

**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.

TITLE V—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:

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

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

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

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

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

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

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

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

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

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

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

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

3 “(3) SELECTED DRUG PUBLICATION DATE.—

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

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

12 “(A) beginning on the sooner of—

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

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

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

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

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

4                   “(A) in the case such drug is furnished or  
5                   dispensed to the individual at a pharmacy or by  
6                   a mail order service—

7                           “(i) an individual who is enrolled  
8                           under a prescription drug plan under part  
9                           D of title XVIII or an MA–PD plan under  
10                          part C of such title under which coverage  
11                          is provided for such drug; 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 dispensed;  
21                           and

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

1                   “(i) an individual who is entitled to  
2                   benefits under part A of title XVIII or en-  
3                   rolled under part B of such title if such se-  
4                   lected drug is covered under the respective  
5                   part; and

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

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

23                  “(3) AVERAGE INTERNATIONAL MARKET PRICE  
24                  DEFINED.—

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

17           “(B) APPLICABLE COUNTRIES.—

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

1                   “(ii) COUNTRIES DESCRIBED.—For  
2                   purposes of this paragraph, the following  
3                   are countries described in this clause:

4                               “(I) Australia.

5                               “(II) Canada.

6                               “(III) France.

7                               “(IV) Germany.

8                               “(V) Japan.

9                               “(VI) The United Kingdom.

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

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

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

20                               “(1)(A) with respect to an initial price applica-  
21                   bility year during the period beginning with 2023  
22                   and ending with 2027, at least 25 negotiation-eli-  
23                   gible drugs described in subparagraphs (A) and (B),  
24                   but not subparagraph (C), of subsection (d)(1) (or,  
25                   with respect to an initial price applicability year dur-



1       ing such period beginning after 2023, the maximum  
2       number (if such number is less than 25) of such ne-  
3       gotiation-eligible drugs for the year) with respect to  
4       such year;

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

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

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

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

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

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

1 be projected across different dosage forms and strengths  
2 of the drugs and not based on the specific formulation or  
3 package size or package type of the drugs, taking into con-  
4 sideration both the volume of drugs for which payment  
5 is made, to the extent such data is available, and the  
6 amount by which the net price for the drugs exceeds the  
7 AIM price for the drugs.

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

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

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

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

22               “(2) continue to be marketed.

23       “(d) NEGOTIATION-ELIGIBLE DRUG.—

24               “(1) IN GENERAL.—For purposes of this part,  
25               the term ‘negotiation-eligible drug’ means, with re-

1       spect to the selected drug publication date with re-  
2       spect to an initial price applicability year, a quali-  
3       fying single source drug, as defined in subsection  
4       (e), that meets any of the following criteria:

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

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

21             “(C) INSULIN.—The drug is a qualifying  
22             single source drug described in subsection  
23             (e)(3).

24             “(2) CLARIFICATION.—In determining whether  
25             a qualifying single source drug satisfies any of the

1 criteria described in paragraph (1), the Secretary  
2 shall, to the extent practicable, use data that is ag-  
3 gregated across dosage forms and strengths of the  
4 drug and not based on the specific formulation or  
5 package size or package type of the drug.

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

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

15 “(1) DRUG PRODUCTS.—A drug that—

16 “(A) is approved under section 505(c) of  
17 the Federal Food, Drug, and Cosmetic Act and  
18 continues to be marketed pursuant to such ap-  
19 proval; and

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

23 “(2) BIOLOGICAL PRODUCTS.—A biological  
24 product that—

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

9           “(B) is not the reference product for any  
10          biological product that is licensed and continues  
11          to be marketed under section 351(k) of such  
12          Act.

13          “(3)   INSULIN    PRODUCT.—Notwithstanding  
14          paragraphs (1) and (2), any insulin product that is  
15          approved under subsection (c) or (j) of section 505  
16          of the Federal Food, Drug, and Cosmetic Act or li-  
17          censed under subsection (a) or (k) of section 351 of  
18          the Public Health Service Act and continues to be  
19          marketed under such section 505 or 351, including  
20          any insulin product that has been deemed to be li-  
21          censed under section 351(a) of the Public Health  
22          Service Act pursuant to section 7002(e)(4) of the  
23          Biologics Price Competition and Innovation Act of  
24          2009 and continues to be marketed pursuant to such  
25          licensure.

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

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

18 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE  
19 DRUGS.—

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

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

5           “(B) that the Secretary determines under  
6           paragraph (2) is likely to be a negotiation-eli-  
7           gible drug with respect to the subsequent selected  
8           drug publication date.

9           “(2) DETERMINATION.—In the case of a quali-  
10          fying single source drug that meets the criteria de-  
11          scribed in subparagraphs (A) and (B) of paragraph  
12          (1), with respect to an initial price applicability year,  
13          if the wholesale acquisition cost at which such drug  
14          is first marketed in the United States is equal to or  
15          greater than the median household income (as deter-  
16          mined according to the most recent data collected by  
17          the United States Census Bureau), the Secretary  
18          shall determine before the selected drug publication  
19          date with respect to the initial price applicability  
20          year, if the drug is likely to be included as a negotia-  
21          tion-eligible drug with respect to the subsequent se-  
22          lected drug publication date, based on the projected  
23          spending under title XVIII or in the United States  
24          on such drug. For purposes of this paragraph the  
25          term ‘United States’ includes the 50 States, the Dis-



1        trict of Columbia, and the territories of the United  
2        States.

3        **“SEC. 1193. MANUFACTURER AGREEMENTS.**

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

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

18            “(A) to fair price eligible individuals who  
19            with respect to such drug are described in sub-  
20            paragraph (A) of section 1191(c)(1) and are  
21            furnished or dispensed such drug during, sub-  
22            ject to subparagraph (2), the price applicability  
23            period; and

24            “(B) to hospitals, physicians, and other  
25            providers of services and suppliers with respect

1 to fair price eligible individuals who with re-  
2 spect to such drug are described in subpara-  
3 graph (B) of such section and are furnished or  
4 administered such drug during, subject to sub-  
5 paragraph (2), the price applicability period;

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

18 “(A) to fair price eligible individuals who  
19 with respect to such drug are described in sub-  
20 paragraph (A) of section 1191(c)(1) and are  
21 furnished or dispensed such drug during any  
22 year during the price applicability period (be-  
23 ginning after such renegotiation) with respect  
24 to such selected drug; and

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

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

15          “(4) the manufacturer, subject to subsection  
16          (c), submits to the Secretary, in a form and manner  
17          specified by the Secretary—

18                 “(A) for the voluntary negotiation period  
19                 for the price applicability period (and, if appli-  
20                 cable, before any period of renegotiation speci-  
21                 fied pursuant to paragraph (2)) with respect to  
22                 such drug all information that the Secretary re-  
23                 quires to carry out the negotiation (or renegoti-  
24                 ation process) under this part, including infor-

1 mation described in section 1192(f) and section  
2 1194(d)(1); and

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

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

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

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

24 “(c) SPECIAL RULE FOR CERTAIN SELECTED DRUGS  
25 WITHOUT AIM PRICE.—

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

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

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

23           “(2) AMOUNTS DESCRIBED.—

24           “(A) WEIGHTED AVERAGE PRICE BEFORE  
25 AIM PRICE AVAILABLE.—For purposes of para-

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

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

22 “(d) CONFIDENTIALITY OF INFORMATION.—Infor-  
23 mation submitted to the Secretary under this part by a  
24 manufacturer of a selected drug that is proprietary infor-  
25 mation of such manufacturer (as determined by the Sec-

1 retary) may be used only by the Secretary or disclosed  
2 to and used by the Comptroller General of the United  
3 States or the Medicare Payment Advisory Commission for  
4 purposes of carrying out this part.

5 “(e) REGULATIONS.—

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

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

21 “(f) COMPLIANCE WITH REQUIREMENTS FOR AD-  
22 MINISTRATION OF PROGRAM.—Each manufacturer with  
23 an agreement in effect under this section shall comply with  
24 requirements imposed by the Secretary or a third party

1 with a contract under section 1196(e)(1), as applicable,  
2 for purposes of administering the program.

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

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

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

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

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

22 “(1) IN GENERAL.—The Secretary shall develop  
23 and use a consistent methodology for negotiations  
24 under subsection (a) that, in accordance with para-  
25 graph (2) and subject to paragraph (3), achieves the



1 lowest maximum fair price for each selected drug  
2 while appropriately rewarding innovation.

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

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

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

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

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

20 “(3) REQUIREMENT.—

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

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

11 “(B) TARGET PRICE.—

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

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

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

24 “(4) ANNUAL REPORT.—After the completion  
25 of each voluntary negotiation period, the Secretary

1 shall submit to Congress a report on the maximum  
2 fair prices negotiated (or, as applicable, renegoti-  
3 ated) for such period. Such report shall include in-  
4 formation on how such prices so negotiated (or re-  
5 negotiated) meet the requirements of this part, in-  
6 cluding the requirements of this subsection.

7 “(c) LIMITATION.—

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

15 “(2) SELECTED DRUGS WITHOUT AIM PRICE.—  
16 In the case of a selected drug for which there is no  
17 AIM price available with respect to the initial price  
18 applicability year for such drug, for each plan year  
19 during the price applicability period before the first  
20 plan year for which there is an AIM price available  
21 for such drug, the maximum fair price negotiated  
22 (including as renegotiated) under this section for the  
23 selected drug shall not exceed the amount equal to  
24 85 percent of the average manufacturer price for the  
25 drug with respect to such year.

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

8           “(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, including as sub-  
9 mitted by the manufacturer:  
10

11           “(A) Research and development costs of  
12 the manufacturer for the drug and the extent to  
13 which the manufacturer has recouped research  
14 and development costs.

15           “(B) Market data for the drug, including  
16 the distribution of sales across different pro-  
17 grams and purchasers and projected future rev-  
18 enues for the drug.

19           “(C) Unit costs of production and distribu-  
20 tion of the drug.

21           “(D) Prior Federal financial support for  
22 novel therapeutic discovery and development  
23 with respect to the drug.

24           “(E) Data on patents and on existing and  
25 pending exclusivity for the drug.

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

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

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

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

12 “(B) Information on approval by the Food  
13 and Drug Administration of alternative drug  
14 products.

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

21 In considering information described in subpara-  
22 graph (C), the Secretary shall not use evidence or  
23 findings from comparative clinical effectiveness re-  
24 search in a manner that treats extending the life of  
25 an elderly, disabled, or terminally ill individual as of

1 lower value than extending the life of an individual  
2 who is younger, nondisabled, or not terminally ill.  
3 Nothing in the previous sentence shall affect the ap-  
4 plication or consideration of an AIM price for a se-  
5 lected drug

6 “(3) FOREIGN SALES INFORMATION.—To the  
7 extent available on a timely basis, including as pro-  
8 vided by a manufacturer of the selected drug or oth-  
9 erwise, information on sales of the selected drug in  
10 each of the countries described in section  
11 1191(e)(3)(B).

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

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

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

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

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

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

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

15 “(a) IN GENERAL.—With respect to an initial price  
16 applicability year and selected drug with respect to such  
17 year, not later than April 1 of the plan year prior to such  
18 initial price applicability year, the Secretary shall publish  
19 in the Federal Register the maximum fair price for such  
20 drug negotiated under this part with the manufacturer of  
21 such drug.

22 “(b) UPDATES.—

23 “(1) SUBSEQUENT YEAR MAXIMUM FAIR  
24 PRICES.—For a selected drug, for each plan year  
25 subsequent to the initial price applicability year for



1 such drug with respect to which an agreement for  
2 such drug is in effect under section 1193, the Sec-  
3 retary shall publish in the Federal Register—

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

11 “(B) in the case the maximum fair price  
12 for such drug was renegotiated, for the first  
13 year for which such price as so renegotiated ap-  
14 plies, such renegotiated maximum fair price.

15 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

16 In the case of a selected drug with respect to an ini-  
17 tial price applicability year for which the maximum  
18 fair price is determined under this part after the  
19 date of publication under this section, the Secretary  
20 shall publish such maximum fair price in the Fed-  
21 eral Register by not later than 30 days after the  
22 date such maximum price is so determined.

23 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**  
24 **VISIONS.**

25 “(a) ADMINISTRATIVE DUTIES.—

1           “(1) IN GENERAL.—For purposes of section  
2           1191, the administrative duties described in this sec-  
3           tion are the following:

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

22                   “(B) The establishment of procedures (in-  
23                   cluding through agreements with manufacturers  
24                   under this part and contracts with hospitals,  
25                   physicians, and other providers of services and

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

18 “(C) The establishment of procedures (in-  
19 cluding through agreements and contracts de-  
20 scribed in subparagraphs (A) and (B)) to en-  
21 sure that, not later than 90 days after the dis-  
22 pensing of a selected drug to a fair price eligi-  
23 ble individual by a pharmacy or mail order serv-  
24 ice, the pharmacy or mail order service is reim-

1           bursed for an amount equal to the difference  
2           between—

3                   “(i) the lesser of—

4                           “(I) the wholesale acquisition  
5                           cost of the drug;

6                           “(II) the national average drug  
7                           acquisition cost of the drug; and

8                           “(III) any other similar deter-  
9                           mination of pharmacy acquisition  
10                           costs of the drug, as determined by  
11                           the Secretary; and

12                           “(ii) the maximum fair price for the  
13                           drug.

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

17                           “(i) any coverage or financial assist-  
18                           ance under other health benefit plans or  
19                           programs that provide coverage or finan-  
20                           cial assistance for the purchase or provi-  
21                           sion of prescription drug coverage on be-  
22                           half of fair price eligible individuals as the  
23                           Secretary may specify; and

24                           “(ii) any other discounts.

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

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

17          “(G) The establishment of procedures to  
18          negotiate and apply the maximum fair price in  
19          a manner that does not include any dispensing  
20          or similar fee.

21          “(H) The establishment of procedures to  
22          carry out the provisions of this part, as applica-  
23          ble, with respect to—

24                  “(i) fair price eligible individuals who  
25                  are enrolled under a prescription drug plan

1 under part D of title XVIII or an MA–PD  
2 plan under part C of such title;

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

10 “(iii) fair price eligible individuals who  
11 are entitled to benefits under part A of  
12 title XVIII or enrolled under part B of  
13 such title.

14 “(I) The establishment of a negotiation  
15 process and renegotiation process in accordance  
16 with section 1194, including a process for ac-  
17 quiring information described in subsection (d)  
18 of such section and determining amounts de-  
19 scribed in subsection (b) of such section.

20 “(J) The provision of a reasonable dispute  
21 resolution mechanism to resolve disagreements  
22 between manufacturers, fair price eligible indi-  
23 viduals, and the third party with a contract  
24 under subsection (c)(1).

25 “(2) MONITORING COMPLIANCE.—

1           “(A) IN GENERAL.—The Secretary shall  
2           monitor compliance by a manufacturer with the  
3           terms of an agreement under section 1193, in-  
4           cluding by establishing a mechanism through  
5           which violations of such terms may be reported.

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

14          “(b) COLLECTION OF DATA.—

15               “(1) FROM PRESCRIPTION DRUG PLANS AND  
16               MA–PD PLANS.—The Secretary may collect appro-  
17               priate data from prescription drug plans under part  
18               D of title XVIII and MA–PD plans under part C of  
19               such title in a timeframe that allows for maximum  
20               fair prices to be provided under this part for selected  
21               drugs.

22               “(2) FROM HEALTH PLANS.—The Secretary  
23               may collect appropriate data from group health  
24               plans or health insurance issuers offering group or  
25               individual health insurance coverage in a timeframe

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

3 “(c) CONTRACT WITH THIRD PARTIES.—

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

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

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

19 “(C) provide adequate and timely informa-  
20 tion to manufacturers, consistent with the  
21 agreement with the manufacturer under this  
22 part, as necessary for the manufacturer to ful-  
23 fill its obligations under this part; and

24 “(D) permit manufacturers to conduct  
25 periodic audits, directly or through contracts, of



1 the data and information used by the third  
2 party to determine discounts for applicable  
3 drugs of the manufacturer under the program.

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

10 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**  
11 **HEALTH PLANS.**

12 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-  
13 GRAM.—

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

23 “(A) with respect to such selected drug  
24 furnished or dispensed at a pharmacy or by  
25 mail order service if coverage is provided under

1           such plan or coverage during such period for  
2           such selected drug as so furnished or dispensed;  
3           and

4                   “(B) with respect to such selected drug  
5           furnished or administered by a hospital, physi-  
6           cian, or other provider of services or supplier if  
7           coverage is provided under such plan or cov-  
8           erage during such period for such selected drug  
9           as so furnished or administered.

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

20                   “(b) PUBLICATION OF ELECTION.—With respect to  
21           each price applicability period and each selected drug with  
22           respect to such period, the Secretary and the Secretary  
23           of Labor and the Secretary of the Treasury, as applicable,  
24           shall make public a list of each group health plan and each  
25           issuer of health insurance coverage, with respect to which

1 coverage is provided under such plan or coverage for such  
2 drug, that has elected under subsection (a) not to partici-  
3 pate under the program with respect to such period and  
4 drug.

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

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

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

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

24 shall be subject to a civil monetary penalty equal to ten  
25 times the amount equal to the difference between the price

1 for such drug made available for such year by such manu-  
2 facturer with respect to such individual or hospital, physi-  
3 cian, provider, or supplier and the maximum fair price for  
4 such drug for such year.

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

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

18 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

22 “(b) NATIONAL ACADEMY OF MEDICINE STUDY.—  
23 Not later than December 31, 2025, the National Academy  
24 of Medicine shall conduct a study, and submit to Congress  
25 a report, on recommendations for improvements to the

1 program under this part, including the determination of  
2 the limits applied under section 1194(c).

3 “(c) MEDPAC STUDY.—Not later than December 31,  
4 2025, the Medicare Payment Advisory Commission shall  
5 conduct a study, and submit to Congress a report, on the  
6 program under this part with respect to the Medicare pro-  
7 gram under title XVIII, including with respect to the ef-  
8 fect of the program on individuals entitled to benefits or  
9 enrolled under such title.

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

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

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

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

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

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

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

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

7           (1) UNDER MEDICARE.—

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

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

1 (C) APPLICATION AS NEGOTIATED PRICE  
2 UNDER PART D.—Section 1860D–2(d)(1) of the  
3 Social Security Act (42 U.S.C. 1395w–  
4 102(d)(1)) is amended—

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

8 (ii) by adding at the end the following  
9 new subparagraph:

10 “(D) APPLICATION OF MAXIMUM FAIR  
11 PRICE FOR SELECTED DRUGS.—In applying this  
12 section, in the case of a covered part D drug  
13 that is a selected drug (as defined in section  
14 1192(c)), with respect to a price applicability  
15 period (as defined in section 1191(b)(2)), the  
16 negotiated prices used for payment (as de-  
17 scribed in this subsection) shall be the max-  
18 imum fair price (as defined in section  
19 1191(c)(2)) for such drug and for each plan  
20 year during such period.”.

21 (D) INFORMATION FROM PRESCRIPTION  
22 DRUG PLANS AND MA–PD PLANS REQUIRED.—

23 (i) PRESCRIPTION DRUG PLANS.—Sec-  
24 tion 1860D–12(b) of the Social Security  
25 Act (42 U.S.C. 1395w–112(b)) is amended

1           by adding at the end the following new  
2           paragraph:

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

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

15                   “(E) PROVISION OF INFORMATION RE-  
16                   LATED TO MAXIMUM FAIR PRICES.—Section  
17                   1860D–12(b)(8).”.

18           (2) UNDER GROUP HEALTH PLANS AND  
19           HEALTH INSURANCE COVERAGE.—

20                   (A) PHSA.—Part A of title XXVII of the  
21                   Public Health Service Act is amended by insert-  
22                   ing after section 2729 the following new sec-  
23                   tion:



1 **“SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM**  
2 **AND APPLICATION OF MAXIMUM FAIR**  
3 **PRICES.**

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

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

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

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

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

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

1           “(3) the Secretary shall apply the provisions of  
2           such part E to such plan, issuer, and coverage, such  
3           individuals so enrolled in such plans and coverage,  
4           and such hospitals, physicians, and other providers  
5           and suppliers participating in such plans and cov-  
6           erage.

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

20                           (B) ERISA.—

21                           (i) IN GENERAL.—Subpart B of part  
22                           7 of subtitle B of title I of the Employee  
23                           Retirement Income Security Act of 1974  
24                           (29 U.S.C. 1181 et. seq.) is amended by

1 adding at the end the following new sec-  
2 tion:

3 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**  
4 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

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

24 “(2) the plan or issuer shall apply any cost-  
25 sharing responsibilities under such plan or coverage,

1 with respect to such selected drug, by substituting  
2 the maximum fair price negotiated under such part  
3 for such drug in lieu of the contracted rate under  
4 such plan or coverage for such selected drug; and

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

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

20 (ii) CLERICAL AMENDMENT.—The  
21 table of sections for part 7 of subtitle B of  
22 title I of the Employee Retirement Income  
23 Security Act of 1974 is amended by adding  
24 at the end the following:

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

1 (C) IRC.—

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

6 **“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM**  
7 **AND APPLICATION OF MAXIMUM FAIR**  
8 **PRICES.**

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

18 “(1) the provisions of such part shall apply to  
19 the plans offered by such plan, and to the individ-  
20 uals enrolled under such plans, during such period,  
21 with respect to such selected drug, in the same man-  
22 ner as such provisions apply to prescription drug  
23 plans and MA–PD plans, and to individuals enrolled  
24 under such prescription drug plans and MA–PD  
25 plans;

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

7           “(3) the Secretary shall apply the provisions of  
8           such part to such plan and such individuals so en-  
9           rolled in such plan.

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

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

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

1 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**  
2 **IMPOSED DURING NONCOMPLIANCE PERI-**  
3 **ODS.**

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

7 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**  
8 **PERIODS.**

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

14 “(1) such tax, divided by

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

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

20 “(1) The period beginning on the June 16th  
21 immediately following the selected drug publication  
22 date and ending on the first date during which the  
23 manufacturer of the drug has in place an agreement  
24 described in subsection (a) of section 1193 of the  
25 Social Security Act with respect to such drug.



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

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

14          “(4) With respect to information that is re-  
15          quired to be submitted to the Secretary of Health  
16          and Human Services under such agreement, the pe-  
17          riod beginning on the date on which such Secretary  
18          certifies that such information is overdue and ending  
19          on the date that such information is so submitted.

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

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

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

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

9           “(3) in the case of sales of such drug during  
10 the 181st day through the 270th day described in  
11 subsection (b) with respect to such drug, 85 percent,  
12 and

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

15           “(d) DEFINITIONS.—The terms ‘selected drug publi-  
16 cation date’ and ‘maximum fair price’ have the meaning  
17 given such terms in section 1191 of the Social Security  
18 Act and the term ‘selected drug’ has the meaning given  
19 such term in section 1192 of such Act.

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

24           (b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—  
25 Section 275 of the Internal Revenue Code of 1986 is

1 amended by adding “or by section 4192” before the period  
2 at the end of subsection (a)(6).

3 (c) CONFORMING AMENDMENTS.—

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

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

9 (d) CLERICAL AMENDMENTS.—

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

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

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

21 (e) EFFECTIVE DATE.—The amendments made by  
22 this section shall apply to sales after the date of the enact-  
23 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 REBABLE 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 subparagraph (B), the  
12 total number of units of the billing and  
13 payment code for such part B rebatable  
14 drug furnished under this part during the  
15 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 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS  
5 AND EXEMPTION.—

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

22 “(B) TIMELINE FOR PROVISION OF RE-  
23 BATES FOR SUBSEQUENTLY APPROVED  
24 DRUGS.—In the case of a part B rebatable drug  
25 first approved or licensed by the Food and

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

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

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

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

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

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

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

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

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

20          “(8) STUDY AND REPORT.—

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

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

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

7                   “(iii) Including drugs excluded under  
8                   paragraph (2)(A) and 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) in paragraph (4), by inserting “subject  
6                   to paragraph (1)(DD),” before “the applicable  
7                   amount”; and

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

10 “For purposes of applying paragraph (1)(DD), subsection  
11 (t)(23), and section 1834(x)(5), the Secretary shall make  
12 such estimates and use such data as the Secretary deter-  
13 mines appropriate, and notwithstanding any other provi-  
14 sion of law, may do so by program instruction or other-  
15 wise.”;

16                   (2) in subsection (t), by adding at the end the  
17                   following new paragraph:

18                   “(23) PART B REBATABLE DRUGS.—The  
19                   amount of payment under this subsection for a part  
20                   B rebatable drug (as defined in paragraph (2) of  
21                   section 1834(x)) for which the payment amount for  
22                   a calendar quarter under paragraph (3)(A)(ii)(I) of  
23                   such section for such quarter exceeds the inflation  
24                   adjusted payment under paragraph (3)(A)(ii)(II) of  
25                   such section for such quarter and that is furnished



1 as part of a covered OPD service (or group of serv-  
2 ices), shall be the difference between—

3 “(A) the payment under paragraph  
4 (3)(A)(ii)(I) of such section for such drug; and

5 “(B) 20 percent of the inflation-adjusted  
6 payment amount under paragraph (3)(A)(ii)(II)  
7 of such section for such drug.”.

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

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

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

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

19 “(a) IN GENERAL.—

20 “(1) IN GENERAL.—Subject to the provisions of  
21 this section, in order for coverage to be available  
22 under this part for a part D rebatable drug (as de-  
23 fined in subsection (h)(1)) of a manufacturer (as de-  
24 fined in section 1927(k)(5)) dispensed during an ap-  
25 plicable year, the manufacturer must have entered

1 into and have in effect an agreement described in  
2 subsection (b).

3 “(2) AUTHORIZING COVERAGE FOR DRUGS NOT  
4 COVERED UNDER AGREEMENTS.—Paragraph (1)  
5 shall not apply to the dispensing of a covered part  
6 D drug if—

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

10 “(B) the Secretary determines that in a  
11 specified period (as specified by the Secretary),  
12 there were extenuating circumstances.

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

16 “(b) AGREEMENTS.—

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

21 “(A) SECRETARIAL PROVISION OF INFOR-  
22 MATION.—Not later than 9 months after the  
23 end of each applicable year with respect to  
24 which the agreement is in effect, the Secretary,  
25 for each part D rebatable drug of the manufac-

1 turer, shall report to the manufacturer the fol-  
2 lowing for such year:

3 “(i) Information on the total number  
4 of units (as defined in subsection (h)(2))  
5 for each dosage form and strength with re-  
6 spect to such part D rebatable drug and  
7 year.

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

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

18 “(B) MANUFACTURER REQUIREMENTS.—  
19 For each applicable year with respect to which  
20 the agreement is in effect, the manufacturer of  
21 the part D rebatable drug, for each dosage  
22 form and strength with respect to such drug,  
23 not later than 30 days after the date of receipt  
24 from the Secretary of the information described  
25 in subparagraph (A) for such year, shall pro-

1           vide to the Secretary a rebate that is equal to  
2           the amount specified in subsection (c) for such  
3           dosage form and strength with respect to such  
4           drug for such year.

5           “(2) LENGTH OF AGREEMENT.—

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

13                   “(B) TERMINATION.—

14                           “(i) BY SECRETARY.—The Secretary  
15           may provide for termination of an agree-  
16           ment under this section for violation of the  
17           requirements of the agreement or other  
18           good cause shown. Such termination shall  
19           not be effective earlier than 30 days after  
20           the date of notice of such termination. The  
21           Secretary shall provide, upon request, a  
22           manufacturer with a hearing concerning  
23           such a termination, but such hearing shall  
24           not delay the effective date of the termi-  
25           nation.

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 the plan year, as  
8                                 of the day after the end of the plan  
9                                 year; and

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

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

19                                “(D) DELAY BEFORE REENTRY.—In the  
20                   case of any agreement under this section with  
21                   a manufacturer that is terminated in a plan  
22                   year, the Secretary may not enter into another  
23                   such agreement with the manufacturer (or a  
24                   successor manufacturer) before the subsequent  
25                   plan year, unless the Secretary finds good cause

1           for an earlier reinstatement of such an agree-  
2           ment.

3           “(c) REBATE AMOUNT.—

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

10           “(A) the total number of units of such dos-  
11           age form and strength with respect to such part  
12           D rebtable drug and year; and

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

14           “(i) the annual manufacturer price  
15           (as determined in paragraph (2)) paid for  
16           such dosage form and strength with re-  
17           spect to such part D rebtable drug for the  
18           year; exceeds

19           “(ii) the inflation-adjusted payment  
20           amount determined under paragraph (3)  
21           for such dosage form and strength with re-  
22           spect to such part D rebtable drug for the  
23           year.

24           “(2) DETERMINATION OF ANNUAL MANUFAC-  
25           TURER PRICE.—The annual manufacturer price de-

1       terminated under this paragraph for a dosage form  
2       and strength, with respect to a part D rebatable  
3       drug and an applicable year, is the sum of the prod-  
4       ucts of—

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

10              “(B) the ratio of—

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

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

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

23                      “(A) the benchmark year manufacturer  
24       price determined under paragraph (4) for such

1 dosage form and strength with respect to such  
2 drug and an applicable year; increased by

3 “(B) the percentage by which the applica-  
4 ble year CPI-U (as defined in subsection  
5 (h)(5)) for the applicable year exceeds the  
6 benchmark period CPI-U (as defined in sub-  
7 section (h)(4)).

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

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

20 “(B) the ratio of—

21 “(i) the total number of units of such  
22 dosage form and strength dispensed during  
23 such calendar quarter of the payment  
24 amount benchmark year; to



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

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

6                   “(A) SUBSEQUENTLY APPROVED DRUGS.—

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

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

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

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

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

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

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

3 “(D) SELECTED DRUGS.—In the case of a  
4 part D rebatable drug that is a selected drug  
5 (as defined in section 1192(c)) for a price appli-  
6 cability period (as defined in section  
7 1191(b)(2)) and is determined (pursuant to  
8 such section 1192(c)) to no longer be a selected  
9 drug, for each applicable year beginning after  
10 the price applicability period with respect to  
11 such drug, subparagraphs (A) and (B) of para-  
12 graph (4) shall be applied as if the term ‘pay-  
13 ment amount benchmark year’ were defined  
14 under subsection (h)(3) as the last year begin-  
15 ning during such price applicability period with  
16 respect to such selected drug and subparagraph  
17 (B) of paragraph (3) shall be applied as if the  
18 term ‘benchmark period CPI-U’ were defined  
19 under subsection (h)(4) as if the reference to  
20 ‘January 2016’ under such subsection were a  
21 reference to January of the last year beginning  
22 during such price applicability period with re-  
23 spect to such drug.

24 “(d) REBATE DEPOSITS.—Amounts paid as rebates  
25 under subsection (c) shall be deposited into the Medicare

1 Prescription Drug Account in the Federal Supplementary  
2 Medical Insurance Trust Fund established under section  
3 1841.

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

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

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

23 “(1) The determination of units under this sec-  
24 tion.

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

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

5           “(h) DEFINITIONS.—In this section:

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

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

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

22           “(i) for 2023, shall be the dollar  
23 amount specified under such subparagraph  
24 for 2022, increased by the percentage in-  
25 crease in the consumer price index for all

1 urban consumers (United States city aver-  
2 age) for the 12-month period beginning  
3 with January of 2022; and

4 “(ii) for a subsequent year, shall be  
5 the dollar amount specified in this sub-  
6 paragraph (or subparagraph (A)) for the  
7 previous year, increased by the percentage  
8 increase in the consumer price index for all  
9 urban consumers (United States city aver-  
10 age) for the 12-month period beginning  
11 with January of the previous year.

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

15 “(2) UNIT DEFINED.—The term ‘unit’ means,  
16 with respect to a part D rebatable drug, the lowest  
17 identifiable quantity (such as a capsule or tablet,  
18 milligram of molecules, or grams) of the part D  
19 rebatable drug that is dispensed to individuals under  
20 this part.

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

24 “(4) BENCHMARK PERIOD CPI–U.—The term  
25 ‘benchmark period CPI–U’ means the consumer

1 price index for all urban consumers (United States  
2 city average) for January 2016.

3 “(5) APPLICABLE YEAR CPI-U.—The term ‘ap-  
4 plicable year CPI-U’ means, with respect to an ap-  
5 plicable year, the consumer price index for all urban  
6 consumers (United States city average) for January  
7 of such year.

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

14 **TITLE III—PART D IMPROVE-**  
15 **MENTS AND MAXIMUM OUT-**  
16 **OF-POCKET CAP FOR MEDI-**  
17 **CARE BENEFICIARIES**

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

19 (a) BENEFIT STRUCTURE REDESIGN.—Section  
20 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
21 102(b)) is amended—

22 (1) in paragraph (2)—

23 (A) in subparagraph (A), in the matter  
24 preceding clause (i), by inserting “for a year  
25 preceding 2022 and for costs above the annual

1           deductible specified in paragraph (1) and up to  
2           the annual out-of-pocket threshold specified in  
3           paragraph (4)(B) for 2022 and each subsequent  
4           year” after “paragraph (3)”;

5           (B) in subparagraph (C)—

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

10          (ii) in clause (ii)(III), by striking  
11          “and each subsequent year” and inserting  
12          “and 2021”; and

13          (C) in subparagraph (D)—

14          (i) in clause (i)—

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

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

23          (ii) in clause (ii)(V), by striking  
24          “2019 and each subsequent year” and in-



1                   serting “each of years 2019 through  
2                   2021”;

3                   (2) in paragraph (3)(A)—

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

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

10                  (3) in paragraph (4)—

11                  (A) in subparagraph (A)—

12                  (i) in clause (i)—

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

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

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

24                         (III) by striking the period at the  
25                         end of item (bb), as redesignated by

1 subclause (I), and inserting “; and”;  
2 and  
3 (IV) by adding at the end the fol-  
4 lowing:  
5 “(II) for 2022 and each suc-  
6 ceeding year, \$0.”; and  
7 (ii) in clause (ii), by striking “clause  
8 (i)(I)” and inserting “clause (i)(I)(aa)”;  
9 (B) in subparagraph (B)—  
10 (i) in clause (i)—  
11 (I) in subclause (V), by striking  
12 “or” at the end;  
13 (II) in subclause (VI)—  
14 (aa) by striking “for a sub-  
15 sequent year” and inserting “for  
16 2021”; and  
17 (bb) by striking the period  
18 at the end and inserting a semi-  
19 colon; and  
20 (III) by adding at the end the  
21 following new subclauses:  
22 “(VII) for 2022, is equal to  
23 \$2,000; or  
24 “(VIII) for a subsequent year, is  
25 equal to the amount specified in this

1                   subparagraph for the previous year,  
2                   increased by the annual percentage in-  
3                   crease described in paragraph (6) for  
4                   the year involved.”; and

5                   (ii) in clause (ii), by striking “clause  
6                   (i)(II)” and inserting “clause (i)”;

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

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

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

18                  (c)     MANUFACTURER DISCOUNT PROGRAM.—

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

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

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

12       “(b) TERMS OF AGREEMENT.—

13               “(1) IN GENERAL.—

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

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

26                       “(C) TIMING OF AGREEMENT.—

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

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

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

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

10           “(4) LENGTH OF AGREEMENT.—

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

17           “(B) TERMINATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

21 “(2) MONITORING COMPLIANCE.—

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

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

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

13          “(d) ADMINISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

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

11 “(e) ENFORCEMENT.—

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

15 “(2) CIVIL MONEY PENALTY.—

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

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

1           then be used to pay the discounts which  
2           the manufacturer had failed to provide;  
3           and

4                   “(ii) 25 percent of such amount.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 “(4) DISCOUNTED PRICE.—

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

24 “(h) SUNSET OF PROGRAM.—

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

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

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

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

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

20                                 “(I) the reinsurance”; and

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

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

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

3 (B) in subsection (c)(1)(C)—

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

7 “(i) the reinsurance”;

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

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

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

16 (d) CONFORMING AMENDMENTS.—

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

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

23 (B) in subsection (c)(1)(C)—

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

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

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

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

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

19 (A) in paragraph (1)—

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

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

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

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

9 (ii) in subparagraph (E), by striking  
10 “1860D–2(b)(4)(A)(i)(I)” and inserting  
11 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

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

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

1 (C) by adding at the end the following new  
2 clause:

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

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

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

10 (B) by inserting “for such year” before the  
11 period.

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

14 (A) in subsection (a)—

15 (i) by striking paragraph (1) and in-  
16 serting the following:

17 “(1) participate in—

18 “(A) for 2011 through 2021, the Medicare  
19 coverage gap discount program under section  
20 1860D–14A; and

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

24 (ii) by striking paragraph (2) and in-  
25 serting the following:

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

2 “(A) for 2011 through 2021, an agreement  
3 described in subsection (b) of section 1860D–  
4 14A with the Secretary; and

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

8 (iii) by striking paragraph (3) and in-  
9 serting the following:

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

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

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

20 (B) by striking subsection (b) and insert-  
21 ing the following:

22 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),  
23 and (3)(A) of subsection (a) shall apply to covered part  
24 D drugs dispensed under this part on or after January  
25 1, 2011, and before January 1, 2022, and paragraphs



1 (1)(B), (2)(B), and (3)(B) of such subsection shall apply  
2 to covered part D drugs dispensed under this part on or  
3 after January 1, 2022.”.

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

7 **SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**  
8 **TION DRUGS PLANS AND MA-PD PLANS**  
9 **UNDER MEDICARE PROGRAM TO SPREAD**  
10 **OUT COST-SHARING UNDER CERTAIN CIR-**  
11 **CUMSTANCES.**

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

15 (1) in subparagraph (A), by striking “Subject  
16 to subparagraphs (C) and (D)” and inserting “Sub-  
17 ject to subparagraphs (C), (D), and (E)”; and

18 (2) by adding at the end the following new sub-  
19 paragraph:

20 “(E) ENROLLEE OPTION REGARDING  
21 SPREADING COST-SHARING.—The Secretary  
22 shall establish by regulation a process under  
23 which, with respect to plan year 2022 and sub-  
24 sequent plan years, a prescription drug plan or  
25 an MA–PD plan shall, in the case of a part D

1 eligible individual enrolled with such plan for  
2 such plan year who is not a subsidy eligible in-  
3 dividual (as defined in section 1860D–14(a)(3))  
4 and with respect to whom the plan projects that  
5 the dispensing of the first fill of a covered part  
6 D drug to such individual will result in the indi-  
7 vidual incurring costs that are equal to or above  
8 the annual out-of-pocket threshold specified in  
9 paragraph (4)(B) for such plan year, provide  
10 such individual with the option to make the co-  
11 insurance payment required under subpara-  
12 graph (A) (for the portion of such costs that  
13 are not above such annual out-of-pocket thresh-  
14 old) in the form of periodic installments over  
15 the remainder of such plan year.”.

16 **SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**  
17 **URES UNDER MEDICARE PART D.**

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

20 (1) by redesignating the paragraph (6), as  
21 added by section 50354 of division E of the Bipar-  
22 tisan Budget Act of 2018 (Public Law 115–123), as  
23 paragraph (7); and

24 (2) by adding at the end the following new  
25 paragraph:

1           “(8) APPLICATION OF PHARMACY QUALITY  
2 MEASURES.—

3           “(A) IN GENERAL.—A PDP sponsor that  
4 implements incentive payments to a pharmacy  
5 or price concessions paid by a pharmacy based  
6 on quality measures shall use measures estab-  
7 lished or approved by the Secretary under sub-  
8 paragraph (B) with respect to payment for cov-  
9 ered part D drugs dispensed by such pharmacy.

10           “(B) STANDARD PHARMACY QUALITY  
11 MEASURES.—The Secretary shall establish or  
12 approve standard quality measures from a con-  
13 sensus and evidence-based organization for pay-  
14 ments described in subparagraph (A). Such  
15 measures shall focus on patient health outcomes  
16 and be based on proven criteria measuring  
17 pharmacy performance.

18           “(C) EFFECTIVE DATE.—The requirement  
19 under subparagraph (A) shall take effect for  
20 plan years beginning on or after January 1,  
21 2021, or such earlier date specified by the Sec-  
22 retary if the Secretary determines there are suf-  
23 ficient measures established or approved under  
24 subparagraph (B) to meet the requirement  
25 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                   **TITLE V—DRUG PRICE**  
2                   **TRANSPARENCY**

3 **SEC. 501. DRUG PRICE TRANSPARENCY.**

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

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

7           “(a) **DEFINITIONS.**—In this section:

8                   “(1) **MANUFACTURER.**—The term ‘manufac-  
9 turer’ means the person—

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

15                           “(B) who is responsible for setting the  
16 wholesale acquisition cost for the drug.

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

23                           “(A) that has a wholesale acquisition cost  
24 of \$100 or more, adjusted for inflation occur-  
25 ring after the date of enactment of this section,

1 for a month's supply or a typical course of  
2 treatment that lasts less than a month, and  
3 is—

4 “(i) subject to section 503(b)(1) of  
5 the Federal Food, Drug, and Cosmetic  
6 Act; and

7 “(ii) not a preventative vaccine; and

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

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

17 “(b) REPORT.—

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

21 “(A) there is an increase in the price of  
22 the qualifying drug that results in an increase  
23 in the wholesale acquisition cost of that drug  
24 that is equal to—

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

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

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

14                  “(2) REPORT DEADLINE.—Each report de-  
15                  scribed in paragraph (1) shall be submitted to the  
16                  Secretary—

17                         “(A) in the case of a report with respect  
18                         to an increase in the price of a qualifying drug  
19                         that occurs during the period beginning on Janu-  
20                         ary 1, 2019, and ending on the day that is 60  
21                         days after the date of the enactment of this sec-  
22                         tion, not later than 90 days after such date of  
23                         enactment;

24                         “(B) in the case of a report with respect  
25                         to an increase in the price of a qualifying drug

1           that occurs after the period described in sub-  
2           paragraph (A), not later than 30 days prior to  
3           the planned effective date of such price increase  
4           for such qualifying drug; and

5           “(C) in the case of a report with respect  
6           to a qualifying drug that meets the criteria  
7           under paragraph (1)(B), not later than 30 days  
8           after such drug meets such criteria.

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

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

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

1           “(B) an explanation for, and description  
2 of, each price increase for such drug that will  
3 occur during the 12-month period or the 36-  
4 month period described in subsection  
5 (b)(1)(A)(i) or (b)(1)(A)(ii), as applicable;

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

10           “(D) if known and different from the man-  
11 ufacturer of the qualifying drug, the identity  
12 of—

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

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

22           “(II) for licensure of the drug  
23 under section 351 of the Pubic Health  
24 Service Act; and

1                   “(ii) the sponsor of an application for  
2                   the drug approved under such section 505  
3                   of the Federal Food, Drug, and Cosmetic  
4                   Act or licensed under section 351 of the  
5                   Public Health Service Act;

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

15                  “(F) the current wholesale acquisition cost  
16                  of the drug;

17                  “(G) the total expenditures of the manu-  
18                  facturer on—

19                         “(i) materials and manufacturing for  
20                         such drug;

21                         “(ii) acquiring patents and licensing  
22                         for such drug; and

23                         “(iii) purchasing or acquiring such  
24                         drug from another manufacturer, if appli-  
25                         cable;

1           “(H) the percentage of total expenditures  
2 of the manufacturer on research and develop-  
3 ment for such drug that was derived from Fed-  
4 eral funds;

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

13           “(J) the total expenditures of the manufac-  
14 turer on pursuing new or expanded indications  
15 or dosage changes for such drug under section  
16 505 of the Federal Food, Drug, and Cosmetic  
17 Act or section 351 of the Public Health Service  
18 Act;

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

24           “(L) the total revenue and the net profit  
25 generated from the qualifying drug for each cal-



1           endar year since the approval of the application  
2           for the drug under section 505 of the Federal  
3           Food, Drug, and Cosmetic Act or the issuance  
4           of the license for the drug under section 351 of  
5           the Public Health Service Act, or since the  
6           manufacturer acquired such approved applica-  
7           tion or license; and

8                   “(M) the total costs associated with mar-  
9                   keting and advertising for the qualifying drug;  
10                   “(2) with respect to the manufacturer—

11                   “(A) the total revenue and the net profit  
12                   of the manufacturer for each of the 12-month  
13                   period described in subsection (b)(1)(A)(i) or  
14                   the 36-month period described in subsection  
15                   (b)(1)(A)(ii), as applicable;

16                   “(B) all stock-based performance metrics  
17                   used by the manufacturer to determine execu-  
18                   tive compensation for each of the 12-month pe-  
19                   riods described in subsection (b)(1)(A)(i) or the  
20                   36-month periods described in subsection  
21                   (b)(1)(A)(ii), as applicable; and

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

1 “(i) drug research and development;

2 or

3 “(ii) clinical trials, including on drugs

4 that failed to receive approval by the Food

5 and Drug Administration; and

6 “(3) such other related information as the Sec-

7 retary considers appropriate and as specified by the

8 Secretary.

9 “(d) INFORMATION PROVIDED.—The manufacturer

10 of a qualifying drug that is required to submit a report

11 under subsection (b), shall ensure that such report and

12 any explanation for, and description of, each price increase

13 described in subsection (c)(1) shall be truthful, not mis-

14 leading, and accurate.

15 “(e) CIVIL MONETARY PENALTY.—Any manufac-

16 turer of a qualifying drug that fails to submit a report

17 for the drug as required by this section, following notifica-

18 tion by the Secretary to the manufacturer that the manu-

19 facturer is not in compliance with this section, shall be

20 subject to a civil monetary penalty of \$75,000 for each

21 day on which the violation continues.

22 “(f) FALSE INFORMATION.—Any manufacturer that

23 submits a report for a drug as required by this section

24 that knowingly provides false information in such report

1 is subject to a civil monetary penalty in an amount not  
2 to exceed \$100,000 for each item of false information.

3 “(g) PUBLIC POSTING.—

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

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

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

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

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

1 manufacturer was required to submit such report  
2 based on a qualifying price increase or whether such  
3 drug meets the criteria under subsection (b)(1)(B).

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

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

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

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

20 “(2) including copies of the reports and sup-  
21 porting detailed economic analyses submitted pursu-  
22 ant to such section;

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

1           “(4) explaining how the Department of Health  
2           and Human Services is improving consumer and  
3           provider information about drug value and drug  
4           price transparency.

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

