

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO COMMITTEE PRINT FOR SUBTITLE E RE-
LATING TO DRUG PRICING
OFFERED BY M__ . _____**

In lieu of the proposed recommendations, insert the following:

1 **Subtitle E—Drug Pricing**
2 **PART 1—LOWERING PRICES THROUGH FAIR**
3 **DRUG PRICE NEGOTIATION**
4 **SEC. 30501. PROVIDING FOR LOWER PRICES FOR CERTAIN**
5 **HIGH-PRICED SINGLE SOURCE DRUGS.**

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

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

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

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

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

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

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

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

13 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
14 term ‘initial price applicability year’ means a plan
15 year (beginning with plan year 2025) or, if agreed
16 to in an agreement under section 1193 by the Sec-
17 retary and manufacturer involved, a period of more
18 than one plan year (beginning on or after January
19 1, 2025).

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

1 “(3) SELECTED DRUG PUBLICATION DATE.—

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

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

10 “(A) beginning on the sooner of—

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

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

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

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

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

1 “(A) in the case such drug is furnished or
2 dispensed to the individual at a pharmacy or by
3 a mail order service—

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

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

20 “(B) in the case such drug is furnished or
21 administered to the individual by a hospital,
22 physician, or other provider of services or sup-
23 plier—

24 “(i) an individual who is entitled to
25 benefits under part A of title XVIII or en-

1 rolled under part B of such title if such se-
2 lected drug is covered under the respective
3 part; and

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

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

21 “(3) AVERAGE INTERNATIONAL MARKET PRICE
22 DEFINED.—

23 “(A) IN GENERAL.—The terms ‘average
24 international market price’ and ‘AIM price’
25 mean, with respect to a drug, the average price

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

14 “(B) APPLICABLE COUNTRIES.—

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

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

25 “(I) Australia.

1 “(II) Canada.

2 “(III) France.

3 “(IV) Germany.

4 “(V) Japan.

5 “(VI) The United Kingdom.

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

10 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
11 **AS SELECTED DRUGS.**

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

16 “(1)(A) with respect to an initial price applica-
17 bility year during 2025, at least 25 negotiation-eli-
18 gible drugs described in subparagraphs (A) and (B),
19 but not subparagraph (C), of subsection (d)(1) (or,
20 with respect to an initial price applicability year dur-
21 ing such period beginning after 2025, the maximum
22 number (if such number is less than 25) of such ne-
23 gotation-eligible drugs for the year) with respect to
24 such year; and

1 “(B) with respect to an initial price applica-
2 bility year during 2026 or a subsequent year, at
3 least 50 negotiation-eligible drugs described in sub-
4 paragraphs (A) and (B), but not subparagraph (C),
5 of subsection (d)(1) (or, with respect to an initial
6 price applicability year during such period, the max-
7 imum number (if such number is less than 50) of
8 such negotiation-eligible drugs for the year) with re-
9 spect to such year;

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

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

16 Each drug published on the list pursuant to the previous
17 sentence shall be subject to the negotiation process under
18 section 1194 for the voluntary negotiation period with re-
19 spect to such initial price applicability year (and the re-
20 negotiation process under such section as applicable for
21 any subsequent year during the applicable price applica-
22 bility period). In applying this subsection, any negotiation-
23 eligible drug that is selected under this subsection for an
24 initial price applicability year shall not count toward the
25 required minimum amount of drugs to be selected under

1 paragraph (1) for any subsequent year, including such a
2 drug so selected that is subject to renegotiation under sec-
3 tion 1194.

4 “(b) SELECTION OF DRUGS.—In carrying out sub-
5 section (a)(1) the Secretary shall select for inclusion on
6 the published list described in subsection (a) with respect
7 to a price applicability period, the negotiation-eligible
8 drugs that the Secretary projects will result in the greatest
9 savings to the Federal Government or fair price eligible
10 individuals during the price applicability period. In making
11 this projection of savings for drugs for which there is an
12 AIM price for a price applicability period, the savings shall
13 be projected across different dosage forms and strengths
14 of the drugs and not based on the specific formulation or
15 package size or package type of the drugs, taking into con-
16 sideration both the volume of drugs for which payment
17 is made, to the extent such data is available, and the
18 amount by which the net price for the drugs exceeds the
19 AIM price for the drugs.

20 “(c) SELECTED DRUG.—For purposes of this part,
21 each drug included on the list published under subsection
22 (a) with respect to an initial price applicability year shall
23 be referred to as a ‘selected drug’ with respect to such
24 year and each subsequent plan year beginning before the

1 first plan year beginning after the date on which the Sec-
2 retary determines two or more drug products—

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

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

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

10 “(2) continue to be marketed.

11 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

1 “(B) OTHER DRUGS.—The drug is among
2 the 125 drugs for which there was an estimated
3 greatest net spending in the United States (in-
4 cluding the 50 States, the District of Columbia,
5 and the territories of the United States), as de-
6 termined by the Secretary, during the most re-
7 cent plan year prior to such drug publication
8 date for which data are available.

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

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

19 “(3) PUBLICATION.—Not later than the se-
20 lected drug publication date with respect to an ini-
21 tial price applicability year, the Secretary shall pub-
22 lish in the Federal Register a list of negotiation-eli-
23 gible drugs with respect to such selected drug publi-
24 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, including
8 any insulin product that has been deemed to be li-
9 censed under section 351(a) of the Public Health
10 Service Act pursuant to section 7002(e)(4) of the
11 Biologics Price Competition and Innovation Act of
12 2009 and continues to be marketed pursuant to such
13 licensure.

14 For purposes of applying paragraphs (1) and (2), a drug
15 or biological product that is marketed by the same sponsor
16 or manufacturer (or an affiliate thereof or a cross-licensed
17 producer or distributor) as the listed drug or reference
18 product described in such respective paragraph shall not
19 be taken into consideration.

20 “(f) INFORMATION ON INTERNATIONAL DRUG
21 PRICES.—For purposes of determining which negotiation-
22 eligible drugs to select under subsection (a) and, in the
23 case of such drugs that are selected drugs, to determine
24 the maximum fair price for such a drug and whether such
25 maximum fair price should be renegotiated under section

1 1194, the Secretary shall use data relating to the AIM
2 price with respect to such drug as available or provided
3 to the Secretary and shall on an ongoing basis request
4 from manufacturers of selected drugs information on the
5 AIM price of such a drug.

6 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE
7 DRUGS.—

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

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

17 “(B) that the Secretary determines under
18 paragraph (2) is likely to be included as a nego-
19 tiation-eligible drug with respect to the subse-
20 quent selected drug publication date.

21 “(2) DETERMINATION.—In the case of a quali-
22 fying single source drug that meets the criteria de-
23 scribed in subparagraph (A) of paragraph (1), with
24 respect to an initial price applicability year, if the
25 wholesale acquisition cost at which such drug is first

1 marketed in the United States is equal to or greater
2 than the median household income (as determined
3 according to the most recent data collected by the
4 United States Census Bureau), the Secretary shall
5 determine before the selected drug publication date
6 with respect to the initial price applicability year, if
7 the drug is likely to be included as a negotiation-eli-
8 gible drug with respect to the subsequent selected
9 drug publication date, based on the projected spend-
10 ing under title XVIII or in the United States on
11 such drug. For purposes of this paragraph the term
12 ‘United States’ includes the 50 States, the District
13 of Columbia, and the territories of the United
14 States.

15 “(h) CONFLICT OF INTEREST.—

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

24 “(2) MATTER DESCRIBED.—A matter described
25 in this paragraph is—

1 “(A) a financial interest (as described in
2 section 2635.402 of title 5, Code of Federal
3 Regulations, as in effect on the date of the en-
4 actment of this section, (except for an interest
5 described in subsection (b)(2)(iv) of such sec-
6 tion)) on the date of the selected drug publica-
7 tion date, with respect the price applicability
8 year (as applicable);

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

13 “(C) employment by a manufacturer of a
14 negotiation-eligible drug during the preceding
15 10-year period beginning on the date of the se-
16 lected drug publication date, with respect to
17 each price applicability year; and

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

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

22 “(A) the highest-ranking officer or em-
23 ployee of the Department of Health and
24 Human Services (as determined by the organi-

1 zational chart of the Department) that does not
2 have a conflict under this subsection; and

3 “(B) is nominated by the President and
4 confirmed by the Senate with respect to the po-
5 sition.

6 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

7 “(a) IN GENERAL.—For purposes of section
8 1191(a)(2), the Secretary shall enter into agreements with
9 manufacturers of selected drugs with respect to a price
10 applicability period, by not later than June 15 following
11 the selected drug publication date with respect to such se-
12 lected drug, under which—

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

21 “(A) to fair price eligible individuals who
22 with respect to such drug are described in sub-
23 paragraph (A) of section 1191(c)(1) and are
24 furnished or dispensed such drug during, sub-

1 ject to subparagraph (2), the price applicability
2 period; and

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

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

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

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

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

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

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

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

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

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

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

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

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

1 “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS
2 WITHOUT AIM PRICE.—

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

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

20 “(B) the number of units of such drug sold
21 in the United States, including the 50 States,
22 the District of Columbia, and the territories of
23 the United States, during the period described
24 in paragraph (2)(B).

25 “(2) AMOUNTS DESCRIBED.—

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

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

24 “(d) CONFIDENTIALITY OF INFORMATION.—Infor-
25 mation submitted to the Secretary under this part by a

1 manufacturer of a selected drug that is proprietary infor-
2 mation of such manufacturer (as determined by the Sec-
3 retary) may be used only by the Secretary or disclosed
4 to and used by the Comptroller General of the United
5 States or the Medicare Payment Advisory Commission for
6 purposes of carrying out this part.

7 “(e) REGULATIONS.—

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

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

23 “(f) COMPLIANCE WITH REQUIREMENTS FOR AD-
24 MINISTRATION OF PROGRAM.—Each manufacturer with
25 an agreement in effect under this section shall comply with

1 requirements imposed by the Secretary or a third party
2 with a contract under section 1196(e)(1), as applicable,
3 for purposes of administering the program.

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

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

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

16 “(2) as applicable pursuant to section
17 1193(a)(2) and in accordance with the process speci-
18 fied pursuant to such section, renegotiate such max-
19 imum fair price for such drug for the purpose de-
20 scribed in such section.

21 “(b) NEGOTIATING METHODOLOGY AND OBJEC-
22 TIVE.—

23 “(1) IN GENERAL.—The Secretary shall develop
24 and use a consistent methodology for negotiations
25 under subsection (a) that, in accordance with para-

1 graph (2) and subject to paragraph (3), achieves the
2 lowest maximum fair price for each selected drug
3 while appropriately rewarding innovation.

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

10 “(A) RESEARCH AND DEVELOPMENT
11 COSTS.—The factor described in paragraph
12 (1)(A) of subsection (d).

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

15 “(C) UNIT COSTS OF PRODUCTION AND
16 DISTRIBUTION.—The factor described in para-
17 graph (1)(C) of such subsection.

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

21 “(3) REQUIREMENT.—

22 “(A) IN GENERAL.—In negotiating the
23 maximum fair price of a selected drug, with re-
24 spect to an initial price applicability year for
25 the selected drug, and, as applicable, in renego-

1 tiating the maximum fair price for such drug,
2 with respect to a subsequent year during the
3 price applicability period for such drug, in the
4 case that the manufacturer of the selected drug
5 offers under the negotiation or renegotiation, as
6 applicable, a price for such drug that is not
7 more than the target price described in sub-
8 paragraph (B) for such drug for the respective
9 year, the Secretary shall agree under such ne-
10 gotiation or renegotiation, respectively, to such
11 offered price as the maximum fair price.

12 “(B) TARGET PRICE.—

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

1 that, with respect to such year, has the
2 lowest average price for such drug as com-
3 pared to the average prices (as so com-
4 puted) of such drug with respect to such
5 year in the other applicable countries de-
6 scribed in such section with respect to such
7 drug.

8 “(ii) SELECTED DRUGS WITHOUT AIM
9 PRICE.—In applying this paragraph in the
10 case of negotiating the maximum fair price
11 of a selected drug for which there is no
12 AIM price available with respect to the ini-
13 tial price applicability year for such drug,
14 or, as applicable, renegotiating the max-
15 imum fair price for such drug with respect
16 to a subsequent year during the price ap-
17 plicability period for such drug before the
18 first plan year for which there is an AIM
19 price available for such drug, the target
20 price described in this subparagraph for
21 such drug and respective year is the
22 amount that is 80 percent of the average
23 manufacturer price (as defined in section
24 1927(k)(1)) for such drug and year.

25 “(c) LIMITATION.—

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

8 “(2) SELECTED DRUGS WITHOUT AIM PRICE.—
9 In the case of a selected drug for which there is no
10 AIM price available with respect to the initial price
11 applicability year for such drug, for each plan year
12 during the price applicability period before the first
13 plan year for which there is an AIM price available
14 for such drug, the maximum fair price negotiated
15 (including as renegotiated) under this section for the
16 selected drug shall not exceed the amount equal to
17 85 percent of the average manufacturer price for the
18 drug with respect to such year.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(b) UPDATES.—

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

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

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

21 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

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

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

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

6 “(a) ADMINISTRATIVE DUTIES.—

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

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

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

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

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

1 scribed in subparagraphs (A) and (B)) to en-
2 sure that, not later than 90 days after the dis-
3 pensing of a selected drug to a fair price eligi-
4 ble individual by a pharmacy or mail order serv-
5 ice, the pharmacy or mail order service is reim-
6 bursed for an amount equal to the difference
7 between—

8 “(i) the lesser of—

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

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

13 “(III) any other similar deter-
14 mination of pharmacy acquisition
15 costs of the drug, as determined by
16 the Secretary; and

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

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

22 “(i) any coverage or financial assist-
23 ance under other health benefit plans or
24 programs that provide coverage or finan-
25 cial assistance for the purchase or provi-

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

4 “(ii) any other discounts.

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

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

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

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

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

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

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

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

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

6 “(2) MONITORING COMPLIANCE.—

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

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

20 “(b) COLLECTION OF DATA.—

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

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

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

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

15 “(c) CONTRACT WITH THIRD PARTIES.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(b) LIMITATION ON JUDICIAL REVIEW.—The fol-
11 lowing shall not be subject to judicial review:

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

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

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

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

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

1 “(d) DATA SHARING.—The Secretary shall share
2 with the Secretary of the Treasury such information as
3 is necessary to determine the tax imposed by section 4192
4 of the Internal Revenue Code of 1986.”.

5 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
6 CONFORMING AMENDMENTS.—

7 (1) UNDER MEDICARE.—

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

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

24 (C) APPLICATION AS NEGOTIATED PRICE
25 UNDER PART D.—Section 1860D–2(d)(1) of the

1 Social Security Act (42 U.S.C. 1395w–
2 102(d)(1)) is amended—

3 (i) in subparagraph (B), by inserting
4 “, subject to subparagraph (D),” after
5 “negotiated prices”; and

6 (ii) by adding at the end the following
7 new subparagraph:

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

19 (D) INFORMATION FROM PRESCRIPTION
20 DRUG PLANS AND MA–PD PLANS REQUIRED.—

21 (i) PRESCRIPTION DRUG PLANS.—Sec-
22 tion 1860D–12(b) of the Social Security
23 Act (42 U.S.C. 1395w–112(b)) is amended
24 by adding at the end the following new
25 paragraph:

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

8 (ii) MA–PD PLANS.—Section
9 1857(f)(3) of the Social Security Act (42
10 U.S.C. 1395w–27(f)(3)) is amended by
11 adding at the end the following new sub-
12 paragraph:

13 “(E) PROVISION OF INFORMATION RE-
14 LATED TO MAXIMUM FAIR PRICES.—Section
15 1860D–12(b)(8).”.

16 (2) UNDER GROUP HEALTH PLANS AND
17 HEALTH INSURANCE COVERAGE.—

18 (A) PHSA.—Part D of title XXVII of the
19 Public Health Service Act (42 U.S.C. 300gg–
20 111 et seq.) is amended by adding at the end
21 the following new section:

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

24 “(a) IN GENERAL.—In the case of a group health
25 plan or health insurance issuer offering group or indi-

1 vidual health insurance coverage that is treated under sec-
2 tion 1197 of the Social Security Act as having in effect
3 an agreement with the Secretary under the Fair Price Ne-
4 gotiation Program under part E of title XI of such Act,
5 with respect to a price applicability period (as defined in
6 section 1191(b) of such Act) and a selected drug (as de-
7 fined in section 1192(e) of such Act) with respect to such
8 period with respect to which coverage is provided under
9 such plan or coverage—

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

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

23 “(B) if coverage of such selected drug is
24 provided under such plan or coverage if the
25 drug is furnished or administered by a hospital,

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

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

23 “(3) the Secretary shall apply the provisions of
24 such part E to such plan, issuer, and coverage, such
25 individuals so enrolled in such plans and coverage,

1 and such hospitals, physicians, and other providers
2 and suppliers participating in such plans and cov-
3 erage.

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

16 (B) ERISA.—

17 (i) IN GENERAL.—Subpart B of part
18 7 of subtitle B of title I of the Employee
19 Retirement Income Security Act of 1974
20 (29 U.S.C. 1181 et seq.) is amended by
21 adding at the end the following new sec-
22 tion:

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

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

14 “(1) the provisions of such part shall apply, as
15 applicable—

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

1 under such prescription drug plans and MA-
2 PD plans during such period; and

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

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

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

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

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

18 (ii) APPLICATION TO RETIREE AND
19 CERTAIN SMALL GROUP HEALTH PLANS.—
20 Section 732(a) of the Employee Retire-
21 ment Income Security Act of 1974 (29
22 U.S.C. 1191a(a)) is amended by striking
23 “section 711” and inserting “sections 711
24 and 726”.

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

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

7 (C) IRC.—

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

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

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

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

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

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

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

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

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

24 (ii) APPLICATION TO RETIREE AND
25 CERTAIN SMALL GROUP HEALTH PLANS.—

1 Section 9831(a)(2) of the Internal Revenue
2 Code of 1986 is amended by inserting
3 “other than with respect to section 9826,”
4 before “any group health plan”.

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

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

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

13 (A) in subsection (c)(1)(C)(ii)—

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

16 (ii) in subclause (IV), by striking at
17 the end the period and inserting “; and”;
18 and

19 (iii) by adding at the end the fol-
20 lowing new subclause:

21 “(V) in the case of a rebate pe-
22 riod and a covered outpatient drug
23 that is a selected drug (as defined in
24 section 1192(e)) during such rebate

1 period, shall be inclusive of the price
2 for such drug made available from the
3 manufacturer during the rebate period
4 by reason of application of part E of
5 title XI to any wholesaler, retailer,
6 provider, health maintenance organi-
7 zation, nonprofit entity, or govern-
8 mental entity within the United
9 States.”; and

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

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

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

4 “(p) A contract may not be made or a plan approved
5 under this chapter with any carrier that has affirmatively
6 elected, pursuant to section 1197 of the Social Security
7 Act, not to participate in the Fair Price Negotiation Pro-
8 gram established under section 1191 of such Act for any
9 selected drug (as that term is defined in section 1192(c)
10 of such Act).”.

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

15 (A) in subsection (a)(2), by inserting “,
16 subject to subsection (j),” after “may not ex-
17 ceed”;

18 (B) in subsection (d), in the matter pre-
19 ceding paragraph (1), by inserting “, subject to
20 subsection (j)” after “for the procurement of
21 the drug”; and

22 (C) by adding at the end the following new
23 subsection:

24 “(j)(1) In the case of a covered drug that is a selected
25 drug, for any year during the price applicability period for

1 such drug, if the Secretary determines that the maximum
2 fair price of such drug for such year is less than the price
3 for such drug otherwise in effect pursuant to this section
4 (including after application of any reduction under sub-
5 section (a)(2) and any discount under subsection (c)), at
6 the option of the Secretary, in lieu of the maximum price
7 (determined after application of the reduction under sub-
8 section (a)(2) and any discount under subsection (c), as
9 applicable) that would be permitted to be charged during
10 such year for such drug pursuant to this section without
11 application of this subsection, the maximum price per-
12 mitted to be charged during such year for such drug pur-
13 suant to this section shall be such maximum fair price for
14 such drug and year.

15 “(2) For purposes of this subsection:

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

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

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

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

7 **SEC. 30502. SELECTED DRUG MANUFACTURER EXCISE TAX**
8 **IMPOSED DURING NONCOMPLIANCE PERI-**
9 **ODS.**

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

13 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
14 **PERIODS.**

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

20 “(1) such tax, divided by

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

23 “(b) NONCOMPLIANCE PERIODS.—A day is described
24 in this subsection with respect to a selected drug if it is
25 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.—For purposes of
8 this section, the term ‘applicable 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) SELECTED DRUG.—For purposes of this sec-
22 tion—

23 “(1) IN GENERAL.—The term ‘selected drug’
24 means any selected drug (within the meaning of sec-
25 tion 1192 of the Social Security Act) which is manu-

1 factured or produced in the United States or entered
2 into the United States for consumption, use, or
3 warehousing.

4 “(2) UNITED STATES.—The term ‘United
5 States’ has the meaning given such term by section
6 4612(a)(4).

7 “(3) COORDINATION WITH RULES FOR POSSES-
8 SIONS OF THE UNITED STATES.—Rules similar to
9 the rules of paragraphs (2) and (4) of section
10 4132(e) shall apply for purposes of this section.

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

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

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

23 (c) CONFORMING AMENDMENTS.—

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

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

6 (d) CLERICAL AMENDMENTS.—

7 (1) The heading of subchapter E of chapter 32
8 of the Internal Revenue Code of 1986 is amended by
9 striking “**Medical Devices**” and inserting
10 “**Other Medical Products**”.

11 (2) The table of subchapters for chapter 32 of
12 such Code is amended by striking the item relating
13 to subchapter E and inserting the following new
14 item:

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

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

21 **SEC. 30503. FAIR PRICE NEGOTIATION IMPLEMENTATION**
22 **FUND.**

23 (a) IN GENERAL.—There is hereby established a Fair
24 Price Negotiation Implementation Fund (referred to in

1 this section as the “Fund”). The Secretary of Health and
2 Human Services may obligate and expend amounts in the
3 Fund to carry out this part and parts 2 and 3 (and the
4 amendments made by such parts).

5 (b) FUNDING.—In addition to amounts otherwise
6 available, there is appropriated to the Fund, out of any
7 money in the Treasury not otherwise appropriated, to re-
8 main available until expended—

9 (1) \$600,000,000 for fiscal year 2022;

10 (2) \$600,000,000 for fiscal year 2023;

11 (3) \$600,000,000 for fiscal year 2024;

12 (4) \$600,000,000 for fiscal year 2025; and

13 (5) \$600,000,000 for fiscal year 2026.

14 **PART 2—PRESCRIPTION DRUG INFLATION**

15 **REBATES**

16 **SEC. 30511. MEDICARE PART B REBATE BY MANUFACTUR-**
17 **ERS.**

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

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

24 “(1) REQUIREMENTS.—

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

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

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

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

21 “(B) MANUFACTURER REQUIREMENT.—
22 For each calendar quarter beginning on or after
23 July 1, 2023, the manufacturer of a part B
24 rebatable drug shall, for such drug, not later
25 than 30 days after the date of receipt from the

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

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

7 “(A) IN GENERAL.—In this subsection, the
8 term ‘part B rebatable drug’ means a single
9 source drug or biological (as defined in sub-
10 paragraph (D) of section 1847A(e)(6)), includ-
11 ing a biosimilar biological product (as defined
12 in subparagraph (H) of such section), payable
13 (if such drug were furnished to an individual
14 enrolled under this part) under this part, except
15 such term shall not include such a drug or bio-
16 logical—

17 “(i) if the average total allowed
18 charges under this part as determined by
19 the Secretary for a year per individual that
20 uses such a drug or biological, as deter-
21 mined by the Secretary, are less than, sub-
22 ject to subparagraph (B), \$100; or

23 “(ii) that is a vaccine described in
24 subparagraph (A) or (B) of section
25 1861(s)(10).

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

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

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

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

21 “(3) REBATE AMOUNT.—

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

1 ter is, subject to subparagraph (B) and para-
2 graph (4), the amount equal to the product
3 of—

4 “(i) the total number of units, as de-
5 scribed in section 1847A(c)(1)(B), with re-
6 spect to such drug during the calendar
7 quarter; and

8 “(ii) the amount (if any) by which—

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

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

19 “(B) EXCLUDED UNITS.—For purposes of
20 subparagraph (A)(i), the Secretary shall exclude
21 from the total number of units with respect to
22 a part B rebatable drug and calendar quarter
23 units of such part B rebatable drug for which
24 payment was made under a State plan under
25 title XIX (or waiver of such plan), as reported

1 by States under section 1927(b)(2)(A) for the
2 most recent rebate period.

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 or licensed
15 by the Food and Drug Administration after
16 July 1, 2015, clause (i) of paragraph (3)(C)
17 shall be applied as if the term ‘payment amount
18 benchmark quarter’ were defined under para-
19 graph (3)(D) as the third full calendar quarter
20 after the day on which the drug was first mar-
21 keted and clause (ii) of paragraph (3)(C) shall
22 be applied as if the term ‘benchmark period
23 CPI–U’ were defined under paragraph (3)(E)
24 as if the reference to ‘July 2015’ under such
25 paragraph were a reference to ‘the first month

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

3 “(B) TIMELINE FOR PROVISION OF RE-
4 BATES FOR SUBSEQUENTLY APPROVED
5 DRUGS.—In the case of a part B rebatable drug
6 first approved or licensed by the Food and
7 Drug Administration after July 1, 2015, para-
8 graph (1)(B) shall be applied as if the reference
9 to ‘July 1, 2023’ under such paragraph were a
10 reference to the later of the 6th full calendar
11 quarter after the day on which the drug was
12 first marketed or July 1, 2023.

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

22 “(D) SELECTED DRUGS.—In the case of a
23 part B rebatable drug that is a selected drug
24 (as defined in section 1192(c)) for a price appli-

1 cability period (as defined in section
2 1191(b)(2))—

3 “(i) for calendar quarters during such
4 period for which a maximum fair price (as
5 defined in section 1191(c)(2)) for such
6 drug has been determined and is applied
7 under part E of title XI, the rebate
8 amount under paragraph (1)(B) shall be
9 waived; and

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

1 under such paragraph were a reference to
2 the July of the year preceding such last
3 year.

4 “(5) APPLICATION TO BENEFICIARY COINSUR-
5 ANCE.—In the case of a part B rebatable drug, if
6 the payment amount under this part for a quarter
7 exceeds the inflation adjusted payment for such
8 quarter—

9 “(A) in computing the amount of any coin-
10 surance applicable under this part to an indi-
11 vidual to whom such drug is furnished, the
12 computation of such coinsurance shall be based
13 on the inflation-adjusted payment amount de-
14 termined under paragraph (3)(C) for such part
15 B rebatable drug; and

16 “(B) the amount of such coinsurance is
17 equal to 20 percent of such inflation-adjusted
18 payment amount so determined.

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

23 “(7) CIVIL MONEY PENALTY.—If a manufac-
24 turer of a part B rebatable drug has failed to com-
25 ply with the requirements under paragraph (1)(B)

1 for such drug for a calendar quarter, the manufac-
2 turer shall be subject to, in accordance with a proc-
3 ess established by the Secretary pursuant to regula-
4 tions, a civil money penalty in an amount equal to
5 at least 125 percent of the amount specified in para-
6 graph (3) for such drug for such calendar quarter.
7 The provisions of section 1128A (other than sub-
8 sections (a) (with respect to amounts of penalties or
9 additional assessments) and (b)) shall apply to a
10 civil money penalty under this paragraph in the
11 same manner as such provisions apply to a penalty
12 or proceeding under section 1128A(a).

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

22 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
23 1833 of the Social Security Act (42 U.S.C. 1395l) is
24 amended—

25 (1) in subsection (a)—

- 1 (A) in paragraph (1)—
- 2 (i) in subparagraph (G), by inserting
- 3 “, subject to subsection (i)(9),” after “the
- 4 amounts paid”;
- 5 (ii) in subparagraph (S), by striking
- 6 “with respect to” and inserting “subject to
- 7 subparagraph (DD), with respect to”;
- 8 (iii) by striking “and (DD)” and in-
- 9 serting “(EE)”; and
- 10 (iv) by inserting before the semicolon
- 11 at the end the following: “, and (EE) with
- 12 respect to a part B rebatable drug (as de-
- 13 fined in paragraph (2) of section 1834(z))
- 14 for which the payment amount for a cal-
- 15 endar quarter under paragraph
- 16 (3)(A)(ii)(I) of such section for such quar-
- 17 ter exceeds the inflation-adjusted payment
- 18 under paragraph (3)(A)(ii)(II) of such sec-
- 19 tion for such quarter, the amounts paid
- 20 shall be the difference between (i) the pay-
- 21 ment amount under paragraph
- 22 (3)(A)(ii)(I) of such section for such drug,
- 23 and (ii) 20 percent of the inflation-ad-
- 24 justed payment amount under paragraph

1 (3)(A)(ii)(II) of such section for such
2 drug”; and

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

5 “For purposes of applying paragraph (1)(EE), sub-
6 sections (i)(9) and (t)(8)(F), and section 1834(z)(5), the
7 Secretary shall make such estimates and use such data
8 as the Secretary determines appropriate, and may do so
9 by program instruction or otherwise.”;

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

12 “(9) In the case of a part B rebatable drug (as de-
13 fined in paragraph (2) of section 1834(z)) for which pay-
14 ment under this subsection is not packaged into a payment
15 for a covered OPD service (as defined in subsection
16 (t)(1)(B)) (or group of services) furnished on or after July
17 1, 2023, under the system under this subsection, in lieu
18 of calculation of coinsurance and the amount of payment
19 otherwise applicable under this subsection, the provisions
20 of section 1834(z)(5), paragraph (1)(EE) of subsection
21 (a), and the flush left matter following paragraph (9) of
22 subsection (a), shall, as determined appropriate by the
23 Secretary, apply under this subsection in the same manner
24 as such provisions of section 1834(z)(5) and subsection
25 (a) apply under such section and subsection.”; and

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

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

19 (c) CONFORMING AMENDMENTS.—

20 (1) TO PART B ASP CALCULATION.—Section
21 1847A(c)(3) of the Social Security Act (42 U.S.C.
22 1395w–3a(c)(3)) is amended by inserting “or section
23 1834(z)” after “section 1927”.

24 (2) EXCLUDING PARTS B DRUG INFLATION RE-
25 BATE FROM BEST PRICE.—Section

1 1927(e)(1)(C)(ii)(I) of the Social Security Act (42
2 U.S.C. 1396r–8(e)(1)(C)(ii)(I)) is amended by in-
3 serting “or section 1834(z)” after “this section”.

4 (3) COORDINATION WITH MEDICAID REBATE IN-
5 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
6 of the Social Security Act (42 U.S.C. 1396r–
7 8(b)(3)(D)(i)) is amended by striking “or to carry
8 out section 1847B” and inserting “to carry out sec-
9 tion 1847B or section 1834(z)”.

10 **SEC. 30512. MEDICARE PART D REBATE BY MANUFACTUR-**
11 **ERS.**

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

15 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
16 **DRUGS WITH PRICES INCREASING FASTER**
17 **THAN INFLATION.**

18 “(a) REQUIREMENTS.—

19 “(1) SECRETARIAL PROVISION OF INFORMA-
20 TION.—Not later than 9 months after the end of
21 each applicable year (as defined in subsection
22 (g)(7)), the Secretary shall, for each part D
23 rebatable drug, report to each manufacturer of such
24 part D rebatable drug the following for such year:

1 “(A) The amount (if any) of the excess an-
2 nual manufacturer price increase described in
3 subsection (b)(1)(A)(ii) for each dosage form
4 and strength with respect to such drug and
5 year.

6 “(B) The rebate amount specified under
7 subsection (b) for each dosage form and
8 strength with respect to such drug and year.

9 “(2) MANUFACTURER REQUIREMENTS.—For
10 each applicable year, the manufacturer of a part D
11 rebatable drug, for each dosage form and strength
12 with respect to such drug, not later than 30 days
13 after the date of receipt from the Secretary of the
14 information described in paragraph (1) for such
15 year, shall provide to the Secretary a rebate that is
16 equal to the amount specified in subsection (b) for
17 such dosage form and strength with respect to such
18 drug for such year.

19 “(b) REBATE AMOUNT.—

20 “(1) IN GENERAL.—

21 “(A) CALCULATION.—For purposes of this
22 section, the amount specified in this subsection
23 for a dosage form and strength with respect to
24 a part D rebatable drug and applicable year is,
25 subject to subparagraphs (B) and (C) of para-

1 graph (5), the amount equal to the product
2 of—

3 “(i) subject to subparagraph (B) if
4 this paragraph, the total number of units
5 that are used to calculate the average man-
6 ufacturer price of such dosage form and
7 strength with respect to such part D
8 rebatable drug, as reported by the manu-
9 facturer of such drug under section 1927
10 for each month, with respect to such year;
11 and

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

13 “(I) the annual manufacturer
14 price (as determined in paragraph
15 (2)) paid for such dosage form and
16 strength with respect to such part D
17 rebatable drug for the year; exceeds

18 “(II) the inflation-adjusted pay-
19 ment amount determined under para-
20 graph (3) for such dosage form and
21 strength with respect to such part D
22 rebatable drug for the year.

23 “(B) EXCLUDED UNITS.—For purposes of
24 subparagraph (A)(i), the Secretary shall exclude
25 from the total number of units for a dosage

1 form and strength with respect to a part D
2 rebatable drug, with respect to an applicable
3 year, units of each dosage form and strength of
4 such part D rebatable drug, for which payment
5 was made under a State plan under title XIX
6 (or waiver of such plan), as reported by States
7 under section 1927(b)(2)(A).

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

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

19 “(B) the ratio of—

20 “(i) the total number of units of such
21 dosage form and strength reported for the
22 purpose of calculating average manufac-
23 turer price under section 1927 during each
24 such calendar quarter of such year; to

1 “(ii) the total number of units of such
2 dosage form and strength reported for the
3 purpose of calculating average manufac-
4 turer price under section 1927 during such
5 year, as determined by the Secretary.

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

12 “(A) the benchmark year manufacturer
13 price determined under paragraph (4) for such
14 dosage form and strength with respect to such
15 drug and year; increased by

16 “(B) the percentage by which the applica-
17 ble year CPI-U (as defined in subsection
18 (g)(5)) for the year exceeds the benchmark pe-
19 riod CPI-U (as defined in subsection (g)(4)).

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

1 “(A) the average manufacturer price (as
2 defined in subsection (g)(6)) of such dosage
3 form and strength, as calculated for a unit of
4 such drug, with respect to each of the calendar
5 quarters of the payment amount benchmark
6 year (as defined in subsection (g)(3)); and

7 “(B) the ratio of—

8 “(i) the total number of units of such
9 dosage form and strength dispensed during
10 each such calendar quarter of such pay-
11 ment amount benchmark year; to

12 “(ii) the total number of units of such
13 dosage form and strength dispensed during
14 such payment amount benchmark year.

15 “(5) SPECIAL TREATMENT OF CERTAIN DRUGS
16 AND EXEMPTION.—

17 “(A) SUBSEQUENTLY APPROVED DRUGS.—

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

1 by any manufacturer and subparagraph (B) of
2 paragraph (3) shall be applied as if the term
3 ‘benchmark period CPI-U’ were defined under
4 subsection (g)(4) as if the reference to ‘January
5 2016’ under such subsection were a reference to
6 ‘January of the first year beginning after the
7 date on which the drug was first marketed by
8 any 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 that is described as currently in
13 shortage on the shortage list in effect under
14 section 506E of the Federal Food, Drug, and
15 Cosmetic Act or in the case of other exigent cir-
16 cumstances, as determined by the Secretary.

17 “(C) TREATMENT OF NEW FORMULA-
18 TIONS.—

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

1 an applicable year with consideration of
2 the original part D rebatable 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, such as an extended release formula-
8 tion, but does not include an abuse-deter-
9 rent formulation of the drug (as deter-
10 mined by the Secretary), regardless of
11 whether such abuse-deterrent formulation
12 is an extended release formulation.

13 “(D) SELECTED DRUGS.—In the case of a
14 part D rebatable drug that is a selected drug
15 (as defined in section 1192(c)) for a price appli-
16 cability period (as defined in section
17 1191(b)(2))—

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

24 “(ii) in the case such drug is deter-
25 mined (pursuant to such section 1192(c))

1 to no longer be a selected drug, for each
2 applicable year beginning after the price
3 applicability period with respect to such
4 drug, subparagraphs (A) and (B) of para-
5 graph (4) shall be applied as if the term
6 ‘payment amount benchmark year’ were
7 defined under subsection (g)(3) as the last
8 year beginning during such price applica-
9 bility period with respect to such selected
10 drug and subparagraph (B) of paragraph
11 (3) shall be applied as if the term ‘bench-
12 mark period CPI-U’ were defined under
13 subsection (g)(4) as if the reference to
14 ‘January 2016’ under such subsection were
15 a reference to January of the last year be-
16 ginning during such price applicability pe-
17 riod with respect to such drug.

18 “(c) REBATE DEPOSITS.—Amounts paid as rebates
19 under subsection (b) shall be deposited into the Medicare
20 Prescription Drug Account in the Federal Supplementary
21 Medical Insurance Trust Fund established under section
22 1841.

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

1 by manufacturers under section 1927(b)(3) and informa-
2 tion submitted by States under section 1927(b)(2)(A).

3 “(e) CIVIL MONEY PENALTY.—If a manufacturer of
4 a part D rebatable drug has failed to comply with the re-
5 quirement under subsection (a)(1)(B) with respect to such
6 drug for an applicable year, the manufacturer shall be
7 subject to, in accordance with a process established by the
8 Secretary pursuant to regulations, a civil money penalty
9 in an amount equal to 125 percent of the amount specified
10 in subsection (b) for such drug for such year. The provi-
11 sions of section 1128A (other than subsections (a) (with
12 respect to amounts of penalties or additional assessments)
13 and (b)) shall apply to a civil money penalty under this
14 subsection in the same manner as such provisions apply
15 to a penalty or proceeding under section 1128A(a).

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

18 “(1) The determination of units under this sec-
19 tion.

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

22 “(3) The calculation of the rebate amount
23 under this section.

24 “(g) DEFINITIONS.—In this section:

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

1 “(A) IN GENERAL.—The term ‘part D
2 rebatable drug’ means a drug or biological that
3 would (without application of this section) be a
4 covered part D drug, except such term shall,
5 with respect to an applicable year, not include
6 such a drug or biological if the average annual
7 total cost under this part for such year per in-
8 dividual who uses such a drug or biological, as
9 determined by the Secretary, is less than, sub-
10 ject to subparagraph (B), \$100, as determined
11 by the Secretary using the most recent data
12 available or, if data is not available, as esti-
13 mated by the Secretary.

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

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

23 “(ii) for a subsequent year, shall be
24 the dollar amount specified in this sub-
25 paragraph for the previous year, increased

1 by the percentage increase in the consumer
2 price index for all urban consumers
3 (United States city average) for the 12-
4 month period beginning with January of
5 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 “(2) UNIT DEFINED.—The term ‘unit’ means,
10 with respect to a part D rebatable drug, the lowest
11 identifiable quantity (such as a capsule or tablet,
12 milligram of molecules, or grams) of the part D
13 rebatable drug, including data reported under sec-
14 tion 1927.

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

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

22 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-
23 plicable year CPI–U’ means, with respect to an ap-
24 plicable year, the consumer price index for all urban

1 consumers (United States city average) for January
2 of such year.

3 “(6) AVERAGE MANUFACTURER PRICE.—The
4 term ‘average manufacturer price’ has the meaning,
5 with respect to a part D rebatable drug of a manu-
6 facturer, given such term in section 1927(k)(1), with
7 respect to a covered outpatient drug of a manufac-
8 turer for a rebate period under section 1927.

9 “(7) APPLICABLE YEAR.—The term ‘applicable
10 year’ means a calendar year beginning with 2023.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) TO PART B ASP CALCULATION.—Section
13 1847A(c)(3) of the Social Security Act (42 U.S.C.
14 1395w–3a(c)(3)), as amended by section
15 30511(c)(1), is further amended by striking “section
16 1927 or section 1834(z)” and inserting “section
17 1927, section 1834(z), or section 1860D–14B”.

18 (2) EXCLUDING PART D DRUG INFLATION RE-
19 BATE FROM BEST PRICE.—Section
20 1927(e)(1)(C)(ii)(I) of the Social Security Act (42
21 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
22 tion 30511(c)(2), is further amended by striking “or
23 section 1834(z)” and inserting “, section 1834(z), or
24 section 1860D–14B”.

1 (3) COORDINATION WITH MEDICAID REBATE IN-
2 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
3 of the Social Security Act (42 U.S.C. 1396r-
4 8(b)(3)(D)(i)), as amended by section 30511(c)(3),
5 is further amended by striking “or section 1834(z)”
6 and inserting “, section 1834(z), or section 1860D-
7 14B”.

8 **PART 3—PART D IMPROVEMENTS AND MAXIMUM**
9 **OUT-OF-POCKET CAP FOR MEDICARE BENE-**
10 **FICIARIES**

11 **SEC. 30521. 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 2024 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 2024 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 2024,” after “paragraph
2 (4),”; and

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

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2024,” after “paragraph
11 (4),”; and

12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2019 through
15 2023”; and

16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2023”;

20 (2) in paragraph (3)(A)—

21 (A) in the matter preceding clause (i), by
22 inserting “for a year preceding 2024,” after
23 “and (4),”; and

1 (B) in clause (ii), by striking “for a subse-
2 quent year” and inserting “for each of years
3 2007 through 2023”; and

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

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

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

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

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

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

24 “(II) for 2024 and each suc-
25 ceeding year, \$0.”; and

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

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

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

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

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

14 (c) MANUFACTURER DISCOUNT PROGRAM.—

15 (1) IN GENERAL.—Part D of title XVIII of the
16 Social Security Act (42 U.S.C. 1395w–101 et seq.),
17 as amended by section 30512, is further amended by
18 inserting after section 1860D–14B the following new
19 section:

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

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

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

6 “(b) TERMS OF AGREEMENT.—

7 “(1) IN GENERAL.—

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

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

20 “(C) TIMING OF AGREEMENT.—

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

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

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

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

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

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

4 “(4) LENGTH OF AGREEMENT.—

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

11 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) MONITORING COMPLIANCE.—

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

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

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

7 “(d) ADMINISTRATION.—

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

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

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

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

1 individuals or entities the Secretary determines
2 appropriate;

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

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

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

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

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

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

7 “(e) ENFORCEMENT.—

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

11 “(2) CIVIL MONEY PENALTY.—

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

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

25 “(ii) 25 percent of such amount.

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

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

14 “(g) DEFINITIONS.—In this section:

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

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

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

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

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

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

6 “(A) means a covered part D drug—

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

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

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

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

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

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

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

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

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

16 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(h) SUNSET OF PROGRAM.—

4 “(1) IN GENERAL.—The program shall not
5 apply with respect to applicable drugs dispensed on
6 or after January 1, 2024, and, subject to paragraph
7 (2), agreements under this section shall be termi-
8 nated as of such date.

9 “(2) CONTINUED APPLICATION FOR APPLICA-
10 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
11 provisions of this section (including all responsibil-
12 ities and duties) shall continue to apply on and after
13 January 1, 2024, with respect to applicable drugs
14 dispensed prior to such date.”.

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

19 (A) in subsection (b)(2)(C)(iii)—

20 (i) by striking “assumptions regarding
21 the reinsurance” and inserting “assump-
22 tions regarding—

23 “(I) the reinsurance”; and

24 (ii) by adding at the end the fol-
25 lowing:

1 “(II) for 2024 and each subse-
2 quent year, the manufacturer dis-
3 counts provided under section 1860D–
4 14C subtracted from the actuarial
5 value to produce such bid; and”;

6 (B) in subsection (c)(1)(C)—

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

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

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

16 “(ii) for 2024 and each subsequent
17 year, the manufacturer discounts provided
18 under section 1860D–14C;”.

19 (d) CONFORMING AMENDMENTS.—

20 (1) Section 1860D–2 of the Social Security Act
21 (42 U.S.C. 1395w–102) is amended—

22 (A) in subsection (a)(2)(A)(i)(I), by strik-
23 ing “, or an increase in the initial” and insert-
24 ing “or, for a year preceding 2024, an increase
25 in the initial”;

1 (B) in subsection (c)(1)(C)—

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

5 (ii) by inserting “for a year preceding
6 2024 or the annual out-of-pocket threshold
7 specified in subsection (b)(4)(B) for the
8 year for 2024 and each subsequent year”
9 after “subsection (b)(3) for the year” each
10 place it appears; and

11 (C) in subsection (d)(1)(A), by striking “or
12 an initial” and inserting “or, for a year pre-
13 ceding 2024, an initial”.

14 (2) Section 1860D–4(a)(4)(B)(i) of the Social
15 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
16 amended by striking “the initial” and inserting “for
17 a year preceding 2024, the initial”.

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

20 (A) in paragraph (1)—

21 (i) in subparagraph (C), by striking
22 “The continuation” and inserting “For a
23 year preceding 2024, the continuation”;

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

4 (iii) in subparagraph (E), by striking
5 “The elimination” and inserting “For a
6 year preceding 2024, the elimination”; and
7 (B) in paragraph (2)—

8 (i) in subparagraph (C), by striking
9 “The continuation” and inserting “For a
10 year preceding 2024, the continuation”;
11 and

12 (ii) in subparagraph (E), by striking
13 “1860D–2(b)(4)(A)(i)(I)” and inserting
14 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

24 “(i) for years prior to 2024, any dis-
25 count”;

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

4 (C) by adding at the end the following new
5 clause:

6 “(ii) for 2024 and each subsequent
7 year, any discount provided pursuant to
8 section 1860D–14C.”.

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

11 (A) by inserting “for a year before 2024”
12 after “1860D–2(b)(3)”; and

13 (B) by inserting “for such year” before the
14 period.

15 (7) Section 1860D–43 of the Social Security
16 Act (42 U.S.C. 1395w–153) is amended—

17 (A) in subsection (a)—

18 (i) by striking paragraph (1) and in-
19 serting the following:

20 “(1) participate in—

21 “(A) for 2011 through 2023, the Medicare
22 coverage gap discount program under section
23 1860D–14A; and

1 “(B) for 2024 and each subsequent year,
2 the manufacturer discount program under sec-
3 tion 1860D–14C.”;

4 (ii) by striking paragraph (2) and in-
5 serting the following:

6 “(2) have entered into and have in effect—

7 “(A) for 2011 through 2023, an agreement
8 described in subsection (b) of section 1860D–
9 14A with the Secretary; and

10 “(B) for 2024 and each subsequent year,
11 an agreement described in subsection (b) of sec-
12 tion 1860D–14C with the Secretary; and”;

13 (iii) by striking paragraph (3) and in-
14 serting the following:

15 “(3) have entered into and have in effect, under
16 terms and conditions specified by the Secretary—

17 “(A) for 2011 through 2023, a contract
18 with a third party that the Secretary has en-
19 tered into a contract with under subsection
20 (d)(3) of section 1860D–14A; and

21 “(B) for 2024 and each subsequent year,
22 a contract with a third party that the Secretary
23 has entered into a contract with under sub-
24 section (d)(3) of section 1860D–14C.”; and

1 (B) by striking subsection (b) and insert-
2 ing the following:

3 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),
4 and (3)(A) of subsection (a) shall apply to covered part
5 D drugs dispensed under this part on or after January
6 1, 2011, and before January 1, 2024, and paragraphs
7 (1)(B), (2)(B), and (3)(B) of such subsection shall apply
8 to covered part D drugs dispensed under this part on or
9 after January 1, 2024.”.

10 (8) Section 1927 of the Social Security Act (42
11 U.S.C. 1396r–8) is amended—

12 (A) in subsection (c)(1)(C)(i)(VI), by in-
13 serting before the period at the end the fol-
14 lowing: “or under the manufacturer discount
15 program under section 1860D–14C”; and

16 (B) in subsection (k)(1)(B)(i)(V), by in-
17 serting before the period at the end the fol-
18 lowing: “or under section 1860D–14C”.

19 (e) EFFECTIVE DATE.—The amendments made by
20 this section shall apply with respect to plan year 2024 and
21 subsequent plan years.

1 **SEC. 30522. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
2 **TION DRUG PLANS AND MA-PD PLANS UNDER**
3 **MEDICARE PROGRAM TO SPREAD OUT COST-**
4 **SHARING UNDER CERTAIN CIRCUMSTANCES.**

5 Section 1860D–2(b)(2) of the Social Security Act (42
6 U.S.C. 1395w–102(b)(2)), as amended by section 30521,
7 is further amended—

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

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

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

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

8 **PART 4—REPEAL OF CERTAIN PRESCRIPTION**
9 **DRUG REBATE RULE**

10 **SEC. 30531. PROHIBITING IMPLEMENTATION OF RULE RE-**
11 **LATING TO ELIMINATING THE ANTI-KICK-**
12 **BACK STATUTE SAFE HARBOR PROTECTION**
13 **FOR PRESCRIPTION DRUG REBATES.**

14 Beginning January 1, 2026, the Secretary of Health
15 and Human Services shall not implement, administer, or
16 enforce the provisions of the final rule published by the
17 Office of the Inspector General of the Department of
18 Health and Human Services on November 30, 2020, and
19 titled “Fraud and Abuse; Removal of Safe Harbor Protec-
20 tion for Rebates Involving Prescription Pharmaceuticals
21 and Creation of New Safe Harbor Protection for Certain
22 Point-of-Sale Reductions in Price on Prescription Phar-
23 maceuticals and Certain Pharmacy Benefit Manager Serv-
24 ice Fees” (85 Fed. Reg. 76666).

