

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

Strike all after the enacting clause and insert the following:

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

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

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

Sec. 1. Short title; table of contents.

**TITLE I—LOWERING PRICES THROUGH FAIR DRUG PRICE  
NEGOTIATION**

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

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

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

Sec. 201. Medicare part B rebate by manufacturers.

Sec. 202. Medicare part D rebate by manufacturers.

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

Sec. 301. Medicare part D benefit redesign.

Sec. 302. Allowing certain enrollees of prescription drugs plans and MA-PD plans under Medicare program to spread out cost-sharing under certain circumstances.

Sec. 303. Establishment of pharmacy quality measures under Medicare part D.

**TITLE IV—PRESCRIPTION DRUG POLICIES FOR LOW-INCOME  
INDIVIDUALS**

Sec. 401. Adjustments to Medicare part D cost-sharing reductions for low-income individuals.

- Sec. 402. Dissemination to Medicare part D subsidy eligible individuals of information comparing premiums of certain prescription drug plans.
- Sec. 403. Providing for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA–PD plans.
- Sec. 404. Expanding eligibility for low-income subsidies under part D of the Medicare program.
- Sec. 405. Automatic eligibility of certain low-income territorial residents for premium and cost-sharing subsidies under the Medicare program; Sunset of enhanced allotment program.
- Sec. 406. Automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program.
- Sec. 407. Eliminating the resource requirement with respect to subsidy eligible individuals under part D of the Medicare program.
- Sec. 408. Providing for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program.

TITLE I—DRUG PRICE TRANSPARENCY

- Sec. 501. Drug price transparency.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 “(A) beginning on the sooner of—

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

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

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

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

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

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

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

17          “(ii) an individual who is enrolled  
18          under a group health plan or health insur-  
19          ance coverage offered in the group or indi-  
20          vidual market (as such terms are defined  
21          in section 2791 of the Public Health Serv-  
22          ice Act) with respect to which there is in  
23          effect an agreement with the Secretary  
24          under section 1197 with respect to such se-

1           lected drug as so furnished or dispensed;  
2           and

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

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

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

22                  “(2) MAXIMUM FAIR PRICE.—The term ‘max-  
23                  imum fair price’ means, with respect to a plan year  
24                  during a price applicability period and with respect  
25                  to a selected drug (as defined in section 1192(e))

1 with respect to such period, the price published pur-  
2 suant to section 1195 in the Federal Register for  
3 such drug and year.

4 “(3) AVERAGE INTERNATIONAL MARKET PRICE  
5 DEFINED.—

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

22 “(B) APPLICABLE COUNTRIES.—

23 “(i) IN GENERAL.—For purposes of  
24 subparagraph (A), a country described in  
25 clause (ii) is an applicable country de-

1 scribed in this clause with respect to a  
2 drug if there is available an average price  
3 for any unit for the drug for sales of such  
4 drug in such country.

5 “(ii) COUNTRIES DESCRIBED.—For  
6 purposes of this paragraph, the following  
7 are countries described in this clause:

8 “(I) Australia.

9 “(II) Canada.

10 “(III) France.

11 “(IV) Germany.

12 “(V) Japan.

13 “(VI) The United Kingdom.

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

18 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**

19 **AS SELECTED DRUGS.**

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

24 “(1)(A) with respect to an initial price applica-  
25 bility year during the period beginning with 2023



1 and ending with 2027, at least 25 negotiation-eligible  
2 ble drugs described in subparagraphs (A) and (B),  
3 but not subparagraph (C), of subsection (d)(1) (or,  
4 with respect to an initial price applicability year dur-  
5 ing such period beginning after 2023, the maximum  
6 number (if such number is less than 25) of such ne-  
7 gotiation-eligible drugs for the year) with respect to  
8 such year;

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

18 “(C) with respect to an initial price applicability  
19 year beginning after 2032, at least 35 negotiation-  
20 eligible drugs described in subparagraphs (A) and  
21 (B), but not subparagraph (C), of subsection (d)(1)  
22 (or, with respect to an initial price applicability year  
23 during such period, the maximum number (if such  
24 number is less than 35) of such negotiation-eligible  
25 drugs for the year) with respect to such year;

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

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

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

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

1 individuals during the price applicability period. In making  
2 this projection of savings for drugs for which there is an  
3 AIM price for a price applicability period, the savings shall  
4 be projected across different dosage forms and strengths  
5 of the drugs and not based on the specific formulation or  
6 package size or package type of the drugs, taking into con-  
7 sideration both the volume of drugs for which payment  
8 is made, to the extent such data is available, and the  
9 amount by which the net price for the drugs exceeds the  
10 AIM price for the drugs.

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

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

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

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

25               “(2) continue to be marketed.

1 “(d) NEGOTIATION-ELIGIBLE DRUG.—

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

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

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

1           “(C) INSULIN.—The drug is a qualifying  
2           single source drug described in subsection  
3           (e)(3).

4           “(2) CLARIFICATION.—In determining whether  
5           a qualifying single source drug satisfies any of the  
6           criteria described in paragraph (1), the Secretary  
7           shall, to the extent practicable, use data that is ag-  
8           gregated across dosage forms and strengths of the  
9           drug and not based on the specific formulation or  
10          package size or package type of the drug.

11          “(3) PUBLICATION.—Not later than the se-  
12          lected drug publication date with respect to an ini-  
13          tial price applicability year, the Secretary shall pub-  
14          lish in the Federal Register a list of negotiation-eli-  
15          gible drugs with respect to such selected drug publi-  
16          cation date.

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

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

21                         “(A) is approved under section 505(c) of  
22                         the Federal Food, Drug, and Cosmetic Act and  
23                         continues to be marketed pursuant to such ap-  
24                         proval; and

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

4           “(2) BIOLOGICAL PRODUCTS.—A biological  
5           product that—

6           “(A) is licensed under section 351(a) of  
7           the Public Health Service Act, including any  
8           product that has been deemed to be licensed  
9           under section 351 of such Act pursuant to sec-  
10          tion 7002(e)(4) of the Biologics Price Competi-  
11          tion and Innovation Act of 2009, and continues  
12          to be marketed under section 351 of such Act;  
13          and

14          “(B) is not the reference product for any  
15          biological product that is licensed and continues  
16          to be marketed under section 351(k) of such  
17          Act.

18          “(3) INSULIN PRODUCT.—Notwithstanding  
19          paragraphs (1) and (2), any insulin product that is  
20          approved under subsection (c) or (j) of section 505  
21          of the Federal Food, Drug, and Cosmetic Act or li-  
22          censed under subsection (a) or (k) of section 351 of  
23          the Public Health Service Act and continues to be  
24          marketed under such section 505 or 351, including  
25          any insulin product that has been deemed to be li-

1 censed under section 351(a) of the Public Health  
2 Service Act pursuant to section 7002(e)(4) of the  
3 Biologics Price Competition and Innovation Act of  
4 2009 and continues to be marketed pursuant to such  
5 licensure.

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

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

23 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE  
24 DRUGS.—

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

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

10                   “(B) that the Secretary determines under  
11                   paragraph (2) is likely to be included as a nego-  
12                   tiation-eligible drug with respect to the subse-  
13                   quent selected drug publication date.

14           “(2) DETERMINATION.—In the case of a quali-  
15           fying single source drug that meets the criteria de-  
16           scribed in subparagraph (A) of paragraph (1), with  
17           respect to an initial price applicability year, if the  
18           wholesale acquisition cost at which such drug is first  
19           marketed in the United States is equal to or greater  
20           than the median household income (as determined  
21           according to the most recent data collected by the  
22           United States Census Bureau), the Secretary shall  
23           determine before the selected drug publication date  
24           with respect to the initial price applicability year, if  
25           the drug is likely to be included as a negotiation-eli-



1       gible drug with respect to the subsequent selected  
2       drug publication date, based on the projected spend-  
3       ing under title XVIII or in the United States on  
4       such drug. For purposes of this paragraph the term  
5       ‘United States’ includes the 50 States, the District  
6       of Columbia, and the territories of the United  
7       States.

8       **“SEC. 1193. MANUFACTURER AGREEMENTS.**

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

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

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

1 furnished or dispensed such drug during, sub-  
2 ject to subparagraph (2), the price applicability  
3 period; 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, subject to sub-  
10 paragraph (2), the price applicability period;

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

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

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

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

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

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

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

1 such drug all information that the Secretary re-  
2 quires to carry out the negotiation (or renegoti-  
3 ation process) under this part, including infor-  
4 mation described in section 1192(f) and section  
5 1194(d)(1); and

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

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

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

22 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO  
23 LONGER A SELECTED DRUG.—An agreement entered into  
24 under this section shall be effective, with respect to a drug,

1 until such drug is no longer considered a selected drug  
2 under section 1192(c).

3 “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS  
4 WITHOUT AIM PRICE.—

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

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

22 “(B) the number of units of such drug sold  
23 in the United States, including the 50 States,  
24 the District of Columbia, and the territories of

1 the United States, during the period described  
2 in paragraph (2)(B).

3 “(2) AMOUNTS DESCRIBED.—

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

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

1           for such drug with respect to which there is an  
2           AIM price available for such drug.

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

11          “(e) REGULATIONS.—

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

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

1 such sales from appropriate officials of the govern-  
2 ment of the foreign country involved.

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

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

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

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

21 “(2) as applicable pursuant to section  
22 1193(a)(2) and in accordance with the process speci-  
23 fied pursuant to such section, renegotiate such max-  
24 imum fair price for such drug for the purpose de-  
25 scribed in such section.



1           “(b) NEGOTIATING METHODOLOGY AND OBJEC-  
2 TIVE.—

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

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

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

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

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

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

1 “(3) REQUIREMENT.—

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

17 “(B) TARGET PRICE.—

18 “(i) IN GENERAL.—Subject to clause  
19 (ii), the target price described in this sub-  
20 paragraph for a selected drug with respect  
21 to a year, is the average price (which shall  
22 be the net average price, if practicable, and  
23 volume-weighted, if practicable) for a unit  
24 of such drug for sales of such drug, as  
25 computed (across different dosage forms

1 and strengths of the drug and not based  
2 on the specific formulation or package size  
3 or package type of the drug) in the appli-  
4 cable country described in section  
5 1191(c)(3)(B) with respect to such drug  
6 that, with respect to such year, has the  
7 lowest average price for such drug as com-  
8 pared to the average prices (as so com-  
9 puted) of such drug with respect to such  
10 year in the other applicable countries de-  
11 scribed in such section with respect to such  
12 drug.

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

1           such drug and respective year is the  
2           amount that is 80 percent of the average  
3           manufacturer price (as defined in section  
4           1927(k)(1)) for such drug and year.

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

13          “(c) LIMITATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22               “(C) Information on comparative effective-  
23               ness analysis for such products, taking into  
24               consideration the effects of such products on  
25               specific populations, such as individuals with

1           disabilities, the elderly, terminally ill, children,  
2           and other patient populations.

3           In considering information described in subpara-  
4           graph (C), the Secretary shall not use evidence or  
5           findings from comparative clinical effectiveness re-  
6           search in a manner that treats extending the life of  
7           an elderly, disabled, or terminally ill individual as of  
8           lower value than extending the life of an individual  
9           who is younger, nondisabled, or not terminally ill.  
10          Nothing in the previous sentence shall affect the ap-  
11          plication or consideration of an AIM price for a se-  
12          lected drug.

13           “(3) FOREIGN SALES INFORMATION.—To the  
14          extent available on a timely basis, including as pro-  
15          vided by a manufacturer of the selected drug or oth-  
16          erwise, information on sales of the selected drug in  
17          each of the countries described in section  
18          1191(e)(3)(B).

19           “(4) ADDITIONAL INFORMATION.—Information  
20          submitted to the Secretary, in accordance with a  
21          process specified by the Secretary, by other parties  
22          that are affected by the establishment of a maximum  
23          fair price for the selected drug.

24           “(e) REQUEST FOR INFORMATION.—For purposes of  
25          negotiating and, as applicable, renegotiating (including for

1 purposes of determining whether to renegotiate) the max-  
2 imum fair price of a selected drug under this part with  
3 the manufacturer of the drug, with respect to a price ap-  
4 plicability period, and other relevant data for purposes of  
5 this section—

6 “(1) the Secretary shall, not later than the se-  
7 lected drug publication date with respect to the ini-  
8 tial price applicability year of such period, request  
9 drug pricing information from the manufacturer of  
10 such selected drug, including information described  
11 in subsection (d)(1); and

12 “(2) by not later than October 1 following the  
13 selected drug publication date, the manufacturer of  
14 such selected drug shall submit to the Secretary  
15 such requested information in such form and man-  
16 ner as the Secretary may require.

17 The Secretary shall request, from the manufacturer or  
18 others, such additional information as may be needed to  
19 carry out the negotiation and renegotiation process under  
20 this section.

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

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



1 in the Federal Register the maximum fair price for such  
2 drug negotiated under this part with the manufacturer of  
3 such drug.

4 “(b) UPDATES.—

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

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

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

22 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

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

1 date of publication under this section, the Secretary  
2 shall publish such maximum fair price in the Fed-  
3 eral Register by not later than 30 days after the  
4 date such maximum price is so determined.

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

7 “(a) ADMINISTRATIVE DUTIES.—

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

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

1 drug and providing that such maximum fair  
2 price is used for determining cost-sharing under  
3 such plans or coverage for the selected drug.

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

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

10                   “(i) the lesser of—

11                           “(I) the wholesale acquisition  
12                           cost of the drug;

13                           “(II) the national average drug  
14                           acquisition cost of the drug; and

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

19                           “(ii) the maximum fair price for the  
20                           drug.

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

24                           “(i) any coverage or financial assist-  
25                           ance under other health benefit plans or

1 programs that provide coverage or finan-  
2 cial assistance for the purchase or provi-  
3 sion of prescription drug coverage on be-  
4 half of fair price eligible individuals as the  
5 Secretary may specify; and

6 “(ii) any other discounts.

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

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

23 “(G) The establishment of procedures to  
24 negotiate and apply the maximum fair price in

1 a manner that does not include any dispensing  
2 or similar fee.

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

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

10 “(ii) fair price eligible individuals who  
11 are enrolled under a group health plan or  
12 health insurance coverage offered by a  
13 health insurance issuer in the individual or  
14 group market with respect to which there  
15 is an agreement in effect under section  
16 1197; and

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

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

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

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

8 “(2) MONITORING COMPLIANCE.—

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

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

22 “(b) COLLECTION OF DATA.—

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

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

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

11 “(c) CONTRACT WITH THIRD PARTIES.—

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

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

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



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

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

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

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

19 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**  
20 **HEALTH PLANS.**

21 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-  
22 GRAM.—

23 “(1) IN GENERAL.—Subject to paragraph (2),  
24 under the program under this part the Secretary  
25 shall be treated as having in effect an agreement

1 with a group health plan or health insurance issuer  
2 offering health insurance coverage (as such terms  
3 are defined in section 2791 of the Public Health  
4 Service Act), with respect to a price applicability pe-  
5 riod and a selected drug with respect to such pe-  
6 riod—

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

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

19 “(2) OPTING OUT OF AGREEMENT.—The Sec-  
20 retary shall not be treated as having in effect an  
21 agreement under the program under this part with  
22 a group health plan or health insurance issuer offer-  
23 ing health insurance coverage with respect to a price  
24 applicability period and a selected drug with respect  
25 to such period if such a plan or issuer affirmatively

1 elects, through a process specified by the Secretary,  
2 not to participate under the program with respect to  
3 such period and drug.

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

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

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

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

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

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

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

22           “(c) APPLICATION.—The provisions of section 1128A  
23 (other than subsections (a) and (b)) shall apply to a civil  
24 monetary penalty under this section in the same manner

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

3 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

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

13 “(c) MEDPAC STUDY.—Not later than December 31,  
14 2025, the Medicare Payment Advisory Commission shall  
15 conduct a study, and submit to Congress a report, on the  
16 program under this part with respect to the Medicare pro-  
17 gram under title XVIII, including with respect to the ef-  
18 fect of the program on individuals entitled to benefits or  
19 enrolled under such title.

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

22 “(1) The selection of drugs for publication  
23 under section 1192(a).

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

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

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

5           “(e) COORDINATION.—In carrying out this part with  
6           respect to group health plans or health insurance coverage  
7           offered in the group market that are subject to oversight  
8           by the Secretary of Labor or the Secretary of the Treas-  
9           ury, the Secretary of Health and Human Services shall  
10          coordinate with such respective Secretary.

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

15          (b) APPLICATION OF MAXIMUM FAIR PRICES AND  
16          CONFORMING AMENDMENTS.—

17                 (1) UNDER MEDICARE.—

18                         (A) APPLICATION TO PAYMENTS UNDER  
19                         PART B.—Section 1847A(b)(1)(B) of the Social  
20                         Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is  
21                         amended by inserting “or in the case of such a  
22                         drug or biological that is a selected drug (as de-  
23                         fined in section 1192(c)), with respect to a  
24                         price applicability period (as defined in section  
25                         1191(b)(2)), 106 percent of the maximum fair

1 price (as defined in section 1191(c)(2) applica-  
2 ble for such drug and a plan year during such  
3 period”.

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

4 (B) ERISA.—

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

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

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

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

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

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

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

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

1 is provided under such plan or coverage before the begin-  
2 ning of the plan year for which such election was made.”.

3 (ii) CLERICAL AMENDMENT.—The  
4 table of sections for part 7 of subtitle B of  
5 title I of the Employee Retirement Income  
6 Security Act of 1974 is amended by adding  
7 at the end the following:

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

8 (C) IRC.—

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

13 **“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM**  
14 **AND APPLICATION OF MAXIMUM FAIR**  
15 **PRICES.**

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

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

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

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

1 other providers and suppliers participating  
2 under title XVIII during such period;

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

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

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

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

1 Section 9831(a)(2) of the Internal Revenue  
2 Code of 1986 is amended by inserting  
3 “other than with respect to section 9816,”  
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. 9816. Fair Price Drug Negotiation Program and application of maximum  
fair prices.”.

9 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**  
10 **IMPOSED DURING NONCOMPLIANCE PERI-**  
11 **ODS.**

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

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

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

22 “(1) such tax, divided by

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



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

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

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

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

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

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

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

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

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

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

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

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

24       “(d) SELECTED DRUG.—For purposes of this sec-  
25       tion—

1           “(1) IN GENERAL.—The term ‘selected drug’  
2           means any selected drug (within the meaning of sec-  
3           tion 1192 of the Social Security Act) which is manu-  
4           factured or produced in the United States or entered  
5           into the United States for consumption, use, or  
6           warehousing.

7           “(2) UNITED STATES.—The term ‘United  
8           States’ has the meaning given such term by section  
9           4612(a)(4).

10           “(3) COORDINATION WITH RULES FOR POSSES-  
11           SIONS OF THE UNITED STATES.—Rules similar to  
12           the rules of paragraphs (2) and (4) of section  
13           4132(e) shall apply for purposes of this section.

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

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

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

1 (c) CONFORMING AMENDMENTS.—

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

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

7 (d) CLERICAL AMENDMENTS.—

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

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

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

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

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

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 “(x) 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, 2021, 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-

1           crease described in subparagraph (A)(ii) of  
2           such paragraph for such drug and calendar  
3           quarter.

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

7           “(B) MANUFACTURER REQUIREMENT.—  
8           For each calendar quarter beginning on or after  
9           July 1, 2021, the manufacturer of a part B  
10          rebtable drug shall, for such drug, not later  
11          than 30 days after the date of receipt from the  
12          Secretary of the information described in sub-  
13          paragraph (A) for such calendar quarter, pro-  
14          vide to the Secretary a rebate that is equal to  
15          the amount specified in paragraph (3) for such  
16          drug for such calendar quarter.

17          “(2) PART B REBTABLE DRUG DEFINED.—

18                 “(A) IN GENERAL.—In this subsection, the  
19                 term ‘part B rebtable drug’ means a single  
20                 source drug or biological (as defined in sub-  
21                 paragraph (D) of section 1847A(c)(6)), includ-  
22                 ing a biosimilar biological product (as defined  
23                 in subparagraph (H) of such section), paid for  
24                 under this part, except such term shall not in-  
25                 clude such a drug or biological—

1           “(i) if the average total allowed  
2 charges for a year per individual that uses  
3 such a drug or biological, as determined by  
4 the Secretary, are less than, subject to  
5 subparagraph (B), \$100; or

6           “(ii) that is a vaccine described in  
7 subparagraph (A) or (B) of section  
8 1861(s)(10).

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

11           “(i) for 2022, shall be the dollar  
12 amount specified under such subparagraph  
13 for 2021, increased by the percentage in-  
14 crease in the consumer price index for all  
15 urban consumers (United States city aver-  
16 age) for the 12 month period ending with  
17 June of the previous year; and

18           “(ii) for a subsequent year, shall be  
19 the dollar amount specified in this clause  
20 (or clause (i)) for the previous year, in-  
21 creased by the percentage increase in the  
22 consumer price index for all urban con-  
23 sumers (United States city average) for  
24 the 12 month period ending with June of  
25 the previous year.

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

4 “(3) REBATE AMOUNT.—

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

11 “(i) subject to subparagraphs (B) and  
12 (G), the total number of units of the bill-  
13 ing and payment code for such part B  
14 rebatable drug furnished under this part  
15 during the calendar quarter; and

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

17 “(I) the payment amount under  
18 subparagraph (B) or (C) of section  
19 1847A(b)(1), as applicable, for such  
20 part B rebatable drug during the cal-  
21 endar quarter; exceeds

22 “(II) the inflation-adjusted pay-  
23 ment amount determined under sub-  
24 paragraph (C) for such part B



1 rebatable drug during the calendar  
2 quarter.

3 “(B) EXCLUDED UNITS.—For purposes of  
4 subparagraph (A)(i), the total number of units  
5 of the billing and payment code for each part  
6 B rebatable drug furnished during a calendar  
7 quarter shall not include—

8 “(i) units packaged into the payment  
9 for a procedure or service under section  
10 1833(t) or under section 1833(i) (instead  
11 of separately payable under such respective  
12 section);

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

16 “(iii) units of a part B rebatable drug  
17 of a manufacturer furnished to an indi-  
18 vidual, if such manufacturer, with respect  
19 to the furnishing of such units of such  
20 drug, provides for discounts under section  
21 340B of the Public Health Service Act or  
22 for rebates under section 1927.

23 “(C) DETERMINATION OF INFLATION-AD-  
24 JUSTED PAYMENT AMOUNT.—The inflation-ad-  
25 justed payment amount determined under this

1           subparagraph for a part B rebatable drug for  
2           a calendar quarter is—

3                   “(i) the payment amount for the bill-  
4                   ing and payment code for such drug in the  
5                   payment amount benchmark quarter (as  
6                   defined in subparagraph (D)); increased by

7                   “(ii) the percentage by which the re-  
8                   bate period CPI-U (as defined in subpara-  
9                   graph (F)) for the calendar quarter ex-  
10                  ceeds the benchmark period CPI-U (as de-  
11                  fined in subparagraph (E)).

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

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

20                  “(F) REBATE PERIOD CPI-U.—The term  
21                  ‘rebate period CPI-U’ means, with respect to a  
22                  calendar quarter described in subparagraph  
23                  (C), the greater of the benchmark period CPI-  
24                  U and the consumer price index for all urban  
25                  consumers (United States city average) for the

1 first month of the calendar quarter that is two  
2 calendar quarters prior to such described cal-  
3 endar quarter.

4 “(G) COUNTING UNITS.—

5 “(i) CUT-OFF PERIOD TO COUNT  
6 UNITS.—For purposes of subparagraph  
7 (A)(i), subject to clause (ii), to count the  
8 total number of billing units for a part B  
9 rebatable drug for a quarter, the Secretary  
10 may use a cut-off period in order to ex-  
11 clude from such total number of billing  
12 units for such quarter claims for services  
13 furnished during such quarter that were  
14 not processed at an appropriate time prior  
15 to the end of the cut-off period.

16 “(ii) COUNTING UNITS FOR CLAIMS  
17 PROCESSED AFTER CUT-OFF PERIOD.—If  
18 the Secretary uses a cut-off period pursu-  
19 ant to clause (i), in the case of units of a  
20 part B rebatable drug furnished during a  
21 quarter but pursuant to application of such  
22 cut-off period excluded for purposes of sub-  
23 paragraph (A)(i) from the total number of  
24 billing units for the drug for such quarter,  
25 the Secretary shall count such units of

1           such drug so furnished in the total number  
2           of billing units for such drug for a subse-  
3           quent quarter, as the Secretary determines  
4           appropriate.

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

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

23          “(B) TIMELINE FOR PROVISION OF RE-  
24          BATES FOR SUBSEQUENTLY APPROVED  
25          DRUGS.—In the case of a part B rebatable drug

1 first approved or licensed by the Food and  
2 Drug Administration after July 1, 2015, para-  
3 graph (1)(B) shall be applied as if the reference  
4 to ‘July 1, 2021’ under such paragraph were a  
5 reference to the later of the 6th full calendar  
6 quarter after the day on which the drug was  
7 first marketed or July 1, 2021.

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

17 “(D) SELECTED DRUGS.—In the case of a  
18 part B rebatable drug that is a selected drug  
19 (as defined in section 1192(e)) for a price appli-  
20 cability period (as defined in section  
21 1191(b)(2)) and is determined (pursuant to  
22 such section 1192(c)) to no longer be a selected  
23 drug, for each applicable year beginning after  
24 the price applicability period with respect to  
25 such drug, clause (i) of paragraph (3)(C) shall

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

12 “(5) APPLICATION TO BENEFICIARY COINSUR-  
13 ANCE.—In the case of a part B rebatable drug, if  
14 the payment amount for a quarter exceeds the infla-  
15 tion adjusted payment for such quarter—

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

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

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

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

20          “(8) STUDY AND REPORT.—

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

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

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

7                   “(iii) Including drugs excluded under  
8                   paragraph (2)(A) and units of the billing  
9                   and payment code of the drugs excluded  
10                  under paragraph (3)(B) in the rebate sys-  
11                  tem under this subsection.

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

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



1 prices for the benchmark period and the rebate pe-  
2 riod.”.

3 (b) AMOUNTS PAYABLE; COST-SHARING.—Section  
4 1833 of the Social Security Act (42 U.S.C. 1395l) is  
5 amended—

6 (1) in subsection (a)—

7 (A) in paragraph (1)—

8 (i) in subparagraph (S), by striking  
9 “with respect to” and inserting “subject to  
10 subparagraph (DD), with respect to”;

11 (ii) by striking “and (CC)” and in-  
12 serting “(CC)”; and

13 (iii) by inserting before the semicolon  
14 at the end the following: “, and (DD) with  
15 respect to a part B rebatable drug (as de-  
16 fined in paragraph (2) of section 1834(x))  
17 for which the payment amount for a cal-  
18 endar quarter under paragraph  
19 (3)(A)(ii)(I) of such section for such quar-  
20 ter exceeds the inflation adjusted payment  
21 under paragraph (3)(A)(ii)(II) of such sec-  
22 tion for such quarter, the amounts paid  
23 shall be the difference between (i) the pay-  
24 ment amount under paragraph  
25 (3)(A)(ii)(I) of such section for such drug,

1                   and (ii) 20 percent of the inflation-ad-  
2                   justed payment amount under paragraph  
3                   (3)(A)(ii)(II) of such section for such  
4                   drug”;

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

7                   “For purposes of applying paragraph (1)(DD), sub-  
8                   sections (i)(9) and (t)(3)(H), and section 1834(x)(5), the  
9                   Secretary shall make such estimates and use such data  
10                  as the Secretary determines appropriate, and notwith-  
11                  standing any other provision of law, may do so by program  
12                  instruction or otherwise.”;

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

15                  “(9) In the case of a part B rebatable drug (as  
16                  defined in paragraph (2) of section 1834(x)) fur-  
17                  nished on or after July 1, 2021, under the system  
18                  under this subsection, in lieu of calculation of coin-  
19                  surance and the amount of payment otherwise appli-  
20                  cable under this subsection, the provisions of section  
21                  1834(x)(5), paragraph (1)(DD) of section 1833(a),  
22                  and the flush left matter following paragraph (9) of  
23                  section 1833(a), shall, as determined appropriate by  
24                  the Secretary, apply under this subsection in the  
25                  same manner as such provisions of sections

1 1834(x)(5) and 1833(a) apply under such sections.”;

2 and

3 (3) in subsection (t)(3), by adding at the end

4 the following new subparagraph:

5 “(H) PART B REBATABLE DRUGS.—In the  
6 case of a part B rebatable drug (as defined in  
7 paragraph (2) of section 1834(x)) furnished on  
8 or after July 1, 2021, under the system under  
9 this subsection, in lieu of calculation of coinsur-  
10 ance and the amount of payment otherwise ap-  
11 plicable under this subsection, the provisions of  
12 section 1834(x)(5), paragraph (1)(DD) of sec-  
13 tion 1833(a), and the flush left matter following  
14 paragraph (9) of section 1833(a), shall, as de-  
15 termined appropriate by the Secretary, apply  
16 under this subsection in the same manner as  
17 such provisions of sections 1834(x)(5) and  
18 1833(a) apply under such sections.”.

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

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

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

5 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**

6 **DRUGS WITH PRICES INCREASING FASTER**

7 **THAN INFLATION.**

8 “(a) IN GENERAL.—

9 “(1) IN GENERAL.—Subject to the provisions of  
10 this section, in order for coverage to be available  
11 under this part for a part D rebatable drug (as de-  
12 fined in subsection (h)(1)) of a manufacturer (as de-  
13 fined in section 1927(k)(5)) dispensed during an ap-  
14 plicable year, the manufacturer must have entered  
15 into and have in effect an agreement described in  
16 subsection (b).

17 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT  
18 COVERED UNDER AGREEMENTS.—Paragraph (1)  
19 shall not apply to the dispensing of a covered part  
20 D drug if—

21 “(A) the Secretary has made a determina-  
22 tion that the availability of the drug is essential  
23 to the health of beneficiaries under this part; or

24 “(B) the Secretary determines that in the  
25 period beginning on January 1, 2022, and end-

1           ing on December 31, 2022, there were extenu-  
2           ating circumstances.

3           “(3) APPLICABLE YEAR.—For purposes of this  
4           section the term ‘applicable year’ means a year be-  
5           ginning with 2022.

6           “(b) AGREEMENTS.—

7           “(1) TERMS OF AGREEMENT.—An agreement  
8           described in this subsection, with respect to a manu-  
9           facturer of a part D rebatable drug, is an agreement  
10          under which the following shall apply:

11          “(A) SECRETARIAL PROVISION OF INFOR-  
12          MATION.—Not later than 9 months after the  
13          end of each applicable year with respect to  
14          which the agreement is in effect, the Secretary,  
15          for each part D rebatable drug of the manufac-  
16          turer, shall report to the manufacturer the fol-  
17          lowing for such year:

18                  “(i) Information on the total number  
19                  of units (as defined in subsection (h)(2))  
20                  for each dosage form and strength with re-  
21                  spect to such part D rebatable drug and  
22                  year.

23                  “(ii) Information on the amount (if  
24                  any) of the excess average manufacturer  
25                  price increase described in subsection

1 (c)(1)(B) for each dosage form and  
2 strength with respect to such drug and  
3 year.

4 “(iii) The rebate amount specified  
5 under subsection (c) for each dosage form  
6 and strength with respect to such drug and  
7 year.

8 “(B) MANUFACTURER REQUIREMENTS.—  
9 For each applicable year with respect to which  
10 the agreement is in effect, the manufacturer of  
11 the part D rebatable drug, for each dosage  
12 form and strength with respect to such drug,  
13 not later than 30 days after the date of receipt  
14 from the Secretary of the information described  
15 in subparagraph (A) for such year, shall pro-  
16 vide to the Secretary a rebate that is equal to  
17 the amount specified in subsection (c) for such  
18 dosage form and strength with respect to such  
19 drug for such year.

20 “(2) LENGTH OF AGREEMENT.—

21 “(A) IN GENERAL.—An agreement under  
22 this section, with respect to a part D rebatable  
23 drug, shall be effective for an initial period of  
24 not less than one year and shall be automati-  
25 cally renewed for a period of not less than one

1           year unless terminated under subparagraph  
2           (B).

3           “(B) TERMINATION.—

4                   “(i) BY SECRETARY.—The Secretary  
5                   may provide for termination of an agree-  
6                   ment under this section for violation of the  
7                   requirements of the agreement or other  
8                   good cause shown. Such termination shall  
9                   not be effective earlier than 30 days after  
10                  the date of notice of such termination. The  
11                  Secretary shall provide, upon request, a  
12                  manufacturer with a hearing concerning  
13                  such a termination, but such hearing shall  
14                  not delay the effective date of the termi-  
15                  nation.

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

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

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

5                   “(C) EFFECTIVENESS OF TERMINATION.—  
6                   Any termination under this paragraph shall not  
7                   affect rebates due under the agreement under  
8                   this section before the effective date of its ter-  
9                   mination.

10                  “(D) DELAY BEFORE REENTRY.—In the  
11                  case of any agreement under this section with  
12                  a manufacturer that is terminated in a plan  
13                  year, the Secretary may not enter into another  
14                  such agreement with the manufacturer (or a  
15                  successor manufacturer) before the subsequent  
16                  plan year, unless the Secretary finds good cause  
17                  for an earlier reinstatement of such an agree-  
18                  ment.

19                  “(c) REBATE AMOUNT.—

20                  “(1) IN GENERAL.—For purposes of this sec-  
21                  tion, the amount specified in this subsection for a  
22                  dosage form and strength with respect to a part D  
23                  rebateable drug and applicable year is, subject to sub-  
24                  paragraphs (B) and (C) of paragraph (5), the  
25                  amount equal to the product of—



1           “(A) the total number of units of such dos-  
2           age form and strength with respect to such part  
3           D rebatable drug and year; and

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

5                 “(i) the annual manufacturer price  
6                 (as determined in paragraph (2)) paid for  
7                 such dosage form and strength with re-  
8                 spect to such part D rebatable drug for the  
9                 year; exceeds

10                “(ii) the inflation-adjusted payment  
11                amount determined under paragraph (3)  
12                for such dosage form and strength with re-  
13                spect to such part D rebatable drug for the  
14                year.

15           “(2) DETERMINATION OF ANNUAL MANUFAC-  
16           TURER PRICE.—The annual manufacturer price de-  
17           termined under this paragraph for a dosage form  
18           and strength, with respect to a part D rebatable  
19           drug and an applicable year, is the sum of the prod-  
20           ucts of—

21                 “(A) the average manufacturer price (as  
22                 defined in subsection (h)(6)) of such dosage  
23                 form and strength, as calculated for a unit of  
24                 such drug, with respect to each of the calendar  
25                 quarters of such year; and

1 “(B) the ratio of—

2 “(i) the total number of units of such  
3 dosage form and strength dispensed during  
4 each such calendar quarter of such year; to

5 “(ii) the total number of units of such  
6 dosage form and strength dispensed during  
7 such year.

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

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

18 “(B) the percentage by which the applica-  
19 ble year CPI-U (as defined in subsection  
20 (h)(5)) for the applicable year exceeds the  
21 benchmark period CPI-U (as defined in sub-  
22 section (h)(4)).

23 “(4) DETERMINATION OF BENCHMARK YEAR  
24 MANUFACTURER PRICE.—The benchmark year man-  
25 ufacturer price determined under this paragraph for

1 a dosage form and strength, with respect to a part  
2 D rebatable drug and an applicable year, is the sum  
3 of the products of—

4 “(A) the average manufacturer price (as  
5 defined in subsection (h)(6)) of such dosage  
6 form and strength, as calculated for a unit of  
7 such drug, with respect to each calendar quar-  
8 ter of the payment amount benchmark year (as  
9 defined in subsection (h)(3)); and

10 “(B) the ratio of—

11 “(i) the total number of units of such  
12 dosage form and strength dispensed during  
13 such calendar quarter of the payment  
14 amount benchmark year; to

15 “(ii) the total number of units of such  
16 dosage form and strength dispensed during  
17 the payment amount benchmark year.

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

20 “(A) SUBSEQUENTLY APPROVED DRUGS.—

21 In the case of a part D rebatable drug first ap-  
22 proved or licensed by the Food and Drug Ad-  
23 ministration after January 1, 2016, subpara-  
24 graphs (A) and (B) of paragraph (4) shall be  
25 applied as if the term ‘payment amount bench-

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

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

20 “(C) TREATMENT OF NEW FORMULA-  
21 TIONS.—

22 “(i) IN GENERAL.—In the case of a  
23 part D rebatable drug that is a line exten-  
24 sion of a part D rebatable drug that is an  
25 oral solid dosage form, the Secretary shall

1           establish a formula for determining the  
2           amount specified in this subsection with  
3           respect to such part D rebatable drug and  
4           an applicable year with consideration of  
5           the original part D rebatable drug.

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

17          “(D) SELECTED DRUGS.—In the case of a  
18          part D rebatable drug that is a selected drug  
19          (as defined in section 1192(c)) for a price appli-  
20          cability period (as defined in section  
21          1191(b)(2)) and is determined (pursuant to  
22          such section 1192(c)) to no longer be a selected  
23          drug, for each applicable year beginning after  
24          the price applicability period with respect to  
25          such drug, subparagraphs (A) and (B) of para-

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

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

18 “(e) INFORMATION.—For purposes of carrying out  
19 this section, the Secretary shall use information submitted  
20 by manufacturers under section 1927(b)(3).

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

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

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

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

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

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

18 “(h) DEFINITIONS.—In this section:

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

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

1 total cost under this part for such year per in-  
2 dividual who uses such a drug or biological, as  
3 determined by the Secretary, is less than, sub-  
4 ject to subparagraph (B), \$100, as determined  
5 by the Secretary using the most recent data  
6 available or, if data is not available, as esti-  
7 mated by the Secretary.

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

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

17 “(ii) for a subsequent year, shall be  
18 the dollar amount specified in this sub-  
19 paragraph (or subparagraph (A)) for the  
20 previous year, increased by the percentage  
21 increase in the consumer price index for all  
22 urban consumers (United States city aver-  
23 age) for the 12-month period beginning  
24 with January of the previous year.



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

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

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

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

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

22 “(6) AVERAGE MANUFACTURER PRICE.—The  
23 term ‘average manufacturer price’ has the meaning,  
24 with respect to a part D rebatable drug of a manu-  
25 facturer, given such term in section 1927(k)(1), with

1       respect to a covered outpatient drug of a manufac-  
2       turer for a rebate period under section 1927.”.

3       (b) CONFORMING AMENDMENT TO PART B ASP  
4       CALCULATION.—Section 1847A(c)(3) of the Social Secu-  
5       rity Act (42 U.S.C. 1395w–3a(c)(3)), as amended by sec-  
6       tion 201(c), is further amended by striking “section 1927  
7       or section 1834(x)” and inserting “section 1927, section  
8       1834(x), or section 1860D–14B”.

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

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

14       (a) BENEFIT STRUCTURE REDESIGN.—Section  
15       1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
16       102(b)) is amended—

17               (1) in paragraph (2)—

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

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

5 (ii) in clause (ii)(III), by striking  
6 “and each subsequent year” and inserting  
7 “and 2021”; and

8 (C) in subparagraph (D)—

9 (i) in clause (i)—

10 (I) in the matter preceding sub-  
11 clause (I), by inserting “for a year  
12 preceding 2022,” after “paragraph  
13 (4),”; and

14 (II) in subclause (I)(bb), by  
15 striking “a year after 2018” and in-  
16 serting “each of years 2018 through  
17 2021”; and

18 (ii) in clause (ii)(V), by striking  
19 “2019 and each subsequent year” and in-  
20 serting “each of years 2019 through  
21 2021”;

22 (2) in paragraph (3)(A)—

23 (A) in the matter preceding clause (i), by  
24 inserting “for a year preceding 2022,” after  
25 “and (4),”; and

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

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

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

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

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

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

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

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

1 (ii) in clause (ii), by striking “clause  
2 (i)(I)” and inserting “clause (i)(I)(aa)”;  
3 (B) in subparagraph (B)—  
4 (i) in clause (i)—  
5 (I) in subclause (V), by striking  
6 “or” at the end;  
7 (II) in subclause (VI)—  
8 (aa) by striking “for a sub-  
9 sequent year” and inserting “for  
10 2021”; and  
11 (bb) by striking the period  
12 at the end and inserting a semi-  
13 colon; and  
14 (III) by adding at the end the  
15 following new subclauses:  
16 “(VII) for 2022, is equal to  
17 \$2,000; or  
18 “(VIII) for a subsequent year, is  
19 equal to the amount specified in this  
20 subparagraph for the previous year,  
21 increased by the annual percentage in-  
22 crease described in paragraph (6) for  
23 the year involved.”; and  
24 (ii) in clause (ii), by striking “clause  
25 (i)(II)” and inserting “clause (i)”;

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

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

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

12 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

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

1 gram by not later than January 1, 2021, in consultation  
2 with manufacturers, and allow for comment on such model  
3 agreement.

4 “(b) TERMS OF AGREEMENT.—

5 “(1) IN GENERAL.—

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

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

18 “(C) TIMING OF AGREEMENT.—

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

1 after the date of the establishment of a  
2 model agreement under subsection (a).

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

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

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



1 under subparagraph (A) of subsection (c)(1) or pro-  
2 cedures established under such subsection (c)(1).

3 “(4) LENGTH OF AGREEMENT.—

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

10 “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

20                                   “(i) the negotiated price of the appli-  
21 cable drug; and

22                                   “(ii) the discounted price of the appli-  
23 cable drug;

24                           “(D) the establishment of procedures to  
25 ensure that the discounted price for an applica-

1 ble drug under this section is applied before any  
2 coverage or financial assistance under other  
3 health benefit plans or programs that provide  
4 coverage or financial assistance for the pur-  
5 chase or provision of prescription drug coverage  
6 on behalf of applicable beneficiaries as the Sec-  
7 retary may specify; and

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

13 “(2) MONITORING COMPLIANCE.—

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

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

23 “(3) COLLECTION OF DATA FROM PRESCRIP-  
24 TION DRUG PLANS AND MA-PD PLANS.—The Sec-  
25 retary may collect appropriate data from prescrip-

1       tion drug plans and MA–PD plans in a timeframe  
2       that allows for discounted prices to be provided for  
3       applicable drugs under this section.

4       “(d) ADMINISTRATION.—

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

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

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

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

24               “(B) receive, distribute, or facilitate the  
25               distribution of funds of manufacturers to ap-

1           appropriate individuals or entities in order to  
2           meet the obligations of manufacturers under  
3           agreements under this section;

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

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

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

20          “(5) IMPLEMENTATION.—Notwithstanding any  
21          other provision of law, the Secretary may implement  
22          the program under this section by program instruc-  
23          tion or otherwise.

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

4           “(e) ENFORCEMENT.—

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

8           “(2) CIVIL MONEY PENALTY.—

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

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

22                   “(ii) 25 percent of such amount.

23           “(B) APPLICATION.—The provisions of  
24           section 1128A (other than subsections (a) and  
25           (b)) shall apply to a civil money penalty under

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

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

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

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

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

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

19           “(C) has incurred costs for covered part D  
20 drugs in the year that are equal to or exceed  
21 the annual deductible specified in section  
22 1860D–2(b)(1) for such year.

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

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



1           “(i) approved under a new drug appli-  
2           cation under section 505(c) of the Federal  
3           Food, Drug, and Cosmetic Act or, in the  
4           case of a biologic product, licensed under  
5           section 351 of the Public Health Service  
6           Act; and

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

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

21          “(III) is provided through an excep-  
22          tion or appeal; and

23          “(B) does not include a selected drug (as  
24          defined in section 1192(c)) during a price appli-

1           cability period (as defined in section  
2           1191(b)(2)) with respect to such drug.

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

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

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

10          “(4) DISCOUNTED PRICE.—

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

15                           “(i) who has not incurred costs for  
16                           covered part D drugs in the year that are  
17                           equal to or exceed the annual out-of-pocket  
18                           threshold specified in section 1860D-  
19                           2(b)(4)(B)(i) for the year, 90 percent of  
20                           the negotiated price of such drug; and

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

1           “(B) CLARIFICATION.—Nothing in this  
2 section shall be construed as affecting the re-  
3 sponsibility of an applicable beneficiary for pay-  
4 ment of a dispensing fee for an applicable drug.

5           “(C) SPECIAL CASE FOR CERTAIN  
6 CLAIMS.—

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

20           “(ii) CLAIMS SPANNING OUT-OF-POCK-  
21 ET THRESHOLD.—In the case where the  
22 entire amount of the negotiated price of an  
23 individual claim for an applicable drug  
24 with respect to an applicable beneficiary  
25 does not fall entirely below or entirely

1 above the annual out-of-pocket threshold  
2 specified in section 1860D–2(b)(4)(B)(i)  
3 for the year, the manufacturer of the ap-  
4 plicable drug shall provide the discounted  
5 price—

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

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

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

24 “(6) NEGOTIATED PRICE.—The term ‘nego-  
25 tiated price’ has the meaning given such term in sec-

1       tion 423.100 of title 42, Code of Federal Regula-  
2       tions (or any successor regulation), except that such  
3       negotiated price shall not include any dispensing fee  
4       for the applicable drug.

5               “(7) QUALIFIED RETIREE PRESCRIPTION DRUG  
6       PLAN.—The term ‘qualified retiree prescription drug  
7       plan’ has the meaning given such term in section  
8       1860D–22(a)(2).”.

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

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

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

18       “(h) SUNSET OF PROGRAM.—

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

24               “(2) CONTINUED APPLICATION FOR APPLICA-  
25       BLE DRUGS DISPENSED PRIOR TO SUNSET.—The

1 provisions of this section (including all responsibil-  
2 ities and duties) shall continue to apply after Janu-  
3 ary 1, 2022, with respect to applicable drugs dis-  
4 pensed prior to such date.”.

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

9 (A) in subsection (b)(2)(C)(iii)—

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

13 “(I) the reinsurance”; and

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

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

21 (B) in subsection (c)(1)(C)—

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

25 “(i) the reinsurance”;

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

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

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

9 (d) CONFORMING AMENDMENTS.—

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

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

16 (B) in subsection (c)(1)(C)—

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

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

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

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

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

10 (A) in paragraph (1)—

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

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

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

20 (B) in paragraph (2)—

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

24 and



1 (ii) in subparagraph (E), by striking  
2 “1860D–2(b)(4)(A)(i)(I)” and inserting  
3 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

13 “(i) for years prior to 2022, any dis-  
14 count”;

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

18 (C) by adding at the end the following new  
19 clause:

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

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

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

3 (B) by inserting “for such year” before the  
4 period.

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

7 (A) in subsection (a)—

8 (i) by striking paragraph (1) and in-  
9 serting the following:

10 “(1) participate in—

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

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

17 (ii) by striking paragraph (2) and in-  
18 serting the following:

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

20 “(A) for 2011 through 2021, an agreement  
21 described in subsection (b) of section 1860D–  
22 14A with the Secretary; and

23 “(B) for 2022 and each subsequent year,  
24 an agreement described in subsection (b) of sec-  
25 tion 1860D–14C with the Secretary; and”;

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

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

5 “(A) for 2011 through 2021, a contract  
6 with a third party that the Secretary has en-  
7 tered into a contract with under subsection  
8 (d)(3) of section 1860D–14A; and

9 “(B) for 2022 and each subsequent year,  
10 a contract with a third party that the Secretary  
11 has entered into a contract with under sub-  
12 section (d)(3) of section 1860D–14C.”; and

13 (B) by striking subsection (b) and insert-  
14 ing the following:

15 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),  
16 and (3)(A) of subsection (a) shall apply to covered part  
17 D drugs dispensed under this part on or after January  
18 1, 2011, and before January 1, 2022, and paragraphs  
19 (1)(B), (2)(B), and (3)(B) of such subsection shall apply  
20 to covered part D drugs dispensed under this part on or  
21 after January 1, 2022.”.

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

1 **SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**  
2 **TION DRUGS PLANS AND MA-PD PLANS**  
3 **UNDER MEDICARE PROGRAM TO SPREAD**  
4 **OUT COST-SHARING UNDER CERTAIN CIR-**  
5 **CUMSTANCES.**

6 Section 1860D–2(b)(2) of the Social Security Act (42  
7 U.S.C. 1395w–102(b)(2)), as amended by section 301, is  
8 further amended—

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

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

14 “(E) ENROLLEE OPTION REGARDING  
15 SPREADING COST-SHARING.—The Secretary  
16 shall establish by regulation a process under  
17 which, with respect to plan year 2022 and sub-  
18 sequent plan years, a prescription drug plan or  
19 an MA–PD plan shall, in the case of a part D  
20 eligible individual enrolled with such plan for  
21 such plan year who is not a subsidy eligible in-  
22 dividual (as defined in section 1860D–14(a)(3))  
23 and with respect to whom the plan projects that  
24 the dispensing of the first fill of a covered part  
25 D drug to such individual will result in the indi-  
26 vidual incurring costs that are equal to or above

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

9 **SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**  
10 **URES UNDER MEDICARE PART D.**

11 Section 1860D–4(c) of the Social Security Act (42  
12 U.S.C. 1395w–104(c)) is amended—

13 (1) by redesignating the paragraph (6), as  
14 added by section 50354 of division E of the Bipar-  
15 tisan Budget Act of 2018 (Public Law 115–123), as  
16 paragraph (7); and

17 (2) by adding at the end the following new  
18 paragraph:

19 “(8) APPLICATION OF PHARMACY QUALITY  
20 MEASURES.—

21 “(A) IN GENERAL.—A PDP sponsor that  
22 implements incentive payments to a pharmacy  
23 or price concessions paid by a pharmacy based  
24 on quality measures shall use measures estab-  
25 lished or approved by the Secretary under sub-

1 paragraph (B) with respect to payment for cov-  
2 ered part D drugs dispensed by such pharmacy.

3 “(B) STANDARD PHARMACY QUALITY  
4 MEASURES.—The Secretary shall establish or  
5 approve standard quality measures from a con-  
6 sensus and evidence-based organization for pay-  
7 ments described in subparagraph (A). Such  
8 measures shall focus on patient health outcomes  
9 and be based on proven criteria measuring  
10 pharmacy performance.

11 “(C) EFFECTIVE DATE.—The requirement  
12 under subparagraph (A) shall take effect for  
13 plan years beginning on or after January 1,  
14 2021, or such earlier date specified by the Sec-  
15 retary if the Secretary determines there are suf-  
16 ficient measures established or approved under  
17 subparagraph (B) to meet the requirement  
18 under subparagraph (A).”.

1 **TITLE IV—PRESCRIPTION DRUG**  
2 **POLICIES FOR LOW-INCOME**  
3 **INDIVIDUALS**

4 **SEC. 401. ADJUSTMENTS TO MEDICARE PART D COST-SHAR-**  
5 **ING REDUCTIONS FOR LOW-INCOME INDIVID-**  
6 **UALS.**

7 Section 1860D–14(a) of the Social Security Act (42  
8 U.S.C. 1395w–114(a)), as amended by section 301(d), is  
9 further amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (D)—

12 (i) in clause (ii)—

13 (I) by striking “that does not ex-  
14 ceed \$1 for” and all that follows  
15 through the period at the end and in-  
16 serting “that does not exceed—

17 “(I) for plan years before plan  
18 year 2021—

19 “(aa) for a generic drug or a  
20 preferred drug that is a multiple  
21 source drug (as defined in section  
22 1927(k)(7)(A)(i)), \$1 or, if less,  
23 the copayment amount applicable  
24 to an individual under clause  
25 (iii); and

1 “(bb) for any other drug, \$3  
2 or, if less, the copayment amount  
3 applicable to an individual under  
4 clause (iii); and”;

5 (II) by adding at the end the fol-  
6 lowing new subclauses:

7 “(II) for plan year 2021—

8 “(aa) for a generic drug, \$0;  
9 and

10 “(bb) for any other drug,  
11 the dollar amount applied under  
12 this clause (after application of  
13 paragraph (4)(A)) for plan year  
14 2020 for a drug described in sub-  
15 clause (I)(bb); and

16 “(III) for a subsequent year, the  
17 dollar amount applied under this  
18 clause for the previous year for the  
19 drug, increased by the annual percent-  
20 age increase in the consumer price  
21 index (all items; U.S. city average) as  
22 of September of such previous year.”;  
23 and

24 (ii) in clause (iii)—



1 (I) by striking “does not exceed  
2 the copayment amount specified  
3 under” and inserting “does not ex-  
4 ceed—

5 “(I) for plan years beginning be-  
6 fore plan year 2021, the copayment  
7 amount specified under”;

8 (II) by striking the period at the  
9 end and inserting “; and”; and

10 (III) by adding at the end the  
11 following new subclause:

12 “(II) for plan year 2021 and  
13 each subsequent plan year, the copay-  
14 ment amount applied under clause (ii)  
15 for the drug and year involved.”; and

16 (B) by adding at the end the following new  
17 subparagraph:

18 “(F) ROUNDING.—Any amount established  
19 under clause (ii) of subparagraph (D), including  
20 as applied under clause (iii) of such subpara-  
21 graph or paragraph (2)(D), that is based on an  
22 increase of \$3, that is not a multiple of 5 cents  
23 or 10 cents, respectively, shall be rounded to  
24 the nearest multiple of 5 cents or 10 cents, re-  
25 spectively.”;

1 (2) in paragraph (2)—

2 (A) in subparagraph (D)—

3 (i) by striking “of coinsurance of” and  
4 inserting “of—

5 “(I) for plan years before plan  
6 year 2021, coinsurance of”;

7 (ii) by striking the period at the end  
8 and inserting “; and”; and

9 (iii) by adding at the end the fol-  
10 lowing new subclause:

11 “(II) for plan year 2021 and  
12 each subsequent plan year, a copay-  
13 ment amount that does not exceed the  
14 copayment amount applied under  
15 paragraph (1)(D)(ii) for the drug and  
16 year involved.”; and

17 (B) in subparagraph (E)—

18 (i) by striking “subsection (c), the  
19 substitution for” and inserting “subsection  
20 (c)—

21 “(i) for plan years before plan year  
22 2021, the substitution for”;

23 (ii) by striking the period at the end  
24 and inserting “; and”; and

1 (iii) by adding at the end the fol-  
2 lowing new clause:

3 “(ii) for plan year 2021, the elimi-  
4 nation of any cost-sharing imposed under  
5 section 1860D–2(b)(4)(A).”; and

6 (3) in paragraph (4)(A)(ii), by inserting “(be-  
7 fore 2021)” after “subsequent year”.

8 **SEC. 402. DISSEMINATION TO MEDICARE PART D SUBSIDY**  
9 **ELIGIBLE INDIVIDUALS OF INFORMATION**  
10 **COMPARING PREMIUMS OF CERTAIN PRE-**  
11 **SCRIPTION DRUG PLANS.**

12 Section 1860D–1(c)(3) of the Social Security Act (42  
13 U.S.C. 1395w–101(c)(3)) is amended by adding at the end  
14 the following new subparagraph:

15 “(C) INFORMATION ON PREMIUMS FOR  
16 SUBSIDY ELIGIBLE INDIVIDUALS.—

17 “(i) IN GENERAL.—For plan year  
18 2022 and each subsequent plan year, the  
19 Secretary shall disseminate to each subsidy  
20 eligible individual (as defined in section  
21 1860D–14(a)(3)) information under this  
22 paragraph comparing premiums that would  
23 apply to such individual for prescription  
24 drug coverage under LIS benchmark plans,  
25 including, in the case of an individual en-

1 rolled in a prescription drug plan under  
2 this part, information that compares the  
3 premium that would apply if such indi-  
4 vidual were to remain enrolled in such plan  
5 to premiums that would apply if the indi-  
6 vidual were to enroll in other LIS bench-  
7 mark plans.

8 “(ii) LIS BENCHMARK PLAN.—For  
9 purposes of clause (i), the term ‘LIS  
10 benchmark plan’ means, with respect to an  
11 individual, a prescription drug plan under  
12 this part that is offered in the region in  
13 which the individual resides and—

14 “(I) that provides for a premium  
15 that is not more than the low-income  
16 benchmark premium amount (as de-  
17 fined in section 1860D–14(b)(2)) for  
18 such region; or

19 “(II) with respect to which the  
20 premium would be waived as de mini-  
21 mis pursuant to section 1860D–  
22 14(a)(5) for such individual.”.

1 **SEC. 403. PROVIDING FOR INTELLIGENT ASSIGNMENT OF**  
2 **CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS**  
3 **AUTO-ENROLLED UNDER MEDICARE PRE-**  
4 **SCRIPTION DRUG PLANS AND MA-PD PLANS.**

5 (a) IN GENERAL.—Section 1860D–1(b)(1) of the So-  
6 cial Security Act (42 U.S.C. 1395w–101(b)(1)) is amend-  
7 ed—

8 (1) in subparagraph (C)—

9 (A) by inserting after “PDP region” the  
10 following: “or through use of an intelligent as-  
11 signment process that is designed to maximize  
12 the access of such individual to necessary pre-  
13 scription drugs while minimizing costs to such  
14 individual and to the program under this part  
15 to the greatest extent possible. In the case the  
16 Secretary enrolls such individuals through use  
17 of an intelligent assignment process, such proc-  
18 ess shall take into account the extent to which  
19 prescription drugs necessary for the individual  
20 are covered in the case of a PDP sponsor of a  
21 prescription drug plan that uses a formulary,  
22 the use of prior authorization or other restric-  
23 tions on access to coverage of such prescription  
24 drugs by such a sponsor, and the overall quality  
25 of a prescription drug plan as measured by

1 quality ratings established by the Secretary”;  
2 and

3 (B) by striking “Nothing in the previous  
4 sentence” and inserting “Nothing in this sub-  
5 paragraph”; and

6 (2) in subparagraph (D)—

7 (A) by inserting after “PDP region” the  
8 following: “or through use of an intelligent as-  
9 signment process that is designed to maximize  
10 the access of such individual to necessary pre-  
11 scription drugs while minimizing costs to such  
12 individual and to the program under this part  
13 to the greatest extent possible. In the case the  
14 Secretary enrolls such individuals through use  
15 of an intelligent assignment process, such proc-  
16 ess shall take into account the extent to which  
17 prescription drugs necessary for the individual  
18 are covered in the case of a PDP sponsor of a  
19 prescription drug plan that uses a formulary,  
20 the use of prior authorization or other restric-  
21 tions on access to coverage of such prescription  
22 drugs by such a sponsor, and the overall quality  
23 of a prescription drug plan as measured by  
24 quality ratings established by the Secretary”;  
25 and

1 (B) by striking “Nothing in the previous  
2 sentence” and inserting “Nothing in this sub-  
3 paragraph”.

4 (b) EFFECTIVE DATE.—The amendments made by  
5 subsection (a) shall apply with respect to plan years begin-  
6 ning with plan year 2022.

7 **SEC. 404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUB-**  
8 **SIDIES UNDER PART D OF THE MEDICARE**  
9 **PROGRAM.**

10 Section 1860D–14(a) of the Social Security Act (42  
11 U.S.C. 1395w–114(a)), as amended by sections 301(d)  
12 and 401, is further amended—

13 (1) in the subsection heading, by striking “IN-  
14 DIVIDUALS” and all that follows through “LINE”  
15 and inserting “CERTAIN INDIVIDUALS”;

16 (2) in paragraph (1)—

17 (A) by striking the paragraph heading and  
18 inserting “INDIVIDUALS WITH CERTAIN LOW IN-  
19 COMES”; and

20 (B) in the matter preceding subparagraph  
21 (A), by inserting “(or, with respect to a plan  
22 year beginning on or after January 1, 2022,  
23 150 percent)” after “135 percent”;

24 (3) in paragraph (2)—

1 (A) by striking the paragraph heading and  
2 inserting “OTHER LOW-INCOME INDIVIDUALS”;  
3 and

4 (B) in subparagraph (A)—

5 (i) by inserting “(or, with respect to a  
6 plan year beginning on or after January 1,  
7 2022, 150 percent)” after “135 percent”;  
8 and

9 (ii) by inserting “(or, with respect to  
10 a plan year beginning on or after January  
11 1, 2022, 200 percent)” after “150 per-  
12 cent”; and

13 (4) in paragraph (3)(A)(ii), by inserting “(or,  
14 with respect to a plan year beginning on or after  
15 January 1, 2022, 200 percent)” after “150 per-  
16 cent”.

17 **SEC. 405. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-**  
18 **COME TERRITORIAL RESIDENTS FOR PRE-**  
19 **MIUM AND COST-SHARING SUBSIDIES UNDER**  
20 **THE MEDICARE PROGRAM; SUNSET OF EN-**  
21 **HANCED ALLOTMENT PROGRAM.**

22 (a) AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-  
23 COME TERRITORIAL RESIDENTS FOR PREMIUM AND  
24 COST-SHARING SUBSIDIES UNDER THE MEDICARE PRO-  
25 GRAM.—



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

4                   (A) in subparagraph (B)(v)—

5                           (i) in subclause (I), by striking “and”  
6                           at the end;

7                           (ii) in subclause (II), by striking the  
8                           period and inserting “; and”; and

9                           (iii) by inserting after subclause (II)  
10                          the following new subclause:

11                                   “(III) with respect to plan years  
12                                   beginning on or after January 1,  
13                                   2021, shall provide that any part D  
14                                   eligible individual who is enrolled for  
15                                   medical assistance under the State  
16                                   Medicaid plan of a territory (as de-  
17                                   fined in section 1935(f)) under title  
18                                   XIX (or a waiver of such a plan) shall  
19                                   be treated as a subsidy eligible indi-  
20                                   vidual described in paragraph (1).”;  
21                                   and

22                           (B) in subparagraph (F), by adding at the  
23                           end the following new sentence: “The previous  
24                           sentence shall not apply with respect to eligi-  
25                           bility determinations for premium and cost-

1 sharing subsidies under this section made on or  
2 after January 1, 2021.”.

3 (2) CONFORMING AMENDMENT.—Section  
4 1860D–31(j)(2)(D) of the Social Security Act (42  
5 U.S.C. 1395w–141(j)(2)(D)) is amended by adding  
6 at the end the following new sentence: “The previous  
7 sentence shall not apply with respect to amounts  
8 made available to a State under this paragraph on  
9 or after January 1, 2021.”.

10 (b) SUNSET OF ENHANCED ALLOTMENT PRO-  
11 GRAM.—

12 (1) IN GENERAL.—Section 1935(e) of the So-  
13 cial Security Act (42 U.S.C. 1396u–5(e)) is amend-  
14 ed—

15 (A) in paragraph (1)(A), by inserting after  
16 “such State” the following: “before January 1,  
17 2021”; and

18 (B) in paragraph (3)—

19 (i) in subparagraph (A), in the matter  
20 preceding clause (i), by inserting after “a  
21 year” the following: “(before 2021)”; and

22 (ii) in subparagraph (B)(iii), by strik-  
23 ing “a subsequent year” and inserting  
24 “each of fiscal years 2008 through 2020”.

1           (2) TERRITORY DEFINED.—Section 1935 of the  
2           Social Security Act (42 U.S.C. 1396u–5) is amended  
3           by adding at the end the following new subsection:

4           “(f) TERRITORY DEFINED.—In this section, the term  
5           ‘territory’ means Puerto Rico, the Virgin Islands, Guam,  
6           the Northern Mariana Islands, and American Samoa.”.

7           **SEC. 406. AUTOMATIC QUALIFICATION OF CERTAIN MED-**  
8   **ICAID BENEFICIARIES FOR PREMIUM AND**  
9   **COST-SHARING SUBSIDIES UNDER PART D OF**  
10   **THE MEDICARE PROGRAM.**

11           Clause (v) of section 1860D–14(a)(3)(B) of the So-  
12           cial Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as  
13           amended by section 405, is further amended—

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

16           (2) in subclause (III), by striking the period  
17           and inserting “; and”; and

18           (3) by inserting after subclause (III) the fol-  
19           lowing new subclause:

20   “(IV) with respect to plan years  
21   beginning on or after January 1,  
22   2022, shall, notwithstanding the pre-  
23   ceding clauses of this subparagraph,  
24   provide that any part D eligible indi-  
25   vidual not described in subclause (I),

1 (II), or (III) who is enrolled, as of the  
2 day before the date on which such in-  
3 dividual attains the age of 65, for  
4 medical assistance under a State plan  
5 under title XIX (or a waiver of such  
6 plan) pursuant to clause (i)(VIII) or  
7 (ii)(XX) of section 1902(a)(10)(A),  
8 and who has income below 200 per-  
9 cent of the poverty line applicable to  
10 a family of the size involved, shall be  
11 treated as a subsidy eligible individual  
12 described in paragraph (1) for a lim-  
13 ited period of time, as specified by the  
14 Secretary.”.

15 **SEC. 407. ELIMINATING THE RESOURCE REQUIREMENT**  
16 **WITH RESPECT TO SUBSIDY ELIGIBLE INDI-**  
17 **VIDUALS UNDER PART D OF THE MEDICARE**  
18 **PROGRAM.**

19 Section 1860D–14(a)(3)(A)(iii) of the Social Security  
20 Act (42 U.S.C. 1395w–114(a)(3)(A)(iii)) is amended by  
21 inserting “in the case of a plan year beginning before Jan-  
22 uary 1, 2022,” before “meets”.

1 **SEC. 408. PROVIDING FOR CERTAIN RULES REGARDING**  
2 **THE TREATMENT OF ELIGIBLE RETIREMENT**  
3 **PLANS IN DETERMINING THE ELIGIBILITY OF**  
4 **INDIVIDUALS FOR PREMIUM AND COST-**  
5 **SHARING SUBSIDIES UNDER PART D OF THE**  
6 **MEDICARE PROGRAM.**

7 Section 1860D–14(a)(3)(C)(i) of the Social Security  
8 Act (42 U.S.C. 1395w–114(a)(3)(C)(i)) is amended, by  
9 striking “except that support and maintenance furnished  
10 in kind shall not be counted as income; and” and inserting  
11 “except that—

12 “(I) support and maintenance  
13 furnished in kind shall not be counted  
14 as income; and

15 “(II) for plan years beginning on  
16 or after January 1, 2022, any dis-  
17 tribution or withdrawal from an eligi-  
18 ble retirement plan (as defined in sub-  
19 paragraph (B) of section 402(c)(8) of  
20 the Internal Revenue Code of 1986,  
21 but excluding any defined benefit plan  
22 described in clause (iv) or (v) of such  
23 subparagraph and any qualified trust  
24 (as defined in subparagraph (A) of  
25 such section) which is part of such a

1 defined benefit plan) shall be counted  
2 as income; and”.

3 **TITLE I—DRUG PRICE**  
4 **TRANSPARENCY**

5 **SEC. 501. DRUG PRICE TRANSPARENCY.**

6 Part A of title XI of the Social Security Act is  
7 amended by adding at the end the following new sections:

8 **“SEC. 1150C. REPORTING ON DRUG PRICES.**

9 “(a) DEFINITIONS.—In this section:

10 “(1) MANUFACTURER.—The term ‘manufac-  
11 turer’ means the person—

12 “(A) that holds the application for a drug  
13 approved under section 505 of the Federal  
14 Food, Drug, and Cosmetic Act or licensed  
15 under section 351 of the Public Health Service  
16 Act; or

17 “(B) who is responsible for setting the  
18 wholesale acquisition cost for the drug.

19 “(2) QUALIFYING DRUG.—The term ‘qualifying  
20 drug’ means any drug that is approved under sub-  
21 section (c) or (j) of section 505 of the Federal Food,  
22 Drug, and Cosmetic Act or licensed under subsection  
23 (a) or (k) of section 351 of the Public Health Serv-  
24 ice Act—

1           “(A) that has a wholesale acquisition cost  
2           of \$100 or more, adjusted for inflation occur-  
3           ring after the date of enactment of this section,  
4           for a month’s supply or a typical course of  
5           treatment that lasts less than a month, and  
6           is—

7                   “(i) subject to section 503(b)(1) of  
8                   the Federal Food, Drug, and Cosmetic  
9                   Act; and

10                   “(ii) not a preventative vaccine; and

11           “(B) for which, during the previous cal-  
12           endar year, at least 1 dollar of the total amount  
13           of sales were for individuals enrolled under the  
14           Medicare program under title XVIII or under a  
15           State Medicaid plan under title XIX or under  
16           a waiver of such plan.

17           “(3) WHOLESALE ACQUISITION COST.—The  
18           term ‘wholesale acquisition cost’ has the meaning  
19           given that term in section 1847A(c)(6)(B).

20           “(b) REPORT.—

21                   “(1) REPORT REQUIRED.—The manufacturer of  
22           a qualifying drug shall submit a report to the Sec-  
23           retary if, with respect to the qualifying drug—

24                   “(A) there is an increase in the price of  
25           the qualifying drug that results in an increase

1 in the wholesale acquisition cost of that drug  
2 that is equal to—

3 “(i) 10 percent or more within a 12-  
4 month period beginning on or after Janu-  
5 ary 1, 2019; or

6 “(ii) 25 percent or more within a 36-  
7 month period beginning on or after Janu-  
8 ary 1, 2019;

9 “(B) the estimated price of the qualifying  
10 drug or spending per individual or per user of  
11 such drug (as estimated by the Secretary) for  
12 the applicable year (or per course of treatment  
13 in such applicable year as determined by the  
14 Secretary) is at least \$26,000 beginning on or  
15 after January 1, 2021; or

16 “(C) there was an increase in the price of  
17 the qualifying drug that resulted in an increase  
18 in the wholesale acquisition cost of that drug  
19 that is equal to—

20 “(i) 10 percent or more within a 12-  
21 month period that begins and ends during  
22 the 5-year period preceding January 1,  
23 2021; or

24 “(ii) 25 percent or more within a 36-  
25 month period that begins and ends during



1           the 5-year period preceding January 1,  
2           2021.

3           “(2) REPORT DEADLINE.—Each report de-  
4           scribed in paragraph (1) shall be submitted to the  
5           Secretary—

6           “(A) in the case of a report with respect  
7           to an increase in the price of a qualifying drug  
8           that occurs during the period beginning on Jan-  
9           uary 1, 2019, and ending on the day that is 60  
10          days after the date of the enactment of this sec-  
11          tion, not later than 90 days after such date of  
12          enactment;

13          “(B) in the case of a report with respect  
14          to an increase in the price of a qualifying drug  
15          that occurs after the period described in sub-  
16          paragraph (A), not later than 30 days prior to  
17          the planned effective date of such price increase  
18          for such qualifying drug;

19          “(C) in the case of a report with respect  
20          to a qualifying drug that meets the criteria  
21          under paragraph (1)(B), not later than 30 days  
22          after such drug meets such criteria; and

23          “(D) in the case of a report with respect  
24          to an increase in the price of a qualifying drug  
25          that occurs during a 12-month or 36-month pe-

1           riod described in paragraph (1)(C), not later  
2           than April 1, 2021.

3           “(c) CONTENTS.—A report under subsection (b), con-  
4           sistent with the standard for disclosures described in sec-  
5           tion 213.3(d) of title 12, Code of Federal Regulations (as  
6           in effect on the date of enactment of this section), shall,  
7           at a minimum, include—

8           “(1) with respect to the qualifying drug—

9           “(A) the percentage by which the manufac-  
10          turer will raise the wholesale acquisition cost of  
11          the drug within the 12-month period or 36-  
12          month period as described in subsection  
13          (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or  
14          (b)(1)(C)(ii), as applicable, and the effective  
15          date of such price increase or the cost associ-  
16          ated with a qualifying drug if such drug meets  
17          the criteria under subsection (b)(1)(B) and the  
18          effective date at which such drug meets such  
19          criteria;

20          “(B) an explanation for, and description  
21          of, each price increase for such drug that will  
22          occur during the 12-month period or the 36-  
23          month period described in subsection  
24          (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or  
25          (b)(1)(C)(ii), as applicable;

1           “(C) an explanation for, and description  
2 of, the cost associated with a qualifying drug if  
3 such drug meets the criteria under subsection  
4 (b)(1)(B), as applicable;

5           “(D) if known and different from the man-  
6 ufacturer of the qualifying drug, the identity  
7 of—

8           “(i) the sponsor or sponsors of any in-  
9 vestigational new drug applications under  
10 section 505(i) of the Federal Food, Drug,  
11 and Cosmetic Act for clinical investigations  
12 with respect to such drug, for which the  
13 full reports are submitted as part of the  
14 application—

15           “(I) for approval of the drug  
16 under section 505 of such Act; or

17           “(II) for licensure of the drug  
18 under section 351 of the Public Health  
19 Service Act; and

20           “(ii) the sponsor of an application for  
21 the drug approved under such section 505  
22 of the Federal Food, Drug, and Cosmetic  
23 Act or licensed under section 351 of the  
24 Public Health Service Act;

1           “(E) a description of the history of the  
2           manufacturer’s price increases for the drug  
3           since the approval of the application for the  
4           drug under section 505 of the Federal Food,  
5           Drug, and Cosmetic Act or the issuance of the  
6           license for the drug under section 351 of the  
7           Public Health Service Act, or since the manu-  
8           facturer acquired such approved application or  
9           license, if applicable;

10           “(F) the current wholesale acquisition cost  
11           of the drug;

12           “(G) the total expenditures of the manu-  
13           facturer on—

14           “(i) materials and manufacturing for  
15           such drug;

16           “(ii) acquiring patents and licensing  
17           for such drug; and

18           “(iii) purchasing or acquiring such  
19           drug from another manufacturer, if appli-  
20           cable;

21           “(H) the percentage of total expenditures  
22           of the manufacturer on research and develop-  
23           ment for such drug that was derived from Fed-  
24           eral funds;

1           “(I) the total expenditures of the manufac-  
2           turer on research and development for such  
3           drug that is necessary to demonstrate that it  
4           meets applicable statutory standards for ap-  
5           proval under section 505 of the Federal Food,  
6           Drug, and Cosmetic Act or licensure under sec-  
7           tion 351 of the Public Health Service Act, as  
8           applicable;

9           “(J) the total expenditures of the manufac-  
10          turer on pursuing new or expanded indications  
11          or dosage changes for such drug under section  
12          505 of the Federal Food, Drug, and Cosmetic  
13          Act or section 351 of the Public Health Service  
14          Act;

15          “(K) the total expenditures of the manu-  
16          facturer on carrying out postmarket require-  
17          ments related to such drug, including under  
18          section 505(o)(3) of the Federal Food, Drug,  
19          and Cosmetic Act;

20          “(L) the total revenue and the net profit  
21          generated from the qualifying drug for each cal-  
22          endar year since the approval of the application  
23          for the drug under section 505 of the Federal  
24          Food, Drug, and Cosmetic Act or the issuance  
25          of the license for the drug under section 351 of

1 the Public Health Service Act, or since the  
2 manufacturer acquired such approved applica-  
3 tion or license; and

4 “(M) the total costs associated with mar-  
5 keting and advertising for the qualifying drug;  
6 “(2) with respect to the manufacturer—

7 “(A) the total revenue and the net profit  
8 of the manufacturer for each of the 12-month  
9 period described in subsection (b)(1)(A)(i) or  
10 (b)(1)(C)(i) or the 36-month period described in  
11 subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as ap-  
12 plicable;

13 “(B) all stock-based performance metrics  
14 used by the manufacturer to determine execu-  
15 tive compensation for each of the 12-month pe-  
16 riods described in subsection (b)(1)(A)(i) or  
17 (b)(1)(C)(i) or the 36-month periods described  
18 in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as  
19 applicable; and

20 “(C) any additional information the manu-  
21 facturer chooses to provide related to drug pric-  
22 ing decisions, such as total expenditures on—

23 “(i) drug research and development;  
24 or

1                   “(ii) clinical trials, including on drugs  
2                   that failed to receive approval by the Food  
3                   and Drug Administration; and

4                   “(3) such other related information as the Sec-  
5                   retary considers appropriate and as specified by the  
6                   Secretary.

7                   “(d) INFORMATION PROVIDED.—The manufacturer  
8                   of a qualifying drug that is required to submit a report  
9                   under subsection (b), shall ensure that such report and  
10                  any explanation for, and description of, each price increase  
11                  described in subsection (c)(1) shall be truthful, not mis-  
12                  leading, and accurate.

13                  “(e) CIVIL MONETARY PENALTY.—Any manufac-  
14                  turer of a qualifying drug that fails to submit a report  
15                  for the drug as required by this section, following notifica-  
16                  tion by the Secretary to the manufacturer that the manu-  
17                  facturer is not in compliance with this section, shall be  
18                  subject to a civil monetary penalty of \$75,000 for each  
19                  day on which the violation continues.

20                  “(f) FALSE INFORMATION.—Any manufacturer that  
21                  submits a report for a drug as required by this section  
22                  that knowingly provides false information in such report  
23                  is subject to a civil monetary penalty in an amount not  
24                  to exceed \$100,000 for each item of false information.

25                  “(g) PUBLIC POSTING.—

1           “(1) IN GENERAL.—Subject to paragraph (4),  
2           the Secretary shall post each report submitted under  
3           subsection (b) on the public website of the Depart-  
4           ment of Health and Human Services the day the  
5           price increase of a qualifying drug is scheduled to go  
6           into effect.

7           “(2) FORMAT.—In developing the format in  
8           which reports will be publicly posted under para-  
9           graph (1), the Secretary shall consult with stake-  
10          holders, including beneficiary groups, and shall seek  
11          feedback from consumer advocates and readability  
12          experts on the format and presentation of the con-  
13          tent of such reports to ensure that such reports  
14          are—

15                   “(A) user-friendly to the public; and

16                   “(B) written in plain language that con-  
17                   sumers can readily understand.

18          “(3) LIST.—In addition to the reports sub-  
19          mitted under subsection (b), the Secretary shall also  
20          post a list of each qualifying drug with respect to  
21          which the manufacturer was required to submit such  
22          a report in the preceding year and whether such  
23          manufacturer was required to submit such report  
24          based on a qualifying price increase or whether such  
25          drug meets the criteria under subsection (b)(1)(B).



1           “(4) PROTECTED INFORMATION.—In carrying  
2           out this section, the Secretary shall enforce applica-  
3           ble law concerning the protection of confidential  
4           commercial information and trade secrets.

5   **“SEC. 1150D. ANNUAL REPORT TO CONGRESS.**

6           “(a) IN GENERAL.—Subject to subsection (b), the  
7           Secretary shall submit to the Committees on Energy and  
8           Commerce and Ways and Means of the House of Rep-  
9           resentatives and the Committees on Health, Education,  
10          Labor, and Pensions and Finance of the Senate, and post  
11          on the public website of the Department of Health and  
12          Human Services in a way that is user-friendly to the pub-  
13          lic and written in plain language that consumers can read-  
14          ily understand, an annual report—

15               “(1) summarizing the information reported pur-  
16               suant to section 1150C;

17               “(2) including copies of the reports and sup-  
18               porting detailed economic analyses submitted pursu-  
19               ant to such section;

20               “(3) detailing the costs and expenditures in-  
21               curred by the Department of Health and Human  
22               Services in carrying out section 1150C; and

23               “(4) explaining how the Department of Health  
24               and Human Services is improving consumer and

1 provider information about drug value and drug  
2 price transparency.

3 “(b) PROTECTED INFORMATION.—In carrying out  
4 this section, the Secretary shall enforce applicable law con-  
5 cerning the protection of confidential commercial informa-  
6 tion and trade secrets.”.

