer of a part B
16 rebatable drug shall, for such drug, not later
17 than 30 days after the date of receipt from the
18 Secretary of the information described in sub-
19 paragraph (A) for such calendar quarter, pro-
20 vide to the Secretary a rebate that is equal to
21 the amount specified in paragraph (3) for such
22 drug for such calendar 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 sub-
2 paragraph (D) of section 1847A(e)(6)), includ-
3 ing a biosimilar biological product (as defined
4 in subparagraph (H) of such section), paid for
5 under this part, except such term shall not in-
6 clude such a drug or biological—

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

12 “(ii) that is a vaccine described in
13 subparagraph (A) or (B) of section
14 1861(s)(10).

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

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

24 “(ii) for a subsequent year, shall be
25 the dollar amount specified in this clause

1 (or clause (i)) for the previous year, in-
2 creased by the percentage increase in the
3 consumer price index for all urban con-
4 sumers (United States city average) as of
5 the first quarter of the previous year.

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

9 “(3) REBATE AMOUNT.—

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

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

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

22 “(I) the payment amount under
23 subparagraph (B) or (C) of section
24 1847A(b)(1), as applicable, for such

1 part B rebatable drug during the cal-
2 endar quarter; exceeds

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

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

12 “(i) units packaged into the payment
13 for a related procedure or service under
14 section 1833(t) or under section 1833(i)
15 (instead of separately payable under such
16 respective section);

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

20 “(iii) units of a part B rebatable drug
21 of a manufacturer that is furnished to an
22 individual, if such manufacturer, with re-
23 spect to the furnishing of such units of
24 such drug, provides for discounts under

1 section 340B of the Public Health Service
2 Act or for rebates under section 1927.

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

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

12 “(ii) the percentage by which the re-
13 bate period CPI–U (as defined in subpara-
14 graph (F)) for the calendar quarter ex-
15 ceeds the benchmark period CPI–U (as de-
16 fined in subparagraph (E)).

17 “(D) PAYMENT AMOUNT BENCHMARK
18 QUARTER.—The term ‘payment amount bench-
19 mark quarter’ means the calendar quarter be-
20 ginning January 1, 2016.

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

1 “(F) REBATE PERIOD CPI-U.—The term
2 ‘rebate period CPI-U’ means, with respect to a
3 calendar quarter described in subparagraph
4 (C), the greater of the benchmark period CPI-
5 U and the consumer price index for all urban
6 consumers (United States city average) for the
7 first month of the calendar quarter that is two
8 calendar quarters prior to such described cal-
9 endar quarter.

10 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
11 AND EXEMPTION.—

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

1 full calendar quarter after the day on which the
2 drug was first marketed’.

3 “(B) TIMELINE FOR PROVISION OF RE-
4 BATES FOR NEW DRUGS.—In the case of a part
5 B rebatable drug first approved by the Food
6 and Drug Administration after July 1, 2015,
7 clause (i) of paragraph (1)(B) shall be applied
8 as if the reference to ‘July 1, 2021’ under such
9 paragraph were a reference to the later of the
10 6th full calendar quarter after the day on which
11 the drug was first marketed or July 1, 2021.

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

20 “(D) SELECTED DRUGS.—In the case of a
21 part B rebatable drug that is a selected drug
22 (as defined in section 1192(e)), for each appli-
23 cable year beginning after the price applicability
24 period (as defined in section 1191(b)(2) with
25 respect to such drug, clause (i) of paragraph

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

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

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

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

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

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

20 “(8) STUDY AND REPORT.—

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

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

4 “(ii) Including drugs and biologicals
5 paid for under MA plans under part C in
6 the rebate system under this subsection.

7 “(iii) Including drugs excluded under
8 paragraph (2)(A) and billing units of
9 drugs excluded under paragraph (3)(B) in
10 the rebate system under this subsection.

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

16 “(9) APPLICATION TO MULTIPLE SOURCE
17 DRUGS.—The Secretary may, based on the report
18 submitted under paragraph (8) and pursuant to
19 rulemaking, apply the provisions of this subsection
20 to multiple source drugs (as defined in section
21 1847A(c)(6)(C)), including, for purposes of deter-
22 mining the rebate amount under paragraph (3), by
23 calculating manufacturer-specific average sales
24 prices for the benchmark period and the rebate pe-
25 riod.”.

1 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
2 1833(a) of the Social Security Act is amended—

3 (1) in paragraph (1)—

4 (A) in subparagraph (S), by striking “with
5 respect to” and inserting “subject to subpara-
6 graph (DD), with respect to”;

7 (B) by striking “and (CC)” and inserting
8 “(CC)”; and

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

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

22 “For purposes of applying paragraph (1)(DD) and section
23 1834(x)(5), the Secretary shall make such estimates and
24 use such data as the Secretary determines appropriate.”.

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

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

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

9 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
10 **DRUGS WITH PRICES INCREASING FASTER**
11 **THAN INFLATION.**

12 “(a) IN GENERAL.—Subject to the provisions of this
13 section, in order for coverage to be available under this
14 part for a part D rebatable drug of a manufacturer dis-
15 pensed during an applicable year, the manufacturer must
16 have entered into and have in effect an agreement de-
17 scribed in subsection (b). For purposes of this section the
18 term ‘applicable year’ means a year beginning with 2022.

19 “(b) AGREEMENTS.—

20 “(1) TERMS OF AGREEMENT.—An agreement
21 described in this subsection, with respect to a manu-
22 facturer of a part D rebatable drug, is an agreement
23 under which the following applies:

24 “(A) SECRETARIAL PROVISION OF INFOR-
25 MATION.—Not later than 9 months after the

1 end of each applicable year with respect to
2 which the agreement is in effect, the Secretary,
3 for the part D rebatable drug of the manufac-
4 turer, reports to the manufacturer the following
5 for such year:

6 “(i) Information on the total units (as
7 defined in subsection (g)(2)) dispensed for
8 each dosage form and strength with re-
9 spect to such part D rebatable drug and
10 year.

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

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

21 “(B) MANUFACTURER REQUIREMENTS.—

22 For each applicable year with respect to which
23 the agreement is in effect, the manufacturer of
24 the part D rebatable drug, for each dosage
25 form and strength with respect to such drug,

1 not later than 30 days after the date of receipt
2 from the Secretary of the information described
3 in subparagraph (A) for such year, provides to
4 the Secretary a rebate that is equal to the
5 amount specified in subsection (c) for such dos-
6 age form and strength with respect to such
7 drug for such year.

8 “(2) LENGTH OF AGREEMENT.—

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

16 “(B) TERMINATION.—

17 “(i) BY SECRETARY.—The Secretary
18 may provide for termination of an agree-
19 ment under this section for violation of the
20 requirements of the agreement or other
21 good cause shown. Such termination shall
22 not be effective earlier than 60 days after
23 the date of notice of such termination. The
24 Secretary shall provide, upon request, a
25 manufacturer with a hearing concerning

1 such a termination, but such hearing shall
2 not delay the effective date of the termi-
3 nation.

4 “(ii) BY A MANUFACTURER.—A man-
5 ufacturer may terminate an agreement
6 under this section for any reason. Any
7 such termination shall not be effective
8 until the year beginning at least 60 days
9 after the date the manufacturer provides
10 notice to the Secretary.

11 “(C) EFFECTIVENESS OF TERMINATION.—
12 Any termination under this paragraph shall not
13 affect rebates due under the agreement under
14 this section before the effective date of its ter-
15 mination.

16 “(D) DELAY BEFORE REENTRY.—In the
17 case of any agreement under this section with
18 a manufacturer which is terminated in a plan
19 year, another such agreement with the manu-
20 facturer (or a successor manufacturer) may not
21 be entered into before the subsequent plan year,
22 unless the Secretary finds good cause for an
23 earlier reinstatement of such an agreement.

24 “(3) INFORMATION.—For purposes of carrying
25 out this section, the Secretary shall use information

1 submitted by manufacturers under section
2 1927(b)(3).

3 “(c) REBATE AMOUNT.—

4 “(1) IN GENERAL.—For purposes of this sec-
5 tion, the amount specified in this subsection for a
6 dosage form and strength with respect to a part D
7 rebatable drug and applicable year is, subject to sub-
8 paragraphs (B) and (C) of paragraph (3), the
9 amount equal to the product of—

10 “(A) the total average number of units
11 weighted by, and dispensed for, such dosage
12 form and strength with respect to such part D
13 rebatable drug and year; and

14 “(B) the amount (if any) by which—

15 “(i) the average manufacturer price
16 (as defined in subsection (g)) paid for such
17 dosage form and strength with respect to
18 such part D rebatable drug during the
19 year; exceeds

20 “(ii) the inflation-adjusted payment
21 amount determined under paragraph (2)
22 for such dosage form and strength with re-
23 spect to such part D rebatable drug during
24 the year.

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

7 “(A) the average manufacturer price paid
8 for such dosage form and strength with respect
9 to such drug in the payment amount bench-
10 mark year (as defined in subsection (g)(3)); in-
11 creased by

12 “(B) the percentage by which the rebate
13 period CPI-U (as defined in subsection (g)(5))
14 for the applicable year exceeds the benchmark
15 period CPI-U (as defined in subsection (g)(4)).

16 “(3) SPECIAL TREATMENT OF CERTAIN DRUGS
17 AND EXEMPTION.—

18 “(A) SUBSEQUENTLY APPROVED DRUGS.—

19 In the case of a part D rebatable drug first ap-
20 proved by the Food and Drug Administration
21 after January 1, 2016, subparagraph (A) of
22 paragraph (2) shall be applied as if the term
23 ‘payment amount benchmark year’ were defined
24 under subsection (g)(3) as the first year begin-
25 ning after the day on which the drug was first

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

9 “(B) EXEMPTION FOR SHORTAGES.—The
10 Secretary may reduce or waive the rebate under
11 paragraph (1) with respect to a part D
12 rebatable drug in the case of a shortage of such
13 drug or other exigent circumstances, as deter-
14 mined by the Secretary.

15 “(C) TREATMENT OF NEW FORMULA-
16 TIONS.—

17 “(i) IN GENERAL.—In the case of a
18 part D rebatable drug that is a line exten-
19 sion of a single source drug or an inno-
20 vator multiple source drug that is an oral
21 solid dosage form, the Secretary shall es-
22 tablish a formula for determining the
23 amount specified in this subsection with
24 respect to such part D rebatable drug and
25 an applicable year with consideration of

1 the single source drug or an innovator
2 multiple source drug.

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

14 “(D) SELECTED DRUGS.—In the case of a
15 part D rebatable drug that is a selected drug
16 (as defined in section 1192(c)), for each appli-
17 cable year beginning after the price applicability
18 period (as defined in section 1191(b)(2) with
19 respect to such drug, subparagraph (A) of para-
20 graph (2) shall be applied as if the term ‘pay-
21 ment amount benchmark year’ were defined
22 under subsection (g)(3) as the last year begin-
23 ning during such price applicability period with
24 respect to such selected drug and subparagraph
25 (B) of paragraph (2) shall be applied as if the

1 term ‘benchmark period CPI–U’ were defined
2 under subsection (g)(4) as if the reference to
3 ‘January 2016’ under such subsection were a
4 reference to January of the last year beginning
5 during such price applicability period with re-
6 spect to such drug.

7 “(d) REBATE DEPOSITS.—Amounts paid as rebates
8 under subsection (c) shall be deposited into the Medicare
9 Prescription Drug Account in the Federal Supplementary
10 Medical Insurance Trust Fund established under section
11 1841.

12 “(e) CIVIL MONEY PENALTY.—In the case of a man-
13 ufacturer of a part D rebatable drug with an agreement
14 in effect under this section who has failed to comply with
15 the terms of the agreement under subsection (b)(1)(B)
16 with respect to such drug for an applicable year, the Sec-
17 retary may impose a civil money penalty on such manufac-
18 turer in an amount equal to 125 percent of the amount
19 specified in subsection (c) for such drug for such year.
20 The provisions of section 1128A (other than subsections
21 (a) (with respect to amounts of penalties or additional as-
22 sessments) and (b)) shall apply to a civil money penalty
23 under this subsection in the same manner as such provi-
24 sions apply to a penalty or proceeding under section
25 1128A(a).

1 “(f) JUDICIAL REVIEW.—There shall be no judicial
2 review of the following:

3 “(1) The determination of units under this sec-
4 tion.

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

7 “(3) The calculation of the rebate amount
8 under this section.

9 “(g) DEFINITIONS.—In this section:

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

11 “(A) IN GENERAL.—The term ‘part D
12 rebatable drug’ means a drug or biological that
13 would (without application of this section) be a
14 covered part D drug, except such term shall,
15 with respect to an applicable year, not include
16 such a drug or biological if the average total
17 cost under a prescription drug plan under this
18 part or MA–PD plan under part C for such
19 year per individual who uses such a drug or bi-
20 ological, as determined by the Secretary, are
21 less than, subject to subparagraph (B), \$100,
22 as determined by the Secretary using the most
23 recent data available or, if data is not available,
24 as estimated by the Secretary.

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

3 “(i) for 2023, shall be the dollar
4 amount specified under such subparagraph
5 for 2022, increased by the percentage in-
6 crease in the consumer price index for all
7 urban consumers (United States city aver-
8 age) as of January of 2022; and

9 “(ii) for a subsequent year, shall be
10 the dollar amount specified in this sub-
11 paragraph (or subparagraph (A)) for the
12 previous year, increased by the percentage
13 increase in the consumer price index for all
14 urban consumers (United States city aver-
15 age) as of January of the previous year.

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

19 “(2) UNIT DEFINED.—The term ‘unit’ means,
20 with respect to a part D rebatable drug, the lowest
21 identifiable quantity (such as a capsule or tablet,
22 milligram of molecules, or grams) of the part D
23 rebatable drug that is dispensed to individuals en-
24 rolled under a prescription drug plan under this part
25 or an MA–PD plan under part C.

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

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

8 “(5) REBATE PERIOD CPI–U.—The term ‘rebate
9 period CPI–U’ means, with respect to an applicable
10 year, the consumer price index for all urban con-
11 sumers (United States city average) for January of
12 such year.

13 “(6) AVERAGE MANUFACTURER PRICE.—The
14 term ‘average manufacturer price’ has the meaning,
15 with respect to a part D rebatable drug of a manu-
16 facturer for an applicable year, given such term in
17 section 1927(k)(1), with respect to a covered out-
18 patient drug of a manufacturer for a rebate period
19 under section 1927. For purposes of applying the
20 previous sentence, with respect to a part D rebatable
21 drug of a manufacturer and an applicable year, the
22 Secretary shall use the information with respect to
23 the average manufacturer price for such drug re-
24 ported by the manufacturer under section
25 1927(b)(3) with respect to each of the quarters in

1 the applicable year and calculate an annual average
2 manufacturer price for such applicable year as the
3 average of such average manufacturer prices for
4 each such quarter, weighted by units of such drug
5 sold or dispensed with respect to such applicable
6 year.”.

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

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

12 (a) **BENEFIT STRUCTURE REDESIGN.**—Section
13 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
14 102(b)) is amended—

15 (1) in paragraph (2)—

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

23 (B) in subparagraph (C)—

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

1 year preceding 2022,” after “paragraph
2 (4),”; and
3 (ii) in clause (ii)(III), by striking
4 “and each subsequent year” and inserting
5 “and 2021”; and
6 (C) in subparagraph (D)—
7 (i) in clause (i)—
8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2022,” after “paragraph
11 (4),”; and
12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2018 through
15 2021”; and
16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2021”;
20 (2) in paragraph (3)(A)—
21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2022,” after
23 “and (4),”; and

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

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

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

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

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

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

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

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

1 (ii) in clause (ii)—

2 (I) by striking “clause (i)(I)” and
3 inserting “clause (i)(I)(aa)”; and

4 (II) by adding at the end the fol-
5 lowing new sentence: “The Secretary
6 shall continue to calculate the dollar
7 amounts specified in clause (i)(I)(aa),
8 including with the adjustment under
9 this clause, after 2021 for purposes of
10 section 1860D–14(a)(1)(D)(iii).”;

11 (B) in subparagraph (B)—

12 (i) in clause (i)—

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

15 (II) in subclause (VI)—

16 (aa) by striking “for a sub-
17 sequent year” and inserting “for
18 2021”; and

19 (bb) by striking the period
20 at the end and inserting a semi-
21 colon; and

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

24 “(VII) for 2022, is equal to
25 \$2,000; or

1 “(VIII) for a subsequent year, is
 2 equal to the amount specified in this
 3 subparagraph for the previous year,
 4 increased by the annual percentage in-
 5 crease described in paragraph (6) for
 6 the year involved.”; and

7 (ii) in clause (ii), by striking “clause
 8 (i)(II)” and inserting “clause (i)”;

9 (C) in subparagraph (C)(i), by striking
 10 “and for amounts” and inserting “and, for a
 11 year preceding 2022, for amounts”; and

12 (D) in subparagraph (E), by striking “In
 13 applying” and inserting “For each of years
 14 2011 through 2021, in applying”.

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

20 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

1 **“SEC. 1860D-14C. MANUFACTURER DISCOUNT PROGRAM.**

2 “(a) ESTABLISHMENT.—The Secretary shall estab-
3 lish a manufacturer discount program (in this section re-
4 ferred to as the ‘program’). Under the program, the Sec-
5 retary shall enter into agreements described in subsection
6 (b) with manufacturers and provide for the performance
7 of the duties described in subsection (c). The Secretary
8 shall establish a model agreement for use under the pro-
9 gram by not later than January 1, 2021, in consultation
10 with manufacturers, and allow for comment on such model
11 agreement.

12 “(b) TERMS OF AGREEMENT.—

13 “(1) IN GENERAL.—

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

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

26 “(C) TIMING OF AGREEMENT.—

1 “(i) SPECIAL RULE FOR 2022.—In
2 order for an agreement with a manufac-
3 turer to be in effect under this section with
4 respect to the period beginning on January
5 1, 2022, and ending on December 31,
6 2022, the manufacturer shall enter into
7 such agreement not later than 30 days
8 after the date of the establishment of a
9 model agreement under subsection (a).

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

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

1 “(3) COMPLIANCE WITH REQUIREMENTS FOR
2 ADMINISTRATION OF PROGRAM.—Each manufac-
3 turer with an agreement in effect under this section
4 shall comply with requirements imposed by the Sec-
5 retary or a third party with a contract under sub-
6 section (d)(3), as applicable, for purposes of admin-
7 istering the program, including any determination
8 under subparagraph (A) of subsection (c)(1) or pro-
9 cedures established under such subsection (c)(1).

10 “(4) LENGTH OF AGREEMENT.—

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

17 “(B) TERMINATION.—

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

1 The Secretary shall provide, upon request,
2 a manufacturer with a hearing concerning
3 such a termination, and such hearing shall
4 take place prior to the effective date of the
5 termination with sufficient time for such
6 effective date to be repealed if the Sec-
7 retary determines appropriate.

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

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

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

21 “(iii) EFFECTIVENESS OF TERMI-
22 NATION.—Any termination under this sub-
23 paragraph shall not affect discounts for
24 applicable drugs of the manufacturer that

1 are due under the agreement before the ef-
2 fective date of its termination.

3 “(iv) NOTICE TO THIRD PARTY.—The
4 Secretary shall provide notice of such ter-
5 mination to a third party with a contract
6 under subsection (d)(3) within not less
7 than 30 days before the effective date of
8 such termination.

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

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

13 “(A) the determination of the amount of
14 the discounted price of an applicable drug of a
15 manufacturer;

16 “(B) the establishment of procedures
17 under which discounted prices are provided to
18 applicable beneficiaries at pharmacies or by
19 mail order service at the point-of-sale of an ap-
20 plicable drug;

21 “(C) the establishment of procedures to
22 ensure that, not later than the applicable num-
23 ber of calendar days after the dispensing of an
24 applicable drug by a pharmacy or mail order
25 service, the pharmacy or mail order service is

1 reimbursed for an amount equal to the dif-
2 ference between—

3 “(i) the negotiated price of the appli-
4 cable drug; and

5 “(ii) the discounted price of the appli-
6 cable drug;

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

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

21 “(2) MONITORING COMPLIANCE.—

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

1 “(B) NOTIFICATION.—If a third party
2 with a contract under subsection (d)(3) deter-
3 mines that the manufacturer is not in compli-
4 ance with such agreement, the third party shall
5 notify the Secretary of such noncompliance for
6 appropriate enforcement under subsection (e).

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

13 “(d) ADMINISTRATION.—

14 “(1) IN GENERAL.—Subject to paragraph (2),
15 the Secretary shall provide for the implementation of
16 this section, including the performance of the duties
17 described in subsection (e).

18 “(2) LIMITATION.—In providing for the imple-
19 mentation of this section, the Secretary shall not re-
20 ceive or distribute any funds of a manufacturer
21 under the program.

22 “(3) CONTRACT WITH THIRD PARTIES.—The
23 Secretary shall enter into a contract with 1 or more
24 third parties to administer the requirements estab-
25 lished by the Secretary in order to carry out this

1 section. At a minimum, the contract with a third
2 party under the preceding sentence shall require
3 that the third party—

4 “(A) receive and transmit information be-
5 tween the Secretary, manufacturers, and other
6 individuals or entities the Secretary determines
7 appropriate;

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

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

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

23 “(4) PERFORMANCE REQUIREMENTS.—The
24 Secretary shall establish performance requirements
25 for a third party with a contract under paragraph

1 (3) and safeguards to protect the independence and
2 integrity of the activities carried out by the third
3 party under the program under this section.

4 “(5) IMPLEMENTATION.—The Secretary may
5 implement the program under this section by pro-
6 gram instruction or otherwise.

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

10 “(e) ENFORCEMENT.—

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

14 “(2) CIVIL MONEY PENALTY.—

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

22 “(i) the amount that the manufac-
23 turer would have paid with respect to such
24 discounts under the agreement, which will
25 then be used to pay the discounts which

1 the manufacturer had failed to provide;
2 and

3 “(ii) 25 percent of such amount.

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

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

17 “(g) DEFINITIONS.—In this section:

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

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

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

1 “(C) has incurred costs for covered part D
2 drugs in the year that are equal to or exceed
3 the annual deductible specified in section
4 1860D–2(b)(1) for such year.

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

7 “(A) means a covered part D drug—

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

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

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

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

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

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

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

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

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

16 “(4) DISCOUNTED PRICE.—

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

21 “(i) who has not incurred costs for
22 covered part D drugs in the year that are
23 equal to or exceed the annual out-of-pocket
24 threshold specified in section 1860D—

1 2(b)(4)(B)(i) for the year, 90 percent of
2 the negotiated price of such drug; and

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

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

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

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

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

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

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

20 “(5) MANUFACTURER.—The term ‘manufac-
21 turer’ means any entity which is engaged in the pro-
22 duction, preparation, propagation, compounding,
23 conversion, or processing of prescription drug prod-
24 ucts, either directly or indirectly by extraction from
25 substances of natural origin, or independently by

1 means of chemical synthesis, or by a combination of
2 extraction and chemical synthesis. Such term does
3 not include a wholesale distributor of drugs or a re-
4 tail pharmacy licensed under State law.

5 “(6) NEGOTIATED PRICE.—The term ‘nego-
6 tiated price’ has the meaning given such term in sec-
7 tion 423.100 of title 42, Code of Federal Regula-
8 tions (as in effect on the date of enactment of sec-
9 tion 1860D–14A), except that such negotiated price
10 shall not include any dispensing fee for the applica-
11 ble drug.

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

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

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

23 (B) by adding at the end the following new
24 subsection:

25 “(h) SUNSET OF PROGRAM.—

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

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

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

16 (A) in subsection (b)(2)(C)(iii)—

17 (i) by striking “assumptions regarding
18 the reinsurance” and inserting “assump-
19 tions regarding—

20 “(I) the reinsurance”; and

21 (ii) by adding at the end the fol-
22 lowing:

23 “(II) for 2022 and each subse-
24 quent year, the manufacturer dis-
25 counts provided under section 1860D–

1 14C subtracted from the actuarial
2 value to produce such bid; and”;

3 (B) in subsection (c)(1)(C)—

4 (i) by striking “an actuarial valuation
5 of the reinsurance” and inserting “an ac-
6 tuarial valuation of—

7 “(i) the reinsurance”;

8 (ii) in clause (i), as inserted by clause
9 (i) of this subparagraph, by adding “and”
10 at the end; and

11 (iii) by adding at the end the fol-
12 lowing:

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

16 (d) CONFORMING AMENDMENTS.—

17 (1) Section 1860D–2 of the Social Security Act
18 (42 U.S.C. 1395w–102) is amended—

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

23 (B) in subsection (c)(1)(C)—

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

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

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

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

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

19 (A) in paragraph (1)—

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

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

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

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

9 (ii) in subparagraph (E)—
10 (I) by inserting “for a year pre-
11 ceding 2022,” after “subsection (e)”;
12 and

13 (II) by striking “1860D-
14 2(b)(4)(A)(i)(I)” and inserting
15 “1860D-2(b)(4)(A)(i)(I)(aa)”.

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

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

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

1 “(i) for years prior to 2022, any dis-
2 count”.

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

6 (C) by adding at the end the following new
7 clause:

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

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

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

15 (B) by inserting “for such year” before the
16 period.

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

20 “(1) participate in—

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

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

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

○