



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

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

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

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

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

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

24           “(3) SELECTED DRUG PUBLICATION DATE.—  
25 The term ‘selected drug publication date’ means,

1 with respect to each initial price applicability year,  
2 April 15 of the plan year that begins 2 years prior  
3 to such year.

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

8 “(A) beginning on the sooner of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(B) APPLICABLE COUNTRIES.—

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

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

25 “(I) Australia.

1 “(II) Canada.

2 “(III) France.

3 “(IV) Germany.

4 “(V) Japan.

5 “(VI) The United Kingdom.

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

10 “(2) continue to be marketed.

11 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

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

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

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

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

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

4           “(1) DRUG PRODUCTS.—A drug that—

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

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

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

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

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

1           “(3)   INSULIN   PRODUCT.—Notwithstanding  
2           paragraphs (1) and (2), any insulin product that is  
3           approved under subsection (c) or (j) of section 505  
4           of the Federal Food, Drug, and Cosmetic Act or li-  
5           censed under subsection (a) or (k) of section 351 of  
6           the Public Health Service Act and continues to be  
7           marketed under such section 505 or 351, including  
8           any insulin product that has been deemed to be li-  
9           censed under section 351(a) of the Public Health  
10          Service Act pursuant to section 7002(e)(4) of the  
11          Biologics Price Competition and Innovation Act of  
12          2009 and continues to be marketed pursuant to such  
13          licensure.

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

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

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

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

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

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

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

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

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

15 “(h) CONFLICT OF INTEREST.—

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25           “(2) AMOUNTS DESCRIBED.—

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

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

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

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

7 “(e) REGULATIONS.—

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

21 “(3) REQUIREMENT.—

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

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

12                   “(B) TARGET PRICE.—

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

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

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

25 “(c) **LIMITATION.**—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

3 “(b) UPDATES.—

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

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

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

21 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

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

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

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

6 “(a) ADMINISTRATIVE DUTIES.—

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

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

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

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

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

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

8                   “(i) the lesser of—

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

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

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

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

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

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

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

4                   “(ii) any other discounts.

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

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

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

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

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

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

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

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

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

6           “(2) MONITORING COMPLIANCE.—

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

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

20           “(b) COLLECTION OF DATA.—

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

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

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

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

15 “(c) CONTRACT WITH THIRD PARTIES.—

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7           (1) UNDER MEDICARE.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

16 (B) ERISA.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (C) IRC.—

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

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

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

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

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

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





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

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

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

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

13 (A) in subsection (c)(1)(C)(ii)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 “(2) For purposes of this subsection:

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

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

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

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

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

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

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

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

20                   “(1) such tax, divided by

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

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

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

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

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

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

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

7           “(c) APPLICABLE PERCENTAGE.—For purposes of  
8           this section, the term ‘applicable percentage’ means—

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

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

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

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

21           “(d) SELECTED DRUG.—For purposes of this sec-  
22           tion—

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



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

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

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

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

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

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

23 (c) CONFORMING AMENDMENTS.—

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

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

6 (d) CLERICAL AMENDMENTS.—

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

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

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

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

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

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

5 (b) FUNDING.—There is authorized to be appro-  
6 priated, and there is hereby appropriated, out of any mon-  
7 ies in the Treasury not otherwise appropriated, to the  
8 Fund \$3,000,000,000, to remain available until expended,  
9 of which—

10 (1) \$600,000,000 shall become available on the  
11 date of the enactment of this Act;

12 (2) \$600,000,000 shall become available on Oc-  
13 tober 1, 2023;

14 (3) \$600,000,000 shall become available on Oc-  
15 tober 1, 2024;

16 (4) \$600,000,000 shall become available on Oc-  
17 tober 1, 2025; and

18 (5) \$600,000,000 shall become available on Oc-  
19 tober 1, 2026.

20 (c) SUPPLEMENT NOT SUPPLANT.—Any amounts  
21 appropriated pursuant to this section shall be in addition  
22 to any other amounts otherwise appropriated pursuant to  
23 any other provision of law.

1           **PART 2—PRESCRIPTION DRUG INFLATION**

2                           **REBATES**

3   **SEC. 30511. MEDICARE PART B REBATE BY MANUFACTUR-**  
4                           **ERS.**

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

8           “(z) REBATE BY MANUFACTURERS FOR SINGLE  
9 SOURCE DRUGS WITH PRICES INCREASING FASTER  
10 THAN INFLATION.—

11                   “(1) REQUIREMENTS.—

12                           “(A) SECRETARIAL PROVISION OF INFOR-  
13 MATION.—Not later than 6 months after the  
14 end of each calendar quarter beginning on or  
15 after July 1, 2023, the Secretary shall, for each  
16 part B rebatable drug, report to each manufac-  
17 turer of such part B rebatable drug the fol-  
18 lowing for such calendar quarter:

19                                   “(i) Information on the total number  
20 of units of the billing and payment code  
21 described in subparagraph (A)(i) of para-  
22 graph (3) with respect to such drug and  
23 calendar quarter.

24                                   “(ii) Information on the amount (if  
25 any) of the excess average sales price in-  
26 crease described in subparagraph (A)(ii) of

1           such paragraph for such drug and calendar  
2           quarter.

3           “(iii) The rebate amount specified  
4           under such paragraph for such part B  
5           rebatable drug and calendar quarter.

6           “(B) MANUFACTURER REQUIREMENT.—  
7           For each calendar quarter beginning on or after  
8           July 1, 2023, the manufacturer of a part B  
9           rebatable drug shall, for such drug, not later  
10          than 30 days after the date of receipt from the  
11          Secretary of the information described in sub-  
12          paragraph (A) for such calendar quarter, pro-  
13          vide to the Secretary a rebate that is equal to  
14          the amount specified in paragraph (3) for such  
15          drug for such calendar quarter.

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

17                 “(A) IN GENERAL.—In this subsection, the  
18                 term ‘part B rebatable drug’ means a single  
19                 source drug or biological (as defined in sub-  
20                 paragraph (D) of section 1847A(e)(6)), includ-  
21                 ing a biosimilar biological product (as defined  
22                 in subparagraph (H) of such section), payable  
23                 (if such drug were furnished to an individual  
24                 enrolled under this part) under this part, except

1 such term shall not include such a drug or bio-  
2 logical—

3 “(i) if the average total allowed  
4 charges under this part as determined by  
5 the Secretary for a year per individual that  
6 uses such a drug or biological, as deter-  
7 mined by the Secretary, are less than, sub-  
8 ject to subparagraph (B), \$100; or

9 “(ii) that is a vaccine described in  
10 subparagraph (A) or (B) of section  
11 1861(s)(10).

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

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

21 “(ii) for a subsequent year, shall be  
22 the dollar amount specified in this clause  
23 (or clause (i)) for the previous year, in-  
24 creased by the percentage increase in the  
25 consumer price index for all urban con-

1           sumers (United States city average) for  
2           the 12-month period ending with June of  
3           the previous year.

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

7           “(3) REBATE AMOUNT.—

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

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

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

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

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

6                   “(B) EXCLUDED UNITS.—For purposes of  
7                   subparagraph (A)(i), the Secretary shall exclude  
8                   from the total number of units with respect to  
9                   a part B rebtable drug and calendar quarter  
10                  units of such part B rebtable drug for which  
11                  payment was made under a State plan under  
12                  title XIX (or waiver of such plan), as reported  
13                  by States under section 1927(b)(2)(A) for the  
14                  most recent rebate period.

15                  “(C) DETERMINATION OF INFLATION-AD-  
16                  JUSTED PAYMENT AMOUNT.—The inflation-ad-  
17                  justed payment amount determined under this  
18                  subparagraph for a part B rebtable drug for  
19                  a calendar quarter is—

20                         “(i) the payment amount for the bill-  
21                         ing and payment code for such drug in the  
22                         payment amount benchmark quarter (as  
23                         defined in subparagraph (D)); increased by

24                                 “(ii) the percentage by which the re-  
25                                 bate period CPI-U (as defined in subpara-



1 graph (F)) for the calendar quarter ex-  
2 ceeds the benchmark period CPI-U (as de-  
3 fined in subparagraph (E)).

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

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

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

21 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS  
22 AND EXEMPTION.—

23 “(A) SUBSEQUENTLY APPROVED DRUGS.—  
24 Subject to subparagraph (B), in the case of a  
25 part B rebatable drug first approved or licensed

1 by the Food and Drug Administration after  
2 July 1, 2015, clause (i) of paragraph (3)(C)  
3 shall be applied as if the term ‘payment amount  
4 benchmark quarter’ were defined under para-  
5 graph (3)(D) as the third full calendar quarter  
6 after the day on which the drug was first mar-  
7 keted and clause (ii) of paragraph (3)(C) shall  
8 be applied as if the term ‘benchmark period  
9 CPI-U’ were defined under paragraph (3)(E)  
10 as if the reference to ‘July 2015’ under such  
11 paragraph were a reference to ‘the first month  
12 of the first full calendar quarter after the day  
13 on which the drug was first marketed’.

14 “(B) TIMELINE FOR PROVISION OF RE-  
15 BATES FOR SUBSEQUENTLY APPROVED  
16 DRUGS.—In the case of a part B rebatable drug  
17 first approved or licensed by the Food and  
18 Drug Administration after July 1, 2015, para-  
19 graph (1)(B) shall be applied as if the reference  
20 to ‘July 1, 2023’ under such paragraph were a  
21 reference to the later of the 6th full calendar  
22 quarter after the day on which the drug was  
23 first marketed or July 1, 2023.

24 “(C) EXEMPTION FOR SHORTAGES.—The  
25 Secretary may reduce or waive the rebate

1 amount under paragraph (1)(B) with respect to  
2 a part B rebatable drug that is described as  
3 currently in shortage on the shortage list in ef-  
4 fect under section 506E of the Federal Food,  
5 Drug, and Cosmetic Act or in the case of other  
6 exigent circumstances, as determined by the  
7 Secretary.

8 “(D) SELECTED DRUGS.—In the case of a  
9 part B rebatable drug that is a selected drug  
10 (as defined in section 1192(e)) for a price appli-  
11 cability period (as defined in section  
12 1191(b)(2))—

13 “(i) for calendar quarters during such  
14 period for which a maximum fair price (as  
15 defined in section 1191(c)(2)) for such  
16 drug has been determined and is applied  
17 under part E of title XI, the rebate  
18 amount under paragraph (1)(B) shall be  
19 waived; and

20 “(ii) in the case such drug is deter-  
21 mined (pursuant to such section 1192(e))  
22 to no longer be a selected drug, for each  
23 applicable year beginning after the price  
24 applicability period with respect to such  
25 drug, clause (i) of paragraph (3)(C) shall

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

14 “(5) APPLICATION TO BENEFICIARY COINSUR-  
15 ANCE.—In the case of a part B rebatable drug, if  
16 the payment amount under this part for a quarter  
17 exceeds the inflation adjusted payment for such  
18 quarter—

19 “(A) in computing the amount of any coin-  
20 surance applicable under this part to an indi-  
21 vidual to whom such drug is furnished, the  
22 computation of such coinsurance shall be based  
23 on the inflation-adjusted payment amount de-  
24 termined under paragraph (3)(C) for such part  
25 B rebatable drug; and

1           “(B) the amount of such coinsurance is  
2           equal to 20 percent of such inflation-adjusted  
3           payment amount so determined.

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

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

23          “(8) APPLICATION TO MULTIPLE SOURCE  
24          DRUGS.—The Secretary may, pursuant to rule-  
25          making, apply the provisions of this subsection to

1 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 of the Social Security Act (42 U.S.C. 1395l) is  
9 amended—

10 (1) in subsection (a)—

11 (A) in paragraph (1)—

12 (i) in subparagraph (G), by inserting  
13 “, subject to subsection (i)(9),” after “the  
14 amounts paid”;

15 (ii) in subparagraph (S), by striking  
16 “with respect to” and inserting “subject to  
17 subparagraph (DD), with respect to”;

18 (iii) by striking “and (DD)” and in-  
19 serting “(EE)”; and

20 (iv) by inserting before the semicolon  
21 at the end the following: “, and (EE) with  
22 respect to a part B rebatable drug (as de-  
23 fined in paragraph (2) of section 1834(z))  
24 for which the payment amount for a cal-  
25 endar quarter under paragraph

1 (3)(A)(ii)(I) of such section for such quar-  
2 ter exceeds the inflation-adjusted payment  
3 under paragraph (3)(A)(ii)(II) of such sec-  
4 tion for such quarter, the amounts paid  
5 shall be the difference between (i) the pay-  
6 ment amount under paragraph  
7 (3)(A)(ii)(I) of such section for such drug,  
8 and (ii) 20 percent of the inflation-ad-  
9 justed payment amount under paragraph  
10 (3)(A)(ii)(II) of such section for such  
11 drug”; and

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

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

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

21 “(9) In the case of a part B rebatable drug (as de-  
22 fined in paragraph (2) of section 1834(z)) for which pay-  
23 ment under this subsection is not packaged into a payment  
24 for a covered OPD service (as defined in subsection  
25 (t)(1)(B)) (or group of services) furnished on or after July

1 1, 2023, under the system under this subsection, in lieu  
2 of calculation of coinsurance and the amount of payment  
3 otherwise applicable under this subsection, the provisions  
4 of section 1834(z)(5), paragraph (1)(EE) of subsection  
5 (a), and the flush left matter following paragraph (9) of  
6 subsection (a), shall, as determined appropriate by the  
7 Secretary, apply under this subsection in the same manner  
8 as such provisions of section 1834(z)(5) and subsection  
9 (a) apply under such section and subsection.”; and

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

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





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

4 “(a) REQUIREMENTS.—

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

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

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

19 “(2) MANUFACTURER REQUIREMENTS.—For  
20 each applicable year, the manufacturer of a part D  
21 rebatable drug, for each dosage form and strength  
22 with respect to such drug, not later than 30 days  
23 after the date of receipt from the Secretary of the  
24 information described in paragraph (1) for such  
25 year, shall provide to the Secretary a rebate that is  
26 equal to the amount specified in subsection (b) for

1 such dosage form and strength with respect to such  
2 drug for such year.

3 “(b) REBATE AMOUNT.—

4 “(1) IN GENERAL.—

5 “(A) CALCULATION.—For purposes of this  
6 section, the amount specified in this subsection  
7 for a dosage form and strength with respect to  
8 a part D rebatable drug and applicable year is,  
9 subject to subparagraph (B) of this paragraph  
10 and subparagraphs (B) and (C) of paragraph  
11 (5), the amount equal to the product of—

12 “(i) the total number of units that are  
13 used to calculate the average manufacturer  
14 price of such dosage form and strength  
15 with respect to such part D rebatable  
16 drug, as reported by the manufacturer of  
17 such drug under section 1927 for each re-  
18 cent rebate period under such section, with  
19 respect to such year, under such section  
20 for which such information is available;  
21 and

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

23 “(I) the annual manufacturer  
24 price (as determined in paragraph  
25 (2)) paid for such dosage form and

1 strength with respect to such part D  
2 rebatable drug for the year; exceeds

3 “(II) the inflation-adjusted pay-  
4 ment amount determined under para-  
5 graph (3) for such dosage form and  
6 strength with respect to such part D  
7 rebatable drug for the year.

8 “(B) EXCLUDED UNITS.—For purposes of  
9 subparagraph (A)(i), the Secretary shall exclude  
10 from the total number of units for a dosage  
11 form and strength with respect to a part D  
12 rebatable drug and the most recent rebate pe-  
13 riod under section 1927, with respect to an ap-  
14 plicable year, for which such information is  
15 available, units of each dosage form and  
16 strength of such part D rebatable drug, for  
17 which payment was made under a State plan  
18 under title XIX (or waiver of such plan), as re-  
19 ported by States under section 1927(b)(2)(A)  
20 for such rebate period.

21 “(2) DETERMINATION OF ANNUAL MANUFAC-  
22 Turer PRICE.—The annual manufacturer price de-  
23 termined under this paragraph for a dosage form  
24 and strength, with respect to a part D rebatable

1 drug and an applicable year, is the sum of the prod-  
2 ucts of—

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

8 “(B) the ratio of—

9 “(i) the total number of units of such  
10 dosage form and strength reported for the  
11 purpose of calculating average manufac-  
12 turer price under section 1927 during each  
13 such calendar quarter of such year; to

14 “(ii) the total number of units of such  
15 dosage form and strength reported for the  
16 purpose of calculating average manufac-  
17 turer price under section 1927 during such  
18 year, as determined by the Secretary.

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

1           “(A) the benchmark year manufacturer  
2 price determined under paragraph (4) for such  
3 dosage form and strength with respect to such  
4 drug and year; increased by

5           “(B) the percentage by which the applica-  
6 ble year CPI-U (as defined in subsection  
7 (g)(5)) for the year exceeds the benchmark pe-  
8 riod CPI-U (as defined in subsection (g)(4)).

9           “(4) DETERMINATION OF BENCHMARK YEAR  
10 MANUFACTURER PRICE.—The benchmark year man-  
11 ufacturer price determined under this paragraph for  
12 a dosage form and strength, with respect to a part  
13 D rebatable drug and an applicable year, is the sum  
14 of the products of—

15           “(A) the average manufacturer price (as  
16 defined in subsection (g)(6)) of such dosage  
17 form and strength, as calculated for a unit of  
18 such drug, with respect to each of the calendar  
19 quarters of the payment amount benchmark  
20 year (as defined in subsection (g)(3)); and

21           “(B) the ratio of—

22           “(i) the total number of units of such  
23 dosage form and strength dispensed during  
24 each such calendar quarter of such pay-  
25 ment amount benchmark year; to

1                   “(ii) the total number of units of such  
2                   dosage form and strength dispensed during  
3                   such payment amount benchmark year.

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

6                   “(A) SUBSEQUENTLY APPROVED DRUGS.—

7                   In the case of a part D rebatable drug first ap-  
8                   proved or licensed by the Food and Drug Ad-  
9                   ministration after January 1, 2016, subpara-  
10                  graphs (A) and (B) of paragraph (4) shall be  
11                  applied as if the term ‘payment amount bench-  
12                  mark year’ were defined under subsection  
13                  (g)(3) as the first calendar year beginning after  
14                  the day on which the drug was first marketed  
15                  by any manufacturer and subparagraph (B) of  
16                  paragraph (3) shall be applied as if the term  
17                  ‘benchmark period CPI-U’ were defined under  
18                  subsection (g)(4) as if the reference to ‘January  
19                  2016’ under such subsection were a reference to  
20                  ‘January of the first year beginning after the  
21                  date on which the drug was first marketed by  
22                  any manufacturer’.

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

1 rebatable drug that is described as currently in  
2 shortage on the shortage list in effect under  
3 section 506E of the Federal Food, Drug, and  
4 Cosmetic Act or in the case of other exigent cir-  
5 cumstances, as determined by the Secretary.

6 “(C) TREATMENT OF NEW FORMULA-  
7 TIONS.—

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

17 “(ii) LINE EXTENSION DEFINED.—In  
18 this subparagraph, the term ‘line exten-  
19 sion’ means, with respect to a part D  
20 rebatable drug, a new formulation of the  
21 drug, such as an extended release formula-  
22 tion, but does not include an abuse-deter-  
23 rent formulation of the drug (as deter-  
24 mined by the Secretary), regardless of



1           whether such abuse-deterrent formulation  
2           is an extended release formulation.

3           “(D) SELECTED DRUGS.—In the case of a  
4           part D rebatable drug that is a selected drug  
5           (as defined in section 1192(c)) for a price appli-  
6           cability period (as defined in section  
7           1191(b)(2))—

8                   “(i) for plan years during such period  
9                   for which a maximum fair price (as defined  
10                  in section 1191(c)(2)) for such drug has  
11                  been determined and is applied under part  
12                  E of title XI, the rebate under subsection  
13                  (a)(1)(B) shall be waived; and

14                   “(ii) in the case such drug is deter-  
15                  mined (pursuant to such section 1192(c))  
16                  to no longer be a selected drug, for each  
17                  applicable year beginning after the price  
18                  applicability period with respect to such  
19                  drug, subparagraphs (A) and (B) of para-  
20                  graph (4) shall be applied as if the term  
21                  ‘payment amount benchmark year’ were  
22                  defined under subsection (g)(3) as the last  
23                  year beginning during such price applica-  
24                  bility period with respect to such selected  
25                  drug and subparagraph (B) of paragraph

1 (3) shall be applied as if the term ‘bench-  
2 mark period CPI-U’ were defined under  
3 subsection (g)(4) as if the reference to  
4 ‘January 2016’ under such subsection were  
5 a reference to January of the last year be-  
6 ginning during such price applicability pe-  
7 riod with respect to such drug.

8 “(c) REBATE DEPOSITS.—Amounts paid as rebates  
9 under subsection (b) shall be deposited into the Medicare  
10 Prescription Drug Account in the Federal Supplementary  
11 Medical Insurance Trust Fund established under section  
12 1841.

13 “(d) INFORMATION.—For purposes of carrying out  
14 this section, the Secretary shall use information submitted  
15 by manufacturers under section 1927(b)(3) and informa-  
16 tion submitted by States under section 1927(b)(2)(A).

17 “(e) CIVIL MONEY PENALTY.—If a manufacturer of  
18 a part D rebatable drug has failed to comply with the re-  
19 quirement under subsection (a)(1)(B) with respect to such  
20 drug for an applicable year, the manufacturer shall be  
21 subject to, in accordance with a process established by the  
22 Secretary pursuant to regulations, a civil money penalty  
23 in an amount equal to 125 percent of the amount specified  
24 in subsection (b) for such drug for such year. The provi-  
25 sions of section 1128A (other than subsections (a) (with

1 respect to amounts of penalties or additional assessments)  
2 and (b)) shall apply to a civil money penalty under this  
3 subsection in the same manner as such provisions apply  
4 to a penalty or proceeding under section 1128A(a).

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

7 “(1) The determination of units under this sec-  
8 tion.

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

11 “(3) The calculation of the rebate amount  
12 under this section.

13 “(g) DEFINITIONS.—In this section:

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

15 “(A) IN GENERAL.—The term ‘part D  
16 rebatable drug’ means a drug or biological that  
17 would (without application of this section) be a  
18 covered part D drug, except such term shall,  
19 with respect to an applicable year, not include  
20 such a drug or biological if the average annual  
21 total cost under this part for such year per in-  
22 dividual who uses such a drug or biological, as  
23 determined by the Secretary, is less than, sub-  
24 ject to subparagraph (B), \$100, as determined  
25 by the Secretary using the most recent data

1 available or, if data is not available, as esti-  
2 mated by the Secretary.

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

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

12 “(ii) for a subsequent year, shall be  
13 the dollar amount specified in this sub-  
14 paragraph for the previous year, increased  
15 by the percentage increase in the consumer  
16 price index for all urban consumers  
17 (United States city average) for the 12-  
18 month period beginning with January of  
19 the previous year.

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

23 “(2) UNIT DEFINED.—The term ‘unit’ means,  
24 with respect to a part D rebatable drug, the lowest  
25 identifiable quantity (such as a capsule or tablet,

1 milligram of molecules, or grams) of the part D  
2 rebatable drug, including data reported under sec-  
3 tion 1927.

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

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

11 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-  
12 plicable year CPI–U’ means, with respect to an ap-  
13 plicable year, the consumer price index for all urban  
14 consumers (United States city average) for January  
15 of such year.

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

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

24 (b) CONFORMING AMENDMENTS.—

1           (1) TO PART B ASP CALCULATION.—Section  
2           1847A(c)(3) of the Social Security Act (42 U.S.C.  
3           1395w–3a(c)(3)), as amended by section  
4           30511(c)(1), is further amended by striking “section  
5           1927 or section 1834(z)” and inserting “section  
6           1927, section 1834(z), or section 1860D–14B”.

7           (2) EXCLUDING PART D DRUG INFLATION RE-  
8           BATE FROM BEST PRICE.—Section  
9           1927(c)(1)(C)(ii)(I) of the Social Security Act (42  
10          U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-  
11          tion 30511(c)(2), is further amended by striking “or  
12          section 1834(z)” and inserting “, section 1834(z), or  
13          section 1860D–14B”.

14          (3) COORDINATION WITH MEDICAID REBATE IN-  
15          FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)  
16          of the Social Security Act (42 U.S.C. 1396r–  
17          8(b)(3)(D)(i)), as amended by section 30511(c)(3),  
18          is further amended by striking “or section 1834(z)”  
19          and inserting “, section 1834(z), or section 1860D–  
20          14B”.

1 **PART 3—PART D IMPROVEMENTS AND MAXIMUM**  
2 **OUT-OF-POCKET CAP FOR MEDICARE BENE-**  
3 **FICIARIES**

4 **SEC. 30521. MEDICARE PART D BENEFIT REDESIGN.**

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

8 (1) in paragraph (2)—

9 (A) in subparagraph (A), in the matter  
10 preceding clause (i), by inserting “for a year  
11 preceding 2024 and for costs above the annual  
12 deductible specified in paragraph (1) and up to  
13 the annual out-of-pocket threshold specified in  
14 paragraph (4)(B) for 2024 and each subsequent  
15 year” after “paragraph (3)”;

16 (B) in subparagraph (C)—

17 (i) in clause (i), in the matter pre-  
18 ceding subclause (I), by inserting “for a  
19 year preceding 2024,” after “paragraph  
20 (4),”; and

21 (ii) in clause (ii)(III), by striking  
22 “and each subsequent year” and inserting  
23 “through 2023”; and

24 (C) in subparagraph (D)—

25 (i) in clause (i)—

1 (I) in the matter preceding sub-  
2 clause (I), by inserting “for a year  
3 preceding 2024,” after “paragraph  
4 (4),”; and

5 (II) in subclause (I)(bb), by  
6 striking “a year after 2018” and in-  
7 serting “each of years 2018 through  
8 2023”; and

9 (ii) in clause (ii)(V), by striking  
10 “2019 and each subsequent year” and in-  
11 serting “each of years 2019 through  
12 2023”;

13 (2) in paragraph (3)(A)—

14 (A) in the matter preceding clause (i), by  
15 inserting “for a year preceding 2024,” after  
16 “and (4),”; and

17 (B) in clause (ii), by striking “for a subse-  
18 quent year” and inserting “for each of years  
19 2007 through 2023”; and

20 (3) in paragraph (4)—

21 (A) in subparagraph (A)—

22 (i) in clause (i)—

23 (I) by redesignating subclauses  
24 (I) and (II) as items (aa) and (bb),  
25 respectively, and moving the margin



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

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

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

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

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

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

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

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)—

24 (aa) by striking “for a sub-  
25 sequent year” and inserting “for

1 each of years 2021 through  
2 2023”; and

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

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

8 “(VII) for 2024, is equal to  
9 \$2,000; or

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

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

18 (C) in subparagraph (C)(i), by striking  
19 “and for amounts” and inserting “and, for a  
20 year preceding 2024, for amounts”; and

21 (D) in subparagraph (E), by striking “In  
22 applying” and inserting “For each of years  
23 2011 through 2023, in applying”.

24 (b) DECREASING REINSURANCE PAYMENT  
25 AMOUNT.—Section 1860D–15(b)(1) of the Social Security

1 Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting  
2 after “80 percent” the following: “(or, with respect to a  
3 coverage year after 2023, 20 percent)”.

4 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

11 “(a) ESTABLISHMENT.—The Secretary shall estab-  
12 lish a manufacturer discount program (in this section re-  
13 ferred to as the ‘program’). Under the program, the Sec-  
14 retary shall enter into agreements described in subsection  
15 (b) with manufacturers and provide for the performance  
16 of the duties described in subsection (c). The Secretary  
17 shall establish a model agreement for use under the pro-  
18 gram by not later than January 1, 2023, in consultation  
19 with manufacturers, and allow for comment on such model  
20 agreement.

21 “(b) TERMS OF AGREEMENT.—

22 “(1) IN GENERAL.—

23 “(A) AGREEMENT.—An agreement under  
24 this section shall require the manufacturer to  
25 provide applicable beneficiaries access to dis-

1 counted prices for applicable drugs of the man-  
2 ufacturer that are dispensed on or after Janu-  
3 ary 1, 2024.

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

10 “(C) TIMING OF AGREEMENT.—

11 “(i) SPECIAL RULE FOR 2024.—In  
12 order for an agreement with a manufac-  
13 turer to be in effect under this section with  
14 respect to the period beginning on January  
15 1, 2024, and ending on December 31,  
16 2024, the manufacturer shall enter into  
17 such agreement not later than 30 days  
18 after the date of the establishment of a  
19 model agreement under subsection (a).

20 “(ii) 2025 AND SUBSEQUENT  
21 YEARS.—In order for an agreement with a  
22 manufacturer to be in effect under this  
23 section with respect to plan year 2025 or  
24 a subsequent plan year, the manufacturer  
25 shall enter into such agreement (or such

1 agreement shall be renewed under para-  
2 graph (4)(A)) not later than January 30 of  
3 the preceding year.

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

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

19 “(4) LENGTH OF AGREEMENT.—

20 “(A) IN GENERAL.—An agreement under  
21 this section shall be effective for an initial pe-  
22 riod of not less than 12 months and shall be  
23 automatically renewed for a period of not less  
24 than 1 year unless terminated under subpara-  
25 graph (B).

1 “(B) TERMINATION.—

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

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

22 “(I) if the termination occurs be-  
23 fore January 30 of a plan year, as of  
24 the day after the end of the plan year;  
25 and

1                   “(II) if the termination occurs on  
2                   or after January 30 of a plan year, as  
3                   of the day after the end of the suc-  
4                   ceeding plan year.

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

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

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

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

21                  “(A) the determination of the amount of  
22                  the discounted price of an applicable drug of a  
23                  manufacturer;

24                  “(B) the establishment of procedures  
25                  under which discounted prices are provided to

1 applicable beneficiaries at pharmacies or by  
2 mail order service at the point-of-sale of an ap-  
3 plicable drug;

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

11 “(i) the negotiated price of the appli-  
12 cable drug; and

13 “(ii) the discounted price of the appli-  
14 cable drug;

15 “(D) the establishment of procedures to  
16 ensure that the discounted price for an applica-  
17 ble drug under this section is applied before any  
18 coverage or financial assistance under other  
19 health benefit plans or programs that provide  
20 coverage or financial assistance for the pur-  
21 chase or provision of prescription drug coverage  
22 on behalf of applicable beneficiaries as the Sec-  
23 retary may specify; and

24 “(E) providing a reasonable dispute resolu-  
25 tion mechanism to resolve disagreements be-



1           tween manufacturers, applicable beneficiaries,  
2           and the third party with a contract under sub-  
3           section (d)(3).

4           “(2) MONITORING COMPLIANCE.—

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

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

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

20           “(d) ADMINISTRATION.—

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

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

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

12                   “(A) receive and transmit information be-  
13                   tween the Secretary, manufacturers, and other  
14                   individuals or entities the Secretary determines  
15                   appropriate;

16                   “(B) receive, distribute, or facilitate the  
17                   distribution of funds of manufacturers to ap-  
18                   propriate individuals or entities in order to  
19                   meet the obligations of manufacturers under  
20                   agreements under this section;

21                   “(C) provide adequate and timely informa-  
22                   tion to manufacturers, consistent with the  
23                   agreement with the manufacturer under this  
24                   section, as necessary for the manufacturer to  
25                   fulfill its obligations under this section; and

1           “(D) permit manufacturers to conduct  
2           periodic audits, directly or through contracts, of  
3           the data and information used by the third  
4           party to determine discounts for applicable  
5           drugs of the manufacturer under the program.

6           “(4) PERFORMANCE REQUIREMENTS.—The  
7           Secretary shall establish performance requirements  
8           for a third party with a contract under paragraph  
9           (3) and safeguards to protect the independence and  
10          integrity of the activities carried out by the third  
11          party under the program under this section.

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

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

18          “(e) ENFORCEMENT.—

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

22                 “(2) CIVIL MONEY PENALTY.—

23                         “(A) IN GENERAL.—The Secretary may  
24                         impose a civil money penalty on a manufacturer  
25                         that fails to provide applicable beneficiaries dis-

1 counts for applicable drugs of the manufacturer  
2 in accordance with such agreement for each  
3 such failure in an amount the Secretary deter-  
4 mines is equal to the sum of—

5 “(i) the amount that the manufac-  
6 turer would have paid with respect to such  
7 discounts under the agreement, which will  
8 then be used to pay the discounts which  
9 the manufacturer had failed to provide;  
10 and

11 “(ii) 25 percent of such amount.

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

18 “(f) CLARIFICATION REGARDING AVAILABILITY OF  
19 OTHER COVERED PART D DRUGS.—Nothing in this sec-  
20 tion shall prevent an applicable beneficiary from pur-  
21 chasing a covered part D drug that is not an applicable  
22 drug (including a generic drug or a drug that is not on  
23 the formulary of the prescription drug plan or MA–PD  
24 plan that the applicable beneficiary is enrolled in).

25 “(g) DEFINITIONS.—In this section:

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

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

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

8                   “(C) has incurred costs, as determined in  
9                   accordance with section 1860D–2(b)(4)(C), for  
10                  covered part D drugs in the year that exceed  
11                  the annual deductible with respect to such indi-  
12                  vidual for such year, as specified in section  
13                  1860D–2(b)(1), section 1860D–14(a)(1)(B), or  
14                  section 1860D–14(a)(2)(B), as applicable.

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

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

18                           “(i) approved under a new drug appli-  
19                           cation under section 505(c) of the Federal  
20                           Food, Drug, and Cosmetic Act or, in the  
21                           case of a biologic product, licensed under  
22                           section 351 of the Public Health Service  
23                           Act; and

24                           “(ii)(I) if the PDP sponsor of the pre-  
25                           scription drug plan or the MA organization

1 offering the MA–PD plan uses a for-  
2 mulary, which is on the formulary of the  
3 prescription drug plan or MA–PD plan  
4 that the applicable beneficiary is enrolled  
5 in;

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

13 “(III) is provided through an excep-  
14 tion or appeal; and

15 “(B) does not include a selected drug (as  
16 defined in section 1192(c)) during a price appli-  
17 cability period (as defined in section  
18 1191(b)(2)) with respect to such drug.

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

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

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

1 “(4) DISCOUNTED PRICE.—

2 “(A) IN GENERAL.—The term ‘discounted  
3 price’ means, with respect to an applicable drug  
4 of a manufacturer dispensed during a year to  
5 an applicable beneficiary—

6 “(i) who has not incurred costs, as de-  
7 termined in accordance with section  
8 1860D–2(b)(4)(C), for covered part D  
9 drugs in the year that are equal to or ex-  
10 ceed the annual out-of-pocket threshold  
11 specified in section 1860D–2(b)(4)(B)(i)  
12 for the year, 90 percent of the negotiated  
13 price of such drug; and

14 “(ii) who has incurred such costs, as  
15 so determined, in the year that are equal  
16 to or exceed such threshold for the year,  
17 70 percent of the negotiated price of such  
18 drug.

19 “(B) CLARIFICATION.—Nothing in this  
20 section shall be construed as affecting the re-  
21 sponsibility of an applicable beneficiary for pay-  
22 ment of a dispensing fee for an applicable drug.

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

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

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

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



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

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

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

17 “(6) NEGOTIATED PRICE.—The term ‘nego-  
18 tiated price’ has the meaning given such term in sec-  
19 tion 423.100 of title 42, Code of Federal Regula-  
20 tions (or any successor regulation), except that, with  
21 respect to an applicable drug, such negotiated price  
22 shall not include any dispensing fee for the applica-  
23 ble drug.

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

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

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

7 (A) in subsection (a), in the first sentence,  
8 by striking “The Secretary” and inserting  
9 “Subject to subsection (h), the Secretary”; and

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

12 “(h) SUNSET OF PROGRAM.—

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

18 “(2) CONTINUED APPLICATION FOR APPLICA-  
19 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The  
20 provisions of this section (including all responsibil-  
21 ities and duties) shall continue to apply after Janu-  
22 ary 1, 2024, with respect to applicable drugs dis-  
23 pensed prior to such date.”.

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

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

3 (A) in subsection (b)(2)(C)(iii)—

4 (i) by striking “assumptions regarding  
5 the reinsurance” and inserting “assump-  
6 tions regarding—

7 “(I) the reinsurance”; and

8 (ii) by adding at the end the fol-  
9 lowing:

10 “(II) for 2024 and each subse-  
11 quent year, the manufacturer dis-  
12 counts provided under section 1860D–  
13 14C subtracted from the actuarial  
14 value to produce such bid; and”; and

15 (B) in subsection (c)(1)(C)—

16 (i) by striking “an actuarial valuation  
17 of the reinsurance” and inserting “an ac-  
18 tuarial valuation of—

19 “(i) the reinsurance”;

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

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

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

4           (d) CONFORMING AMENDMENTS.—

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

7                           (A) in subsection (a)(2)(A)(i)(I), by strik-  
8                           ing “, or an increase in the initial” and insert-  
9                           ing “or, for a year preceding 2024, an increase  
10                           in the initial”;

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

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

15                                   (ii) by inserting “for a year preceding  
16                                   2024 or the annual out-of-pocket threshold  
17                                   specified in subsection (b)(4)(B) for the  
18                                   year for 2024 and each subsequent year”  
19                                   after “subsection (b)(3) for the year” each  
20                                   place it appears; and

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

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

1 amended by striking “the initial” and inserting “for  
2 a year preceding 2024, the initial”.

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

5 (A) in paragraph (1)—

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

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

12 (iii) in subparagraph (E), by striking  
13 “The elimination” and inserting “For a  
14 year preceding 2024, the elimination”;

15 (B) in paragraph (2)—

16 (i) in subparagraph (C), by striking  
17 “The continuation” and inserting “For a  
18 year preceding 2024, the continuation”;

19 and

20 (ii) in subparagraph (E), by striking  
21 “1860D–2(b)(4)(A)(i)(I)” and inserting  
22 “1860D–2(b)(4)(A)(i)(I)(aa)”.

23 (4) Section 1860D–21(d)(7) of the Social Secu-  
24 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended

1 by striking “section 1860D–2(b)(4)(B)(i)” and in-  
2 sserting “section 1860D–2(b)(4)(C)(i)”.

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

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

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

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

13 (C) by adding at the end the following new  
14 clause:

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

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

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

22 (B) by inserting “for such year” before the  
23 period.

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

1 (A) in subsection (a)—

2 (i) by striking paragraph (1) and in-  
3 serting the following:

4 “(1) participate in—

5 “(A) for 2011 through 2023, the Medicare  
6 coverage gap discount program under section  
7 1860D–14A; and

8 “(B) for 2024 and each subsequent year,  
9 the manufacturer discount program under sec-  
10 tion 1860D–14C;”;

11 (ii) by striking paragraph (2) and in-  
12 serting the following:

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

14 “(A) for 2011 through 2023, an agreement  
15 described in subsection (b) of section 1860D–  
16 14A with the Secretary; and

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

20 (iii) by striking paragraph (3) and in-  
21 serting the following:

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

24 “(A) for 2011 through 2023, a contract  
25 with a third party that the Secretary has en-

1           tered into a contract with under subsection  
2           (d)(3) of section 1860D–14A; and

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

7           (B) by striking subsection (b) and insert-  
8           ing the following:

9           “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),  
10          and (3)(A) of subsection (a) shall apply to covered part  
11          D drugs dispensed under this part on or after January  
12          1, 2011, and before January 1, 2024, and paragraphs  
13          (1)(B), (2)(B), and (3)(B) of such subsection shall apply  
14          to covered part D drugs dispensed under this part on or  
15          after January 1, 2024.”.

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

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

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



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

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

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

11 (1) in subparagraph (A), by striking “Subject  
12 to subparagraphs (C) and (D)” and inserting “Sub-  
13 ject to subparagraphs (C), (D), and (E)”; and

14 (2) by adding at the end the following new sub-  
15 paragraph:

16 “(E) ENROLLEE OPTION REGARDING  
17 SPREADING COST-SHARING.—The Secretary  
18 shall establish by regulation a process under  
19 which, with respect to plan year 2024 and sub-  
20 sequent plan years, a prescription drug plan or  
21 an MA–PD plan shall, in the case of a part D  
22 eligible individual enrolled with such plan for  
23 such plan year who is not a subsidy eligible in-  
24 dividual (as defined in section 1860D–14(a)(3))  
25 and with respect to whom the plan projects that

1 the dispensing of the first fill of a covered part  
2 D drug to such individual will result in the indi-  
3 vidual incurring costs that are equal to or above  
4 the annual out-of-pocket threshold specified in  
5 paragraph (4)(B) for such plan year, provide  
6 such individual with the option to make the co-  
7 insurance payment required under subpara-  
8 graph (A) (for the portion of such costs that  
9 are not above such annual out-of-pocket thresh-  
10 old) in the form of periodic installments over  
11 the remainder of such plan year.”.

12 **PART 4—REPEAL OF CERTAIN PRESCRIPTION**

13 **DRUG REBATE RULE**

14 **SEC. 30531. PROHIBITING IMPLEMENTATION OF RULE RE-**  
15 **LATING TO ELIMINATING THE ANTI-KICK-**  
16 **BACK STATUTE SAFE HARBOR PROTECTION**  
17 **FOR PRESCRIPTION DRUG REBATES.**

18 Beginning January 1, 2026, the Secretary of Health  
19 and Human Services shall not implement, administer, or  
20 enforce the provisions of the final rule published by the  
21 Office of the Inspector General of the Department of  
22 Health and Human Services on November 30, 2020, and  
23 titled “Fraud and Abuse; Removal of Safe Harbor Protec-  
24 tion for Rebates Involving Prescription Pharmaceuticals  
25 and Creation of New Safe Harbor Protection for Certain

1 Point-of-Sale Reductions in Price on Prescription Phar-  
2 maceuticals and Certain Pharmacy Benefit Manager Serv-  
3 ices Fees” (85 Fed. Reg. 76666).

