

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 3  
OFFERED BY M . \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

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

2 (a) IN GENERAL.—This Act may be cited as the  
3 “Lower Drug Costs Now Act of 2019”.

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

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE  
NEGOTIATION

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

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

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

Sec. 201. Medicare part B rebate by manufacturers.

Sec. 202. Medicare part D rebate by manufacturers.

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

Sec. 301. Medicare part D benefit redesign.

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

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

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

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

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

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

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

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

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

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

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

5           “(1) INITIAL PRICE APPLICABILITY YEAR.—The  
6           term ‘initial price applicability year’ means a plan  
7           year (beginning with plan year 2023) or, if agreed  
8           to in an agreement under section 1193 by the Sec-  
9           retary and manufacturer involved, a period of more  
10          than one plan year (beginning on or after January  
11          1, 2023).

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

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

23          “(4) VOLUNTARY NEGOTIATION PERIOD.—The  
24          term ‘voluntary negotiation period’ means, with re-

1       spect to an initial price applicability year with re-  
2       spect to a selected drug, the period—

3               “(A) beginning on the sooner of—

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

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

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

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

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

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

22                       “(i) an individual who is enrolled  
23                       under a prescription drug plan under part  
24                       D of title XVIII or an MA–PD plan under

1 part C of such title under which coverage  
2 is provided for such drug; and

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

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

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

22 “(ii) an individual who is enrolled  
23 under a group health plan or health insur-  
24 ance coverage offered in the group or indi-  
25 vidual market (as such terms are defined

1 in section 2791 of the Public Health Serv-  
2 ice Act) with respect to which there is in  
3 effect an agreement with the Secretary  
4 under section 1197 with respect to such se-  
5 lected drug as so furnished or adminis-  
6 tered.

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

14 “(3) AVERAGE INTERNATIONAL MARKET PRICE  
15 DEFINED.—

16 “(A) IN GENERAL.—The terms ‘average  
17 international market price’ and ‘AIM price’  
18 mean, with respect to a drug, the average price  
19 (which shall be the net average price, if prac-  
20 ticable, and volume-weighted, if practicable) for  
21 a unit (as defined in paragraph (4)) of the drug  
22 for sales of such drug (calculated across dif-  
23 ferent dosage forms and strengths of the drug  
24 and not based on the specific formulation or  
25 package size or package type), as computed (as

1 of the date of publication of such drug as a se-  
2 lected drug under section 1192(a)) in all coun-  
3 tries described in clause (ii) of subparagraph  
4 (B) that are applicable countries (as described  
5 in clause (i) of such subparagraph) with respect  
6 to such drug.

7 “(B) APPLICABLE COUNTRIES.—

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

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

18 “(I) Australia.

19 “(II) Canada.

20 “(III) France.

21 “(IV) Germany.

22 “(V) Japan.

23 “(VI) The United Kingdom.

24 “(4) UNIT.—The term ‘unit’ means, with re-  
25 spect to a drug, the lowest identifiable quantity

1 (such as a capsule or tablet, milligram of molecules,  
2 or grams) of the drug that is dispensed.

3 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**  
4 **AS SELECTED DRUGS.**

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

9 “(1)(A) with respect to an initial price applica-  
10 bility year during the period beginning with 2023  
11 and ending with 2027, at least 25 negotiation-eli-  
12 gible drugs described in subparagraphs (A) and (B),  
13 but not subparagraph (C), of subsection (d)(1) (or,  
14 with respect to an initial price applicability year dur-  
15 ing such period beginning after 2023, the maximum  
16 number (if such number is less than 25) of such ne-  
17 gotation-eligible drugs for the year) with respect to  
18 such year;

19 “(B) with respect to an initial price applica-  
20 bility year during the period beginning with 2028  
21 and ending with 2032, at least 30 negotiation-eli-  
22 gible drugs described in subparagraphs (A) and (B),  
23 but not subparagraph (C), of subsection (d)(1) (or,  
24 with respect to an initial price applicability year dur-  
25 ing such period, the maximum number (if such num-



1       ber is less than 30) of such negotiation-eligible drugs  
2       for the year) with respect to such year; and

3           “(C) with respect to an initial price applicability  
4       year beginning after 2032, at least 35 negotiation-  
5       eligible drugs described in subparagraphs (A) and  
6       (B), but not subparagraph (C), of subsection (d)(1)  
7       (or, with respect to an initial price applicability year  
8       during such period, the maximum number (if such  
9       number is less than 35) of such negotiation-eligible  
10      drugs for the year) with respect to such year;

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

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

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

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

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

21 “(c) SELECTED DRUG.—For purposes of this part,  
22 each drug included on the list published under subsection  
23 (a) with respect to an initial price applicability year shall  
24 be referred to as a ‘selected drug’ with respect to such  
25 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 a negotiation-eli-  
19 gible drug with respect to the subsequent selected  
20 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 subparagraphs (A) and (B) of paragraph  
24 (1), with respect to an initial price applicability year,  
25 if the wholesale acquisition cost at which such drug

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

15 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

16 “(a) IN GENERAL.—For purposes of section  
17 1191(a)(2), the Secretary shall enter into agreements with  
18 manufacturers of selected drugs with respect to a price  
19 applicability period, by not later than June 15 following  
20 the selected drug publication date with respect to such se-  
21 lected drug, under which—

22 “(1) during the voluntary negotiation period for  
23 the initial price applicability year for the selected  
24 drug, the Secretary and manufacturer, in accordance  
25 with section 1194, negotiate to determine (and, by



1 not later than the last date of such period and in ac-  
2 cordance with subsection (c), agree to) a maximum  
3 fair price for such selected drug of the manufacturer  
4 in order to provide access to such price—

5 “(A) to fair price eligible individuals who  
6 with respect to such drug are described in sub-  
7 paragraph (A) of section 1191(c)(1) and are  
8 furnished or dispensed such drug during, sub-  
9 ject to subparagraph (2), the price applicability  
10 period; and

11 “(B) to hospitals, physicians, and other  
12 providers of services and suppliers with respect  
13 to fair price eligible individuals who with re-  
14 spect to such drug are described in subpara-  
15 graph (B) of such section and are furnished or  
16 administered such drug during, subject to sub-  
17 paragraph (2), the price applicability period;

18 “(2) the Secretary and the manufacturer shall,  
19 in accordance with a process and during a period  
20 specified by the Secretary pursuant to rulemaking,  
21 renegotiate (and, by not later than the last date of  
22 such period and in accordance with subsection (c),  
23 agree to) the maximum fair price for such drug if  
24 the Secretary determines that there is a material  
25 change in any of the factors described in section

1 1194(d) relating to the drug, including changes in  
2 the AIM price for such drug, in order to provide ac-  
3 cess to such maximum fair price (as so renegoti-  
4 ated)—

5 “(A) to fair price eligible individuals who  
6 with respect to such drug are described in sub-  
7 paragraph (A) of section 1191(c)(1) and are  
8 furnished or dispensed such drug during any  
9 year during the price applicability period (be-  
10 ginning after such renegotiation) with respect  
11 to such selected drug; and

12 “(B) to hospitals, physicians, and other  
13 providers of services and suppliers with respect  
14 to fair price eligible individuals who with re-  
15 spect to such drug are described in subpara-  
16 graph (B) of such section and are furnished or  
17 administered such drug during any year de-  
18 scribed in subparagraph (A);

19 “(3) the maximum fair price (including as re-  
20 negotiated pursuant to paragraph (2)), with respect  
21 to such a selected drug, shall be provided to fair  
22 price eligible individuals, who with respect to such  
23 drug are described in subparagraph (A) of section  
24 1191(c)(1), at the pharmacy or by a mail order serv-  
25 ice at the point-of-sale of such drug;

1           “(4) the manufacturer, subject to subsection  
2           (c), submits to the Secretary, in a form and manner  
3           specified by the Secretary—

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

13                   “(B) on an ongoing basis, information on  
14                   changes in prices for such drug that would af-  
15                   fect the AIM price for such drug or otherwise  
16                   provide a basis for renegotiation of the max-  
17                   imum fair price for such drug pursuant to  
18                   paragraph (2);

19                  “(5) the manufacturer agrees that in the case  
20                  the selected drug of a manufacturer is a drug de-  
21                  scribed in subsection (c), the manufacturer will, in  
22                  accordance with such subsection, make any payment  
23                  required under such subsection with respect to such  
24                  drug; and

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

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

10          “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS  
11          WITHOUT AIM PRICE.—

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

1           “(A) the difference between such amount  
2 described in paragraph (2)(A) for a unit of  
3 such drug and such amount described in para-  
4 graph (2)(B) for a unit of such drug; and

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

10          “(2) AMOUNTS DESCRIBED.—

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

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

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

18          “(e) REGULATIONS.—

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

23                 “(2) INFORMATION SPECIFIED.—Information  
24                 described in paragraph (1), with respect to a se-  
25                 lected drug, shall include information on sales of the

1 drug (by the manufacturer of the drug or by another  
2 entity under license or other agreement with the  
3 manufacturer, with respect to the sales of such drug,  
4 regardless of the name under which the drug is sold)  
5 in any foreign country that is part of the AIM price.  
6 The Secretary shall verify, to the extent practicable,  
7 such sales from appropriate officials of the govern-  
8 ment of the foreign country involved.

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

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

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

22 “(1) shall during the voluntary negotiation pe-  
23 riod with respect to the initial price applicability  
24 year for such drug, in accordance with this section,

1 negotiate a maximum fair price for such drug for  
2 the purpose described in section 1193(a)(1); and

3 “(2) as applicable pursuant to section  
4 1193(a)(2) and in accordance with the process speci-  
5 fied pursuant to such section, renegotiate such max-  
6 imum fair price for such drug for the purpose de-  
7 scribed in such section.

8 “(b) NEGOTIATING METHODOLOGY AND OBJEC-  
9 TIVE.—

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

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

22 “(A) RESEARCH AND DEVELOPMENT  
23 COSTS.—The factor described in paragraph  
24 (1)(A) of subsection (d).



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

3           “(C) UNIT COSTS OF PRODUCTION AND  
4           DISTRIBUTION.—The factor described in para-  
5           graph (1)(C) of such subsection.

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

9           “(3) REQUIREMENT.—

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

25           “(B) TARGET PRICE.—

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

21                  “(ii) SELECTED DRUGS WITHOUT AIM  
22                  PRICE.—In applying this paragraph in the  
23                  case of negotiating the maximum fair price  
24                  of a selected drug for which there is no  
25                  AIM price available with respect to the ini-

1            tial price applicability year for such drug,  
2            or, as applicable, renegotiating the max-  
3            imum fair price for such drug with respect  
4            to a subsequent year during the price ap-  
5            plicability period for such drug before the  
6            first plan year for which there is an AIM  
7            price available for such drug, the target  
8            price described in this subparagraph for  
9            such drug and respective year is the  
10           amount that is 80 percent of the average  
11           manufacturer price (as defined in section  
12           1927(k)(1)) for such drug and year.

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

21           “(c) LIMITATION.—

22           “(1) IN GENERAL.—Subject to paragraph (2),  
23           the maximum fair price negotiated (including as re-  
24           negotiated) under this section for a selected drug,  
25           with respect to each plan year during a price appli-

1       cability period for such drug, shall not exceed 120  
2       percent of the AIM price applicable to such drug  
3       with respect to such year.

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

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

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

22               “(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as sub-  
23      mitted by the manufacturer:  
24

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

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

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

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

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

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

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

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

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

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

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

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

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

22          “(3) FOREIGN SALES INFORMATION.—To the  
23          extent available on a timely basis, including as pro-  
24          vided by a manufacturer of the selected drug or oth-  
25          erwise, information on sales of the selected drug in

1 each of the countries described in section  
2 1191(e)(3)(B).

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

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

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

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

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

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

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

13 “(b) UPDATES.—

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

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



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

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

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

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

17          “(a) ADMINISTRATIVE DUTIES.—

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

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

1 agreements under section 1197 with group  
2 health plans and health insurance issuers of  
3 health insurance coverage offered in the indi-  
4 vidual or group market) under which the max-  
5 imum fair price for a selected drug is provided  
6 to fair price eligible individuals, who with re-  
7 spect to such drug are described in subpara-  
8 graph (A) of section 1191(c)(1), at pharmacies  
9 or by mail order service at the point-of-sale of  
10 the drug for the applicable price period for such  
11 drug and providing that such maximum fair  
12 price is used for determining cost-sharing under  
13 such plans or coverage for the selected drug.

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

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

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

19 “(i) the lesser of—

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

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

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

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

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

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

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

15 “(ii) any other discounts.

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

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

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

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

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

18           “(ii) fair price eligible individuals who  
19 are enrolled under a group health plan or  
20 health insurance coverage offered by a  
21 health insurance issuer in the individual or  
22 group market with respect to which there  
23 is an agreement in effect under section  
24 1197.

1           “(I) The establishment of a negotiation  
2 process and renegotiation process in accordance  
3 with section 1194, including a process for ac-  
4 quiring information described in subsection (d)  
5 of such section and determining amounts de-  
6 scribed in subsection (b) of such section.

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

12           “(2) MONITORING COMPLIANCE.—

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

18           “(B) NOTIFICATION.—If a third party  
19 with a contract under subsection (c)(1) deter-  
20 mines that the manufacturer is not in compli-  
21 ance with such agreement, the third party shall  
22 notify the Secretary of such noncompliance for  
23 appropriate enforcement under section 4192 of  
24 the Internal Revenue Code of 1986 or section  
25 1198, as applicable.

1 “(b) COLLECTION OF DATA.—

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

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

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          “(d) COORDINATION WITH 340B PROGRAM.—In the  
23          case of a manufacturer of a selected drug, with respect  
24          to an initial price applicability year, for each year with  
25          respect to which a maximum fair price is applied under



1 this part for such drug, such drug shall not be considered  
2 a covered outpatient drug subject to an agreement under  
3 section 340B of the Public Health Service Act.

4 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**  
5 **HEALTH PLANS.**

6 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-  
7 GRAM.—

8 “(1) IN GENERAL.—Subject to paragraph (2),  
9 under the program under this part the Secretary  
10 shall be treated as having in effect an agreement  
11 with a group health plan or health insurance issuer  
12 offering health insurance coverage (as such terms  
13 are defined in section 2791 of the Public Health  
14 Service Act), with respect to a price applicability pe-  
15 riod and a selected drug with respect to such pe-  
16 riod—

17 “(A) with respect to such selected drug  
18 furnished or dispensed at a pharmacy or by  
19 mail order service if coverage is provided under  
20 such plan or coverage during such period for  
21 such selected drug as so furnished or dispensed;  
22 and

23 “(B) with respect to such selected drug  
24 furnished or administered by a hospital, physi-  
25 cian, or other provider of services or supplier if

1 coverage is provided under such plan or cov-  
2 erage during such period for such selected drug  
3 as so furnished or administered.

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

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

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

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

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

13 “(2) to a hospital, physician, or other provider  
14 of services or supplier with respect to fair price eligi-  
15 ble individuals who with respect to such drug is de-  
16 scribed in subparagraph (B) of such section and is  
17 furnished or administered such drug by such hos-  
18 pital, physician, or provider or supplier during such  
19 year;

20 shall be subject to a civil monetary penalty equal to ten  
21 times the amount equal to the difference between the price  
22 for such drug made available for such year by such manu-  
23 facturer with respect to such individual or hospital, physi-  
24 cian, provider, or supplier and the maximum fair price for  
25 such drug for such year.

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

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

14 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

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

24       “(c) MEDPAC STUDY.—Not later than December 31,  
25 2025, the Medicare Payment Advisory Commission shall

1 conduct a study, and submit to Congress a report, on the  
2 program under this part with respect to the Medicare pro-  
3 gram under title XVIII, including with respect to the ef-  
4 fect of the program on individuals entitled to benefits or  
5 enrolled under such title.

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

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

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

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

14 “(4) The determination of units of a drug for  
15 purposes of section 1191(e)(3).

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

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

1 (b) APPLICATION OF MAXIMUM FAIR PRICES AND  
2 CONFORMING AMENDMENTS.—

3 (1) UNDER MEDICARE PRESCRIPTION DRUG  
4 PROGRAM.—

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

11 (B) APPLICATION AS NEGOTIATED  
12 PRICE.—Section 1860D–2(d)(1) of the Social  
13 Security Act (42 U.S.C. 1395w–102(d)(1)) is  
14 amended—

15 (i) in subparagraph (B), by inserting  
16 “, subject to subparagraph (D),” after  
17 “negotiated prices”; and

18 (ii) by adding at the end the following  
19 new subparagraph:

20 “(D) APPLICATION OF MAXIMUM FAIR  
21 PRICE FOR SELECTED DRUGS.—In applying this  
22 section, in the case of a covered part D drug  
23 that is a selected drug (as defined in section  
24 1192(c)), with respect to a price applicability  
25 period (as defined in section 1191(b)(2)), the

1 negotiated price described in this subsection  
2 shall be the maximum fair price (as defined in  
3 section 1191(c)(2)) for such drug and for each  
4 plan year during such period.”.

5 (C) INFORMATION FROM PRESCRIPTION  
6 DRUG PLANS AND MA-PD PLANS REQUIRED.—

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

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

19 (ii) MA-PD PLANS.—Section  
20 1857(f)(3) of the Social Security Act (42  
21 U.S.C. 1395w-27(f)(3)) is amended by  
22 adding at the end the following new sub-  
23 paragraph:

1           “(E) PROVISION OF INFORMATION RE-  
2           LATED TO MAXIMUM FAIR PRICES.—Section  
3           1860D–12(b)(8).”.

4           (2) UNDER GROUP HEALTH PLANS AND  
5           HEALTH INSURANCE COVERAGE.—

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

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

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

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



1 and to the individuals enrolled under such plans or  
2 coverage, during such period, with respect to such  
3 selected drug, in the same manner as such provi-  
4 sions apply to prescription drug plans and MA–PD  
5 plans, and to individuals enrolled under such pre-  
6 scription drug plans and MA–PD plans;

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

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

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

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

4 (B) ERISA.—

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

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

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

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

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

13           “(B) if coverage of such selected drug is  
14 provided under such plan or coverage if the  
15 drug is furnished or administered by a hospital,  
16 physician, or other provider of services or sup-  
17 plier, to the plans or coverage offered by such  
18 plan or issuers, to the individuals enrolled  
19 under such plans or coverage, and to hospitals,  
20 physicians, and other providers of services and  
21 suppliers during such period, with respect to  
22 such drug in the same manner as such provi-  
23 sions apply to the Secretary, to individuals enti-  
24 tled to benefits under part A of title XVIII or  
25 enrolled under part B of such title, and to hos-

1           pitals, physicians, and other providers and sup-  
2           pliers participating under title XVIII during  
3           such period;

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

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

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

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

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

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

13 (C) IRC.—

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

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

21 “(a) IN GENERAL.—In the case of a group health  
22 plan that is treated under section 1197 of the Social Secu-  
23 rity Act as having in effect an agreement with the Sec-  
24 retary under the Fair Price Drug Negotiation Program

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

6 “(1) the provisions of such part shall apply to  
7 the plans offered by such plan, and to the individ-  
8 uals enrolled under such plans, during such period,  
9 with respect to such selected drug, in the same man-  
10 ner as such provisions apply to prescription drug  
11 plans and MA–PD plans, and to individuals enrolled  
12 under such prescription drug plans and MA–PD  
13 plans;

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

20 “(3) the Secretary shall apply the provisions of  
21 such part to such plan and such individuals so en-  
22 rolled in such plan.

23 “(b) NOTIFICATION REGARDING NONPARTICIPATION  
24 IN FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group  
25 health plan shall publicly disclose in a manner and in ac-

1 cordance with a process specified by the Secretary any  
2 election made under section 1197 of the Social Security  
3 Act by the plan to not participate in the Fair Drug Price  
4 Negotiation Program under part E of title XI of such Act  
5 with respect to a selected drug (as defined in section  
6 1192(c) of such Act) for which coverage is provided under  
7 such plan before the beginning of the plan year for which  
8 such election was made.”.

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

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

13 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**  
14 **IMPOSED DURING NONCOMPLIANCE PERI-**  
15 **ODS.**

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

19 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**  
20 **PERIODS.**

21 “(a) IN GENERAL.—There is hereby imposed on the  
22 sale by the manufacturer, producer, or importer of any  
23 selected drug during a day described in subsection (b) a

1 tax in an amount such that the applicable percentage is  
2 equal to the ratio of—

3 “(1) such tax, divided by

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

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

9 “(1) The period beginning on the June 16th  
10 immediately following the selected drug publication  
11 date and ending on the first date during which the  
12 manufacturer of the drug has in place an agreement  
13 described in subsection (a) of section 1193 of the  
14 Social Security Act with respect to such drug.

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

20 “(3) In the case of a selected drug with respect  
21 to which the Secretary of Health and Human Serv-  
22 ices has specified a renegotiation period under such  
23 agreement, the period beginning on the first date  
24 after the last date of such renegotiation period and  
25 ending on the first date during which the manufac-



1 turer of the drug has agreed to a renegotiated max-  
2 imum fair price under such agreement.

3 “(4) With respect to information that is re-  
4 quired to be submitted to the Secretary of Health  
5 and Human Services under such agreement, the pe-  
6 riod beginning on the date on which such Secretary  
7 certifies that such information is overdue and ending  
8 on the date that such information is so submitted.

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

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

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

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

23 “(3) in the case of sales of such drug during  
24 the 181st day through the 270th day described in

1 subsection (b) with respect to such drug, 85 percent,  
2 and

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

5 “(d) DEFINITIONS.—The terms ‘selected drug publi-  
6 cation date’ and ‘maximum fair price’ have the meaning  
7 given such terms in section 1191 of the Social Security  
8 Act and the term ‘selected drug’ has the meaning given  
9 such term in section 1192 of such Act.

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

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

18 (c) CONFORMING AMENDMENTS.—

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

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

24 (d) CLERICAL AMENDMENTS.—

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

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

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

## 15 **TITLE II—MEDICARE PARTS B** 16 **AND D PRESCRIPTION DRUG** 17 **INFLATION REBATES**

### 18 **SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.**

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

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

1 “(1) REQUIREMENTS.—

2 “(A) SECRETARIAL PROVISION OF INFOR-  
3 MATION.—Not later than 6 months after the  
4 end of each calendar quarter beginning on or  
5 after July 1, 2021, the Secretary shall, for each  
6 part B rebatable drug, report to each manufac-  
7 turer of such part B rebatable drug the fol-  
8 lowing for such calendar quarter:

9 “(i) Information on the total number  
10 of billing units described in subparagraph  
11 (A)(i) of paragraph (3) with respect to  
12 such drug and 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, 2021, 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), paid for  
13 under this part, except such term shall not in-  
14 clude such a drug or biological—

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

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

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

1           “(i) for 2022, shall be the dollar  
2           amount specified under such subparagraph  
3           for 2021, increased by the percentage in-  
4           crease in the consumer price index for all  
5           urban consumers (United States city aver-  
6           age) as of the first quarter of the previous  
7           year; and

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

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

18          “(3) REBATE AMOUNT.—

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

1 “(i) subject to subparagraph (B), the  
2 total number of billing units, as described  
3 in section 1847A(b)(6)(B), for such part B  
4 rebatable drug furnished under this part  
5 during the calendar quarter; and

6 “(ii) the amount (if any) by which—

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

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

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

21 “(i) units packaged into the payment  
22 for a related procedure or service under  
23 section 1833(t) or under section 1833(i)  
24 (instead of separately payable under such  
25 respective section);

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

4           “(iii) units of a part B rebatable drug  
5           of a manufacturer that is furnished to an  
6           individual, if such manufacturer, with re-  
7           spect to the furnishing of such units of  
8           such drug, provides for discounts under  
9           section 340B of the Public Health Service  
10          Act or for rebates under section 1927.

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

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

20                 “(ii) the percentage by which the re-  
21                 bate period CPI-U (as defined in subpara-  
22                 graph (F)) for the calendar quarter ex-  
23                 ceeds the benchmark period CPI-U (as de-  
24                 fined in subparagraph (E)).



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

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

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

18           “(4) SPECIAL TREATMENT OF CERTAIN DRUGS  
19 AND EXEMPTION.—

20           “(A) SUBSEQUENTLY APPROVED DRUGS.—  
21 Subject to subparagraph (B), in the case of a  
22 part B rebatable drug first approved by the  
23 Food and Drug Administration after July 1,  
24 2015, clause (i) of paragraph (3)(C) shall be  
25 applied as if the term ‘payment amount bench-

1 mark quarter’ were defined under paragraph  
2 (3)(D) as the third full calendar quarter after  
3 the day on which the drug was first marketed  
4 and clause (ii) of paragraph (3)(C) shall be ap-  
5 plied as if the term ‘benchmark period CPI-U’  
6 were defined under paragraph (3)(E) as if the  
7 reference to ‘July 2015’ under such paragraph  
8 were a reference to ‘the first month of the first  
9 full calendar quarter after the day on which the  
10 drug was first marketed’.

11 “(B) TIMELINE FOR PROVISION OF RE-  
12 BATES FOR NEW DRUGS.—In the case of a part  
13 B rebatable drug first approved by the Food  
14 and Drug Administration after July 1, 2015,  
15 clause (i) of paragraph (1)(B) shall be applied  
16 as if the reference to ‘July 1, 2021’ under such  
17 paragraph were a reference to the later of the  
18 6th full calendar quarter after the day on which  
19 the drug was first marketed or July 1, 2021.

20 “(C) EXEMPTION FOR SHORTAGES.—The  
21 Secretary may reduce or waive the rebate under  
22 paragraph (1)(B) with respect to a part B  
23 rebatable drug that appears on the drug short-  
24 age list in effect under section 506(e) of the  
25 Federal Food, Drug, and Cosmetic Act or in

1 the case of other exigent circumstances, as de-  
2 termined by the Secretary.

3 “(D) SELECTED DRUGS.—In the case of a  
4 part B rebatable drug that is a selected drug  
5 (as defined in section 1192(c)), for each appli-  
6 cable year beginning after the price applicability  
7 period (as defined in section 1191(b)(2) with  
8 respect to such drug, clause (i) of paragraph  
9 (3)(C) shall be applied as if the term ‘payment  
10 amount benchmark quarter’ were defined under  
11 paragraph (3)(D) as the calendar quarter be-  
12 ginning January 1 of the last year beginning  
13 during such price applicability period with re-  
14 spect to such selected drug and clause (ii) of  
15 paragraph (3)(C) shall be applied as if the term  
16 ‘benchmark period CPI-U’ were defined under  
17 paragraph (3)(E) as if the reference to ‘July  
18 2015’ under such paragraph were a reference to  
19 the July of the year preceding such last year.

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

23 “(A) in computing the amount of any coin-  
24 surance applicable under this title to an indi-  
25 vidual with respect to such drug, the computa-

1           tion of such coinsurance shall be based on the  
2           inflation-adjusted payment amount determined  
3           under paragraph (3)(C) for such part B  
4           rebate drug; and

5           “(B) the amount of such coinsurance is  
6           equal to 20 percent of such inflation-adjusted  
7           payment amount so determined.

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

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

1 same manner as such provisions apply to a penalty  
2 or proceeding under section 1128A(a).

3 “(8) STUDY AND REPORT.—

4 “(A) STUDY.—The Secretary shall conduct  
5 a study of the feasibility of and operational  
6 issues involved with the following:

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

10 “(ii) Including drugs and biologicals  
11 paid for under MA plans under part C in  
12 the rebate system under this subsection.

13 “(iii) Including drugs excluded under  
14 paragraph (2)(A) and billing units of  
15 drugs excluded under paragraph (3)(B) in  
16 the rebate system under this subsection.

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

22 “(9) APPLICATION TO MULTIPLE SOURCE  
23 DRUGS.—The Secretary may, based on the report  
24 submitted under paragraph (8) and pursuant to  
25 rulemaking, apply the provisions of this subsection

1 to multiple source drugs (as defined in section  
2 1847A(c)(6)(C)), including, for purposes of deter-  
3 mining the rebate amount under paragraph (3), by  
4 calculating manufacturer-specific average sales  
5 prices for the benchmark period and the rebate pe-  
6 riod.”.

7 (b) AMOUNTS PAYABLE; COST-SHARING.—Section  
8 1833(a) of the Social Security Act is amended—

9 (1) in paragraph (1)—

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

13 (B) by striking “and (CC)” and inserting  
14 “(CC)”; and

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

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

3           “For purposes of applying paragraph (1)(DD) and section  
4           1834(x)(5), the Secretary shall make such estimates and  
5           use such data as the Secretary determines appropriate.”.

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

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

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

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

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

24           “(b) AGREEMENTS.—

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

5           “(A) SECRETARIAL PROVISION OF INFOR-  
6 MATION.—Not later than 9 months after the  
7 end of each applicable year with respect to  
8 which the agreement is in effect, the Secretary,  
9 for the part D rebatable drug of the manufac-  
10 turer, reports to the manufacturer the following  
11 for such year:

12           “(i) Information on the total units (as  
13 defined in subsection (g)(2)) dispensed for  
14 each dosage form and strength with re-  
15 spect to such part D rebatable drug and  
16 year.

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

23           “(iii) The rebate amount specified  
24 under subsection (c) for each dosage form



1                   and strength with respect to such drug and  
2                   year.

3                   “(B) MANUFACTURER REQUIREMENTS.—

4                   For each applicable year with respect to which  
5                   the agreement is in effect, the manufacturer of  
6                   the part D rebatable drug, for each dosage  
7                   form and strength with respect to such drug,  
8                   not later than 30 days after the date of receipt  
9                   from the Secretary of the information described  
10                  in subparagraph (A) for such year, provides to  
11                  the Secretary a rebate that is equal to the  
12                  amount specified in subsection (c) for such dos-  
13                  age form and strength with respect to such  
14                  drug for such year.

15                  “(2) LENGTH OF AGREEMENT.—

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

23                  “(B) TERMINATION.—

24                  “(i) BY SECRETARY.—The Secretary  
25                  may provide for termination of an agree-

1           ment under this section for violation of the  
2           requirements of the agreement or other  
3           good cause shown. Such termination shall  
4           not be effective earlier than 60 days after  
5           the date of notice of such termination. The  
6           Secretary shall provide, upon request, a  
7           manufacturer with a hearing concerning  
8           such a termination, but such hearing shall  
9           not delay the effective date of the termi-  
10          nation.

11           “(ii) BY A MANUFACTURER.—A man-  
12          ufacturer may terminate an agreement  
13          under this section for any reason. Any  
14          such termination shall not be effective  
15          until the year beginning at least 60 days  
16          after the date the manufacturer provides  
17          notice to the Secretary.

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

23           “(D) DELAY BEFORE REENTRY.—In the  
24          case of any agreement under this section with  
25          a manufacturer which is terminated in a plan

1           year, another such agreement with the manu-  
2           facturer (or a successor manufacturer) may not  
3           be entered into before the subsequent plan year,  
4           unless the Secretary finds good cause for an  
5           earlier reinstatement of such an agreement.

6           “(3) INFORMATION.—For purposes of carrying  
7           out this section, the Secretary shall use information  
8           submitted by manufacturers under section  
9           1927(b)(3).

10          “(c) REBATE AMOUNT.—

11           “(1) IN GENERAL.—For purposes of this sec-  
12           tion, the amount specified in this subsection for a  
13           dosage form and strength with respect to a part D  
14           rebtable drug and applicable year is, subject to sub-  
15           paragraphs (B) and (C) of paragraph (3), the  
16           amount equal to the product of—

17           “(A) the total average number of units  
18           weighted by, and dispensed for, such dosage  
19           form and strength with respect to such part D  
20           rebtable drug and year; and

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

22           “(i) the average manufacturer price  
23           (as defined in subsection (g)) paid for such  
24           dosage form and strength with respect to

1           such part D rebatable drug during the  
2           year; exceeds

3           “(ii) the inflation-adjusted payment  
4           amount determined under paragraph (2)  
5           for such dosage form and strength with re-  
6           spect to such part D rebatable drug during  
7           the year.

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

14          “(A) the average manufacturer price paid  
15          for such dosage form and strength with respect  
16          to such drug in the payment amount bench-  
17          mark year (as defined in subsection (g)(3)); in-  
18          creased by

19          “(B) the percentage by which the rebate  
20          period CPI-U (as defined in subsection (g)(5))  
21          for the applicable year exceeds the benchmark  
22          period CPI-U (as defined in subsection (g)(4)).

23          “(3) SPECIAL TREATMENT OF CERTAIN DRUGS  
24          AND EXEMPTION.—

1           “(A) SUBSEQUENTLY APPROVED DRUGS.—

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

17          “(B) EXEMPTION FOR SHORTAGES.—The  
18          Secretary may reduce or waive the rebate under  
19          paragraph (1) with respect to a part D  
20          rebatable drug in the case of a shortage of such  
21          drug or other exigent circumstances, as deter-  
22          mined by the Secretary.

23          “(C) TREATMENT OF NEW FORMULA-  
24          TIONS.—

1                   “(i) IN GENERAL.—In the case of a  
2                   part D rebatable drug that is a line exten-  
3                   sion of a single source drug or an inno-  
4                   vator multiple source drug that is an oral  
5                   solid dosage form, the Secretary shall es-  
6                   tablish a formula for determining the  
7                   amount specified in this subsection with  
8                   respect to such part D rebatable drug and  
9                   an applicable year with consideration of  
10                  the single source drug or an innovator  
11                  multiple source drug.

12                  “(ii) LINE EXTENSION DEFINED.—In  
13                  this subparagraph, the term ‘line exten-  
14                  sion’ means, with respect to a part D  
15                  rebatable drug, a new formulation of the  
16                  drug (as determined by the Secretary),  
17                  such as an extended release formulation,  
18                  but does not include an abuse-deterrent  
19                  formulation of the drug (as determined by  
20                  the Secretary), regardless of whether such  
21                  abuse-deterrent formulation is an extended  
22                  release formulation.

23                  “(D) SELECTED DRUGS.—In the case of a  
24                  part D rebatable drug that is a selected drug  
25                  (as defined in section 1192(e)), for each appli-

1 cable year beginning after the price applicability  
2 period (as defined in section 1191(b)(2) with  
3 respect to such drug, subparagraph (A) of para-  
4 graph (2) shall be applied as if the term ‘pay-  
5 ment amount benchmark year’ were defined  
6 under subsection (g)(3) as the last year begin-  
7 ning during such price applicability period with  
8 respect to such selected drug and subparagraph  
9 (B) of paragraph (2) shall be applied as if the  
10 term ‘benchmark period CPI-U’ were defined  
11 under subsection (g)(4) as if the reference to  
12 ‘January 2016’ under such subsection were a  
13 reference to January of the last year beginning  
14 during such price applicability period with re-  
15 spect to such drug.

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

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

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

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

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

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

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

18       “(g) DEFINITIONS.—In this section:

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

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



1 cost under a prescription drug plan under this  
2 part or MA–PD plan under part C for such  
3 year per individual who uses such a drug or bi-  
4 ological, as determined by the Secretary, are  
5 less than, subject to subparagraph (B), \$100,  
6 as determined by the Secretary using the most  
7 recent data available or, if data is not available,  
8 as estimated by the Secretary.

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

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

17 “(ii) for a subsequent year, shall be  
18 the dollar amount specified in this sub-  
19 paragraph (or subparagraph (A)) for the  
20 previous year, increased by the percentage  
21 increase in the consumer price index for all  
22 urban consumers (United States city aver-  
23 age) as of January of the previous year.

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

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

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

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

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

23 “(6) AVERAGE MANUFACTURER PRICE.—The  
24 term ‘average manufacturer price’ has the meaning,  
25 with respect to a part D rebatable drug of a manu-

1        factorer for an applicable year, given such term in  
2        section 1927(k)(1), with respect to a covered out-  
3        patient drug of a manufacturer for a rebate period  
4        under section 1927. For purposes of applying the  
5        previous sentence, with respect to a part D rebatable  
6        drug of a manufacturer and an applicable year, the  
7        Secretary shall use the information with respect to  
8        the average manufacturer price for such drug re-  
9        ported by the manufacturer under section  
10       1927(b)(3) with respect to each of the quarters in  
11       the applicable year and calculate an annual average  
12       manufacturer price for such applicable year as the  
13       average of such average manufacturer prices for  
14       each such quarter, weighted by units of such drug  
15       sold or dispensed with respect to such applicable  
16       year.”.

17 **TITLE III—PART D IMPROVE-**  
18 **MENTS AND MAXIMUM OUT-**  
19 **OF-POCKET CAP FOR MEDI-**  
20 **CARE BENEFICIARIES**

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

22       (a) **BENEFIT STRUCTURE REDESIGN.**—Section  
23 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
24 102(b)) is amended—

25               (1) in paragraph (2)—

1 (A) in subparagraph (A), in the matter  
2 preceding clause (i), by inserting “for a year  
3 preceding 2022 and for costs above the annual  
4 deductible specified in paragraph (1) and up to  
5 the annual out-of-pocket threshold specified in  
6 paragraph (4)(B) for 2022 and each subsequent  
7 year” after “paragraph (3)”;

8 (B) in subparagraph (C)—

9 (i) in clause (i), in the matter pre-  
10 ceding subclause (I), by inserting “for a  
11 year preceding 2022,” after “paragraph  
12 (4),”; and

13 (ii) in clause (ii)(III), by striking  
14 “and each subsequent year” and inserting  
15 “and 2021”; and

16 (C) in subparagraph (D)—

17 (i) in clause (i)—

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

22 (II) in subclause (I)(bb), by  
23 striking “a year after 2018” and in-  
24 serting “each of years 2018 through  
25 2021”; and

1 (ii) in clause (ii)(V), by striking  
2 “2019 and each subsequent year” and in-  
3 serting “each of years 2019 through  
4 2021”;

5 (2) in paragraph (3)(A)—

6 (A) in the matter preceding clause (i), by  
7 inserting “for a year preceding 2022,” after  
8 “and (4),”; and

9 (B) in clause (ii), by striking “for a subse-  
10 quent year” and inserting “for each of years  
11 2007 through 2021”; and

12 (3) in paragraph (4)—

13 (A) in subparagraph (A)—

14 (i) in clause (i)—

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

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

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

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

5 (IV) by adding at the end the fol-  
6 lowing:

7 “(II) for 2022 and each suc-  
8 ceeding year, \$0.”; and  
9 (ii) in clause (ii)—

10 (I) by striking “clause (i)(I)” and  
11 inserting “clause (i)(I)(aa)”;

12 (II) by adding at the end the fol-  
13 lowing new sentence: “The Secretary  
14 shall continue to calculate the dollar  
15 amounts specified in clause (i)(I)(aa),  
16 including with the adjustment under  
17 this clause, after 2021 for purposes of  
18 section 1860D–14(a)(1)(D)(iii).”;

19 (B) in subparagraph (B)—

20 (i) in clause (i)—

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

23 (II) in subclause (VI)—

1 (aa) by striking “for a sub-  
2 sequent year” and inserting “for  
3 2021”; and

4 (bb) by striking the period  
5 at the end and inserting a semi-  
6 colon; and

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

9 “(VII) for 2022, is equal to  
10 \$2,000; or

11 “(VIII) for a subsequent year, is  
12 equal to the amount specified in this  
13 subparagraph for the previous year,  
14 increased by the annual percentage in-  
15 crease described in paragraph (6) for  
16 the year involved.”; and

17 (ii) in clause (ii), by striking “clause  
18 (i)(II)” and inserting “clause (i)”;

19 (C) in subparagraph (C)(i), by striking  
20 “and for amounts” and inserting “and, for a  
21 year preceding 2022, for amounts”; and

22 (D) in subparagraph (E), by striking “In  
23 applying” and inserting “For each of years  
24 2011 through 2021, in applying”.

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

6 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

13 “(a) ESTABLISHMENT.—The Secretary shall estab-  
14 lish a manufacturer discount program (in this section re-  
15 ferred to as the ‘program’). Under the program, the Sec-  
16 retary shall enter into agreements described in subsection  
17 (b) with manufacturers and provide for the performance  
18 of the duties described in subsection (c). The Secretary  
19 shall establish a model agreement for use under the pro-  
20 gram by not later than January 1, 2021, in consultation  
21 with manufacturers, and allow for comment on such model  
22 agreement.

23 “(b) TERMS OF AGREEMENT.—

24 “(1) IN GENERAL.—



1           “(A) AGREEMENT.—An agreement under  
2 this section shall require the manufacturer to  
3 provide applicable beneficiaries access to dis-  
4 counted prices for applicable drugs of the man-  
5 ufacturer that are dispensed on or after Janu-  
6 ary 1, 2022.

7           “(B) PROVISION OF DISCOUNTED PRICES  
8 AT THE POINT-OF-SALE.—The discounted prices  
9 described in subparagraph (A) shall be provided  
10 to the applicable beneficiary at the pharmacy or  
11 by the mail order service at the point-of-sale of  
12 an applicable drug.

13           “(C) TIMING OF AGREEMENT.—

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

23           “(ii) 2023 AND SUBSEQUENT  
24 YEARS.—In order for an agreement with a  
25 manufacturer to be in effect under this

1 section with respect to plan year 2023 or  
2 a subsequent plan year, the manufacturer  
3 shall enter into such agreement (or such  
4 agreement shall be renewed under para-  
5 graph (4)(A)) not later than January 30 of  
6 the preceding year.

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

13 “(3) COMPLIANCE WITH REQUIREMENTS FOR  
14 ADMINISTRATION OF PROGRAM.—Each manufac-  
15 turer with an agreement in effect under this section  
16 shall comply with requirements imposed by the Sec-  
17 retary or a third party with a contract under sub-  
18 section (d)(3), as applicable, for purposes of admin-  
19 istering the program, including any determination  
20 under subparagraph (A) of subsection (c)(1) or pro-  
21 cedures established under such subsection (c)(1).

22 “(4) LENGTH OF AGREEMENT.—

23 “(A) IN GENERAL.—An agreement under  
24 this section shall be effective for an initial pe-  
25 riod of not less than 12 months and shall be

1 automatically renewed for a period of not less  
2 than 1 year unless terminated under subpara-  
3 graph (B).

4 “(B) TERMINATION.—

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

20 “(ii) BY A MANUFACTURER.—A man-  
21 ufacturer may terminate an agreement  
22 under this section for any reason. Any  
23 such termination shall be effective, with re-  
24 spect to a plan year—

1                   “(I) if the termination occurs be-  
2                   fore January 30 of a plan year, as of  
3                   the day after the end of the plan year;  
4                   and

5                   “(II) if the termination occurs on  
6                   or after January 30 of a plan year, as  
7                   of the day after the end of the suc-  
8                   ceeding plan year.

9                   “(iii) EFFECTIVENESS OF TERMI-  
10                  NATION.—Any termination under this sub-  
11                  paragraph shall not affect discounts for  
12                  applicable drugs of the manufacturer that  
13                  are due under the agreement before the ef-  
14                  fective date of its termination.

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

21                  “(e) DUTIES DESCRIBED.—The duties described in  
22                  this subsection are the following:

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

1           “(A) the determination of the amount of  
2           the discounted price of an applicable drug of a  
3           manufacturer;

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

9           “(C) the establishment of procedures to  
10          ensure that, not later than the applicable num-  
11          ber of calendar days after the dispensing of an  
12          applicable drug by a pharmacy or mail order  
13          service, the pharmacy or mail order service is  
14          reimbursed for an amount equal to the dif-  
15          ference between—

16                 “(i) the negotiated price of the appli-  
17                 cable drug; and

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

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

1 chase or provision of prescription drug coverage  
2 on behalf of applicable beneficiaries as the Sec-  
3 retary may specify; and

4 “(E) providing a reasonable dispute resolu-  
5 tion mechanism to resolve disagreements be-  
6 tween manufacturers, applicable beneficiaries,  
7 and the third party with a contract under sub-  
8 section (d)(3).

9 “(2) MONITORING COMPLIANCE.—

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

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

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

25 “(d) ADMINISTRATION.—

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

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

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

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

20                 “(B) receive, distribute, or facilitate the  
21                 distribution of funds of manufacturers to ap-  
22                 propriate individuals or entities in order to  
23                 meet the obligations of manufacturers under  
24                 agreements under this section;

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

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

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

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

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

23          “(e) ENFORCEMENT.—



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

4           “(2) CIVIL MONEY PENALTY.—

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

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

18                   “(ii) 25 percent of such amount.

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

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

8       “(g) DEFINITIONS.—In this section:

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

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

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

16               “(C) has incurred costs for covered part D  
17 drugs in the year that are equal to or exceed  
18 the annual deductible specified in section  
19 1860D–2(b)(1) for such year.

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

22               “(A) means a covered part D drug—

23                       “(i) approved under a new drug appli-  
24 cation under section 505(b) of the Federal  
25 Food, Drug, and Cosmetic Act or, in the

1 case of a biologic product, licensed under  
2 section 351 of the Public Health Service  
3 Act; and

4 “(ii)(I) if the PDP sponsor of the pre-  
5 scription drug plan or the MA organization  
6 offering the MA–PD plan uses a for-  
7 mulary, which is on the formulary of the  
8 prescription drug plan or MA–PD plan  
9 that the applicable beneficiary is enrolled  
10 in;

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

18 “(III) is provided through an excep-  
19 tion or appeal; and

20 “(B) does not include a selected drug (as  
21 defined in section 1192(c)) during a price appli-  
22 cability period (as defined in section  
23 1191(b)(2)) with respect to such drug.

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

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

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

8           “(4) DISCOUNTED PRICE.—

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

13                          “(i) who has not incurred costs for  
14                          covered part D drugs in the year that are  
15                          equal to or exceed the annual out-of-pocket  
16                          threshold specified in section 1860D–  
17                          2(b)(4)(B)(i) for the year, 90 percent of  
18                          the negotiated price of such drug; and

19                          “(ii) who has incurred such costs in  
20                          the year that are equal to or exceed such  
21                          threshold for the year, 70 percent of the  
22                          negotiated price of such drug.

23           “(B) CLARIFICATION.—Nothing in this  
24           section shall be construed as affecting the re-

1           sponsibility of an applicable beneficiary for pay-  
2           ment of a dispensing fee for an applicable drug.

3           “(C) SPECIAL CASE FOR CERTAIN  
4           CLAIMS.—

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

18          “(ii) CLAIMS SPANNING OUT-OF-POCK-  
19          ET THRESHOLD.—In the case where the  
20          entire amount of the negotiated price of an  
21          individual claim for an applicable drug  
22          with respect to an applicable beneficiary  
23          does not fall entirely below or entirely  
24          above the annual out-of-pocket threshold  
25          specified in section 1860D–2(b)(4)(B)(i)

1 for the year, the manufacturer of the ap-  
2 plicable drug shall provide the discounted  
3 price—

4 “(I) in accordance with subpara-  
5 graph (A)(i) on the portion of the ne-  
6 gotiated price of the applicable drug  
7 that falls below such threshold; and

8 “(II) in accordance with subpara-  
9 graph (A)(ii) on the portion of such  
10 price of such drug that falls at or  
11 above such threshold.

12 “(5) MANUFACTURER.—The term ‘manufac-  
13 turer’ means any entity which is engaged in the pro-  
14 duction, preparation, propagation, compounding,  
15 conversion, or processing of prescription drug prod-  
16 ucts, either directly or indirectly by extraction from  
17 substances of natural origin, or independently by  
18 means of chemical synthesis, or by a combination of  
19 extraction and chemical synthesis. Such term does  
20 not include a wholesale distributor of drugs or a re-  
21 tail pharmacy licensed under State law.

22 “(6) NEGOTIATED PRICE.—The term ‘nego-  
23 tiated price’ has the meaning given such term in sec-  
24 tion 423.100 of title 42, Code of Federal Regula-  
25 tions (as in effect on the date of enactment of sec-

1       tion 1860D–14A), except that such negotiated price  
2       shall not include any dispensing fee for the applica-  
3       ble drug.

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

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

12              (A) in subsection (a), in the first sentence,  
13              by striking “The Secretary” and inserting  
14              “Subject to subsection (h), the Secretary”; and

15              (B) by adding at the end the following new  
16      subsection:

17      “(h) SUNSET OF PROGRAM.—

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

23              “(2) CONTINUED APPLICATION FOR APPLICA-  
24              BLE DRUGS DISPENSED PRIOR TO SUNSET.—The  
25              provisions of this section (including all responsibil-

1       ities and duties) shall continue to apply after Janu-  
2       ary 1, 2022, with respect to applicable drugs dis-  
3       pensed prior to such date.”.

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

8               (A) in subsection (b)(2)(C)(iii)—

9                       (i) by striking “assumptions regarding  
10                      the reinsurance” and inserting “assump-  
11                      tions regarding—

12                               “(I) the reinsurance”; and

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

15                               “(II) for 2022 and each subse-  
16                      quent year, the manufacturer dis-  
17                      counts provided under section 1860D–  
18                      14C subtracted from the actuarial  
19                      value to produce such bid; and”; and

20               (B) in subsection (c)(1)(C)—

21                       (i) by striking “an actuarial valuation  
22                      of the reinsurance” and inserting “an ac-  
23                      tuarial valuation of—

24                               “(i) the reinsurance”;



1 (ii) in clause (i), as inserted by clause  
2 (i) of this subparagraph, by adding “and”  
3 at the end; and

4 (iii) by adding at the end the fol-  
5 lowing:

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

9 (d) CONFORMING AMENDMENTS.—

10 (1) Section 1860D–2 of the Social Security Act  
11 (42 U.S.C. 1395w–102) is amended—

12 (A) in subsection (a)(2)(A)(i)(I), by strik-  
13 ing “, or an increase in the initial” and insert-  
14 ing “or, for a year preceding 2022, an increase  
15 in the initial”;

16 (B) in subsection (c)(1)(C)—

17 (i) in the subparagraph heading, by  
18 striking “AT INITIAL COVERAGE LIMIT”;  
19 and

20 (ii) by inserting “for a year preceding  
21 2022 or the annual out-of-pocket threshold  
22 specified in subsection (b)(4)(B) for the  
23 year for 2022 and each subsequent year”  
24 after “subsection (b)(3) for the year” each  
25 place it appears; and

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

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

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

10 (A) in paragraph (1)—

11 (i) in subparagraph (C), by striking  
12 “The continuation” and inserting “For a  
13 year preceding 2022, the continuation”;

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

17 (iii) in subparagraph (E), by striking  
18 “The elimination” and inserting “For a  
19 year preceding 2022, the elimination”; and

20 (B) in paragraph (2)—

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

24 and

25 (ii) in subparagraph (E)—

1 (I) by inserting “for a year pre-  
2 ceding 2022,” after “subsection (e)”;  
3 and

4 (II) by striking “1860D-  
5 2(b)(4)(A)(i)(I)” and inserting  
6 “1860D-2(b)(4)(A)(i)(I)(aa)”.

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

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

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

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

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

21 (C) by adding at the end the following new  
22 clause:

23 “(ii) for 2022 and each subsequent  
24 year, any discount provided pursuant to  
25 section 1860D-14C.”.

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

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

5                   (B) by inserting “for such year” before the  
6                   period.

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

10                   “(1) participate in—

11                           “(A) for 2011 through 2021, the Medicare  
12                           coverage gap discount program under section  
13                           1860D–14A; and

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

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

