

116TH CONGRESS
1ST SESSION

H. R. 3

[Report No. 116-]

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 19, 2019

Mr. PALLONE (for himself, Mr. NEAL, and Mr. SCOTT of Virginia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

OCTOBER --, 2019

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on September 19, 2019]

A BILL

To establish a fair price negotiation program, protect the Medicare program from excessive price increases, and establish an out-of-pocket maximum for Medicare part D enrollees, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
 2 *tives of the United States of America in Congress assembled,*

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

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

6 (b) *TABLE OF CONTENTS.*—*The table of contents is as*
 7 *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 infor-
 mation comparing premiums of certain prescription drug plans.*

*Sec. 403. Providing for intelligent assignment of certain subsidy eligible individ-
 uals 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 pre-
 mium 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 pro-
 gram.*

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.

TITLE VI—MISCELLANEOUS

Sec. 601. Temporary increase in Medicare part B payment for certain biosimilar biological products.

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

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

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

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

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

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

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

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

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

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

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

11 “(1) *INITIAL PRICE APPLICABILITY YEAR.—The*
12 *term ‘initial price applicability year’ means a plan*
13 *year (beginning with plan year 2023) or, if agreed to*
14 *in an agreement under section 1193 by the Secretary*
15 *and manufacturer involved, a period of more than*
16 *one plan year (beginning on or after January 1,*
17 *2023).*

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

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

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

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

8 “(A) *beginning on the sooner of—*

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

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

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

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

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

23 “(A) *in the case such drug is furnished or*
24 *dispensed to the individual at a pharmacy or by*
25 *a mail order service—*

1 “(i) an individual who is enrolled
2 under a prescription drug plan under part
3 D of title XVIII or an MA–PD plan under
4 part C of such title under which coverage is
5 provided for such drug; 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 in
10 section 2791 of the Public Health Service
11 Act) with respect to which there is in effect
12 an agreement with the Secretary under sec-
13 tion 1197 with respect to such selected drug
14 as so furnished or dispensed; and

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

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

24 “(ii) an individual who is enrolled
25 under a group health plan or health insur-

1 *ance coverage offered in the group or indi-*
2 *vidual market (as such terms are defined in*
3 *section 2791 of the Public Health Service*
4 *Act) with respect to which there is in effect*
5 *an agreement with the Secretary under sec-*
6 *tion 1197 with respect to such selected drug*
7 *as so furnished or administered.*

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

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

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

1 *or package type), as computed (as of the date of*
2 *publication of such drug as a selected drug under*
3 *section 1192(a)) in all countries described in*
4 *clause (ii) of subparagraph (B) that are applica-*
5 *ble countries (as described in clause (i) of such*
6 *subparagraph) with respect to such drug.*

7 *“(B) APPLICABLE COUNTRIES.—*

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

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

18 *“(I) Australia.*

19 *“(II) Canada.*

20 *“(III) France.*

21 *“(IV) Germany.*

22 *“(V) Japan.*

23 *“(VI) The United Kingdom.*

24 *“(4) UNIT.—The term ‘unit’ means, with respect*
25 *to a drug, the lowest identifiable quantity (such as a*

1 *capsule or tablet, milligram of molecules, or grams) of*
2 *the drug that is dispensed.*

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

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

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

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

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

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

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

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

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

1 *minimum amount of drugs to be selected under paragraph*
2 *(1) for any subsequent year, including such a drug so se-*
3 *lected that is subject to renegotiation under section 1194.*

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

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

1 *plan year beginning after the date on which the Secretary*
2 *determines two or more drug products—*

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

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

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

10 *“(2) continue to be marketed.*

11 *“(d) NEGOTIATION-ELIGIBLE DRUG.—*

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

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

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

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

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

18 “(3) *PUBLICATION.*—*Not later than the selected*
19 *drug publication date with respect to an initial price*
20 *applicability year, the Secretary shall publish in the*
21 *Federal Register a list of negotiation-eligible drugs*
22 *with respect to such selected drug publication date.*

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

1 “(1) *DRUG PRODUCTS.*—A drug that—

2 “(A) is approved under section 505(c) of the
3 *Federal Food, Drug, and Cosmetic Act* and con-
4 *tinues to be marketed pursuant to such approval;*
5 *and*

6 “(B) is not the listed drug for any drug
7 *that is approved and continues to be marketed*
8 *under section 505(j) of such Act.*

9 “(2) *BIOLOGICAL PRODUCTS.*—A biological prod-
10 *uct that—*

11 “(A) is licensed under section 351(a) of the
12 *Public Health Service Act, including any prod-*
13 *uct that has been deemed to be licensed under*
14 *section 351 of such Act pursuant to section*
15 *7002(e)(4) of the Biologics Price Competition*
16 *and Innovation Act of 2009, and continues to be*
17 *marketed under section 351 of such Act; and*

18 “(B) is not the reference product for any bi-
19 *ological product that is licensed and continues to*
20 *be marketed under section 351(k) of such Act.*

21 “(3) *INSULIN PRODUCT.*—Notwithstanding para-
22 *graphs (1) and (2), any insulin product that is ap-*
23 *proved under subsection (c) or (j) of section 505 of the*
24 *Federal Food, Drug, and Cosmetic Act or licensed*
25 *under subsection (a) or (k) of section 351 of the Pub-*

1 *lic Health Service Act and continues to be marketed*
2 *under such section 505 or 351, including any insulin*
3 *product that has been deemed to be licensed under sec-*
4 *tion 351(a) of the Public Health Service Act pursuant*
5 *to section 7002(e)(4) of the Biologics Price Competi-*
6 *tion and Innovation Act of 2009 and continues to be*
7 *marketed pursuant to such licensure.*

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

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

25 “(g) *NEW-ENTRANT NEGOTIATION-ELIGIBLE DRUGS.—*

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

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

10 “(B) that the Secretary determines under
11 paragraph (2) is likely to be a negotiation-eli-
12 gible drug with respect to the subsequent selected
13 drug publication date.

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

1 *tion-eligible drug with respect to the subsequent se-*
2 *lected drug publication date, based on the projected*
3 *spending under title XVIII or in the United States on*
4 *such drug. For purposes of this paragraph the term*
5 *‘United States’ includes the 50 States, the District of*
6 *Columbia, and the territories of the United States.*

7 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

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

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

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

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

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

10 *“(2) the Secretary and the manufacturer shall,*
11 *in accordance with a process and during a period*
12 *specified by the Secretary pursuant to rulemaking, re-*
13 *negotiate (and, by not later than the last date of such*
14 *period and in accordance with subsection (c), agree*
15 *to) the maximum fair price for such drug if the Sec-*
16 *retary determines that there is a material change in*
17 *any of the factors described in section 1194(d) relat-*
18 *ing to the drug, including changes in the AIM price*
19 *for such drug, in order to provide access to such max-*
20 *imum fair price (as so renegotiated)—*

21 *“(A) to fair price eligible individuals who*
22 *with respect to such drug are described in sub-*
23 *paragraph (A) of section 1191(c)(1) and are fur-*
24 *nished or dispensed such drug during any year*
25 *during the price applicability period (beginning*

1 *after such renegotiation) with respect to such se-*
2 *lected drug; and*

3 *“(B) to hospitals, physicians, and other*
4 *providers of services and suppliers with respect*
5 *to fair price eligible individuals who with respect*
6 *to such drug are described in subparagraph (B)*
7 *of such section and are furnished or adminis-*
8 *tered such drug during any year described in*
9 *subparagraph (A);*

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

17 *“(4) the manufacturer, subject to subsection (d),*
18 *submits to the Secretary, in a form and manner spec-*
19 *ified by the Secretary—*

20 *“(A) for the voluntary negotiation period*
21 *for the price applicability period (and, if appli-*
22 *cable, before any period of renegotiation specified*
23 *pursuant to paragraph (2)) with respect to such*
24 *drug all information that the Secretary requires*
25 *to carry out the negotiation (or renegotiation*

1 *process) under this part, including information*
2 *described in section 1192(f) and section*
3 *1194(d)(1); and*

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

9 *“(5) the manufacturer agrees that in the case the*
10 *selected drug of a manufacturer is a drug described*
11 *in subsection (c), the manufacturer will, in accord-*
12 *ance with such subsection, make any payment re-*
13 *quired 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 drug*
2 *for which there is no AIM price available with respect*
3 *to the initial price applicability year for such drug*
4 *and for which an AIM price becomes available begin-*
5 *ning with respect to a subsequent plan year during*
6 *the price applicability period for such drug, if the*
7 *Secretary determines that the amount described in*
8 *paragraph (2)(A) for a unit of such drug is greater*
9 *than the amount described in paragraph (2)(B) for a*
10 *unit of such drug, then by not later than one year*
11 *after the date of such determination, the manufac-*
12 *turer of such selected drug shall pay to the Treasury*
13 *an amount equal to the product of—*

14 “(A) *the difference between such amount de-*
15 *scribed in paragraph (2)(A) for a unit of such*
16 *drug and such amount described in paragraph*
17 *(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, the*
20 *District of Columbia, and the territories of the*
21 *United States, during the period described in*
22 *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 subpara-*
2 *graph for a selected drug described in such para-*
3 *graph, is the amount equal to the weighted aver-*
4 *age manufacturer price (as defined in section*
5 *1927(k)(1)) for such dosage strength and form for*
6 *the drug during the period beginning with the*
7 *first plan year for which the drug is included on*
8 *the list of negotiation-eligible drugs published*
9 *under section 1192(d) and ending with the last*
10 *plan year during the price applicability period*
11 *for such drug with respect to which there is no*
12 *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 plan*
19 *year during the price applicability period for*
20 *such drug with respect to which there is an AIM*
21 *price available for such drug.*

22 “(d) *CONFIDENTIALITY OF INFORMATION.—Informa-*
23 *tion submitted to the Secretary under this part by a manu-*
24 *facturer of a selected drug that is proprietary information*
25 *of such manufacturer (as determined by the Secretary) may*

1 *be used only by the Secretary or disclosed to and used by*
2 *the Comptroller General of the United States or the Medi-*
3 *care Payment Advisory Commission for purposes of car-*
4 *rying 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 de-*
11 *scribed in paragraph (1), with respect to a selected*
12 *drug, shall include information on sales of the drug*
13 *(by the manufacturer of the drug or by another entity*
14 *under license or other agreement with the manufac-*
15 *turer, with respect to the sales of such drug, regardless*
16 *of the name under which the drug is sold) in any for-*
17 *ign country that is part of the AIM price. The Sec-*
18 *retary shall verify, to the extent practicable, such*
19 *sales from appropriate officials of the government of*
20 *the foreign country involved.*

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

1 *a contract under section 1196(c)(1), as applicable, for pur-*
2 *poses 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 and*
6 *a manufacturer of a selected drug, with respect to the period*
7 *for which such agreement is in effect and in accordance*
8 *with subsections (b) and (c), the Secretary and the manu-*
9 *facturer—*

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 the*
14 *purpose described in section 1193(a)(1); and*

15 *“(2) as applicable pursuant to section 1193(a)(2)*
16 *and in accordance with the process specified pursuant*
17 *to such section, renegotiate such maximum fair price*
18 *for such drug for the purpose described in such sec-*
19 *tion.*

20 **“(b) NEGOTIATING METHODOLOGY AND OBJECTIVE.—**

21 *“(1) IN GENERAL.—The Secretary shall develop*
22 *and use a consistent methodology for negotiations*
23 *under subsection (a) that, in accordance with para-*
24 *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 factors*
8 *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 described*
13 *in paragraph (1)(B) of such subsection.*

14 “(C) *UNIT COSTS OF PRODUCTION AND DIS-*
15 *TRIBUTION.*—*The factor described in paragraph*
16 *(1)(C) of such subsection.*

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

20 “(3) *REQUIREMENT.*—

21 “(A) *IN GENERAL.*—*In negotiating the max-*
22 *imum fair price of a selected drug, with respect*
23 *to an initial price applicability year for the se-*
24 *lected drug, and, as applicable, in renegotiating*
25 *the maximum fair price for such drug, with re-*

1 *spect to a subsequent year during the price ap-*
2 *plicability period for such drug, in the case that*
3 *the manufacturer of the selected drug offers*
4 *under the negotiation or renegotiation, as appli-*
5 *cable, a price for such drug that is not more*
6 *than the target price described in subparagraph*
7 *(B) for such drug for the respective year, the Sec-*
8 *retary shall agree under such negotiation or re-*
9 *negotiation, respectively, to such offered price as*
10 *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 com-
19 puted (across different dosage forms and
20 strengths of the drug and not based on the
21 specific formulation or package size or
22 package type of the drug) in the applicable
23 country described in section 1191(c)(3)(B)
24 with respect to such drug that, with respect
25 to such year, has the lowest average price

1 *for such drug as compared to the average*
2 *prices (as so computed) of such drug with*
3 *respect to such year in the other applicable*
4 *countries described in such section with re-*
5 *spect to such drug.*

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

23 “(4) *ANNUAL REPORT.—After the completion of*
24 *each voluntary negotiation period, the Secretary shall*
25 *submit to Congress a report on the maximum fair*

1 *prices negotiated (or, as applicable, renegotiated) for*
2 *such period. Such report shall include information on*
3 *how such prices so negotiated (or renegotiated) meet*
4 *the requirements of this part, including the require-*
5 *ments of this subsection.*

6 “(c) *LIMITATION.*—

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

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

1 “(d) *CONSIDERATIONS.*—*For purposes of negotiating*
2 *and, as applicable, renegotiating (including for purposes of*
3 *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 factors:*

7 “(1) *MANUFACTURER-SPECIFIC INFORMATION.*—
8 *The following information, including as submitted by*
9 *the manufacturer:*

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

14 “(B) *Market data for the drug, including*
15 *the distribution of sales across different pro-*
16 *grams and purchasers and projected future reve-*
17 *nues for the drug.*

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

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

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

25 “(F) *National sales data for the drug.*

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

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

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

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

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

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

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

5 *“(3) FOREIGN SALES INFORMATION.—To the ex-*
6 *tent available on a timely basis, including as pro-*
7 *vided by a manufacturer of the selected drug or other-*
8 *wise, information on sales of the selected drug in each*
9 *of the countries described in section 1191(c)(3)(B).*

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

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

22 *“(1) the Secretary shall, not later than the se-*
23 *lected drug publication date with respect to the initial*
24 *price applicability year of such period, request drug*
25 *pricing information from the manufacturer of such*

1 *selected drug, including information described in sub-*
2 *section (d)(1); and*

3 “(2) *by not later than October 1 following the se-*
4 *lected drug publication date, the manufacturer of such*
5 *selected drug shall submit to the Secretary such re-*
6 *quested information in such form and manner as the*
7 *Secretary may require.*

8 *The Secretary shall request, from the manufacturer or oth-*
9 *ers, such additional information as may be needed to carry*
10 *out the negotiation and renegotiation process under this sec-*
11 *tion.*

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

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

20 “(b) *UPDATES.—*

21 “(1) *SUBSEQUENT YEAR MAXIMUM FAIR*
22 *PRICES.—For a selected drug, for each plan year sub-*
23 *sequent to the initial price applicability year for such*
24 *drug with respect to which an agreement for such*

1 *drug is in effect under section 1193, the Secretary*
2 *shall publish in the Federal Register—*

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

10 “(B) *in the case the maximum fair price for*
11 *such drug was renegotiated, for the first year for*
12 *which such price as so renegotiated applies, such*
13 *renegotiated maximum fair price.*

14 “(2) *PRICES NEGOTIATED AFTER DEADLINE.—In*
15 *the case of a selected drug with respect to an initial*
16 *price applicability year for which the maximum fair*
17 *price is determined under this part after the date of*
18 *publication under this section, the Secretary shall*
19 *publish such maximum fair price in the Federal Reg-*
20 *ister by not later than 30 days after the date such*
21 *maximum price is so determined.*

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

24 “(a) *ADMINISTRATIVE DUTIES.—*

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

4 “(A) *The establishment of procedures (in-*
5 *cluding through agreements with manufacturers*
6 *under this part, contracts with prescription drug*
7 *plans under part D of title XVIII and MA-PD*
8 *plans under part C of such title, and agreements*
9 *under section 1197 with group health plans and*
10 *health insurance issuers of health insurance cov-*
11 *erage offered in the individual or group market)*
12 *under which the maximum fair price for a se-*
13 *lected drug is provided to fair price eligible indi-*
14 *viduals, who with respect to such drug are de-*
15 *scribed in subparagraph (A) of section*
16 *1191(c)(1), at pharmacies or by mail order serv-*
17 *ice at the point-of-sale of the drug for the appli-*
18 *cable price period for such drug and providing*
19 *that such maximum fair price is used for deter-*
20 *mining cost-sharing under such plans or cov-*
21 *erage 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 the*
4 *individual or group market) under which, in the*
5 *case of a selected drug furnished or administered*
6 *by such a hospital, physician, or other provider*
7 *of services or supplier to fair price eligible indi-*
8 *viduals (who with respect to such drug are de-*
9 *scribed 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 ensure*
21 *that, not later than 90 days after the dispensing*
22 *of a selected drug to a fair price eligible indi-*
23 *vidual by a pharmacy or mail order service, the*
24 *pharmacy or mail order service is reimbursed for*
25 *an amount equal to the difference between—*

1 “(i) the lesser of—

2 “(I) the wholesale acquisition cost
3 of the drug;

4 “(II) the national average drug
5 acquisition cost of the drug; and

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

10 “(ii) the maximum fair price for the
11 drug.

12 “(D) The establishment of procedures to en-
13 sure that the maximum fair price for a selected
14 drug is applied before—

15 “(i) any coverage or financial assist-
16 ance under other health benefit plans or
17 programs that provide coverage or financial
18 assistance for the purchase or provision of
19 prescription drug coverage on behalf of fair
20 price eligible individuals as the Secretary
21 may specify; and

22 “(ii) any other discounts.

23 “(E) The establishment of procedures to
24 enter into appropriate agreements and protocols
25 for the ongoing computation of AIM prices for

1 *selected drugs, including, to the extent possible,*
2 *to compute the AIM price for selected drugs and*
3 *including by providing that the manufacturer of*
4 *such a selected drug should provide information*
5 *for such computation not later than 3 months*
6 *after the first date of the voluntary negotiation*
7 *period for such selected drug.*

8 “(F) *The establishment of procedures to*
9 *compute and apply the maximum fair price*
10 *across different strengths and dosage forms of a*
11 *selected drug and not based on the specific for-*
12 *mulation or package size or package type of the*
13 *drug.*

14 “(G) *The establishment of procedures to ne-*
15 *gotiate and apply the maximum fair price in a*
16 *manner that does not include any dispensing or*
17 *similar fee.*

18 “(H) *The establishment of procedures to*
19 *carry out the provisions of this part, as applica-*
20 *ble, with respect to—*

21 “(i) *fair price eligible individuals who*
22 *are enrolled under a prescription drug plan*
23 *under part D of title XVIII or an MA–PD*
24 *plan under part C of such title;*

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

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

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

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

23 “(2) *MONITORING COMPLIANCE.—*

24 “(A) *IN GENERAL.—The Secretary shall*
25 *monitor compliance by a manufacturer with the*

1 *terms of an agreement under section 1193, in-*
2 *cluding by establishing a mechanism through*
3 *which violations of such terms may be reported.*

4 “(B) *NOTIFICATION.*—*If a third party with*
5 *a contract under subsection (c)(1) determines*
6 *that the manufacturer is not in compliance with*
7 *such agreement, the third party shall notify the*
8 *Secretary of such noncompliance for appropriate*
9 *enforcement under section 4192 of the Internal*
10 *Revenue Code of 1986 or section 1198, as appli-*
11 *cable.*

12 “(b) *COLLECTION OF DATA.*—

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

20 “(2) *FROM HEALTH PLANS.*—*The Secretary may*
21 *collect appropriate data from group health plans or*
22 *health insurance issuers offering group or individual*
23 *health insurance coverage in a timeframe that allows*
24 *for maximum fair prices to be provided under this*
25 *part for selected drugs.*

1 “(c) *CONTRACT WITH THIRD PARTIES.*—

2 “(1) *IN GENERAL.*—*The Secretary may enter*
3 *into a contract with 1 or more third parties to ad-*
4 *minister the requirements established by the Secretary*
5 *in order to carry out this part. At a minimum, the*
6 *contract with a third party under the preceding sen-*
7 *tence shall require that the third party—*

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

12 “(B) *receive, distribute, or facilitate the dis-*
13 *tribution of funds of manufacturers to appro-*
14 *priate individuals or entities in order to meet*
15 *the obligations of manufacturers under agree-*
16 *ments under this part;*

17 “(C) *provide adequate and timely informa-*
18 *tion to manufacturers, consistent with the agree-*
19 *ment with the manufacturer under this part, as*
20 *necessary for the manufacturer to fulfill its obli-*
21 *gations under this part; and*

22 “(D) *permit manufacturers to conduct peri-*
23 *odic audits, directly or through contracts, of the*
24 *data and information used by the third party to*

1 *determine discounts for applicable drugs of the*
2 *manufacturer under the program.*

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

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

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

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

21 “(A) *with respect to such selected drug fur-*
22 *nished or dispensed at a pharmacy or by mail*
23 *order service if coverage is provided under such*
24 *plan or coverage during such period for such se-*
25 *lected drug as so furnished or dispensed; and*

1 “(B) *with respect to such selected drug fur-*
2 *nished or administered by a hospital, physician,*
3 *or other provider of services or supplier if cov-*
4 *erage is provided under such plan or coverage*
5 *during such period for such selected drug as so*
6 *furnished or administered.*

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

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

1 *pate under the program with respect to such period and*
2 *drug.*

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

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

11 *“(1) to a fair price eligible individual who with*
12 *respect to such drug is described in subparagraph (A)*
13 *of section 1191(c)(1) and who is furnished or dis-*
14 *persed such drug during such year; or*

15 *“(2) to a hospital, physician, or other provider*
16 *of services or supplier with respect to fair price eligi-*
17 *ble individuals who with respect to such drug is de-*
18 *scribed in subparagraph (B) of such section and is*
19 *furnished or administered such drug by such hospital,*
20 *physician, or provider or supplier during such year;*
21 *shall be subject to a civil monetary penalty equal to ten*
22 *times the amount equal to the difference between the price*
23 *for such drug made available for such year by such manu-*
24 *facturer with respect to such individual or hospital, physi-*

1 *cian, provider, or supplier and the maximum fair price for*
2 *such drug for such year.*

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

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

16 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

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

1 “(c) *MEDPAC STUDY.*—Not later than December 31,
2 2025, the Medicare Payment Advisory Commission shall
3 conduct a study, and submit to Congress a report, on the
4 program under this part with respect to the Medicare pro-
5 gram under title XVIII, including with respect to the effect
6 of the program on individuals entitled to benefits or enrolled
7 under such title.

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

10 “(1) *The selection of drugs for publication under*
11 *section 1192(a).*

12 “(2) *The determination of whether a drug is a*
13 *negotiation-eligible drug under section 1192(d).*

14 “(3) *The determination of the maximum fair*
15 *price of a selected drug under section 1194.*

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

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

24 “(f) *DATA SHARING.*—The Secretary shall share with
25 the Secretary of the Treasury such information as is nec-

1 *essary to determine the tax imposed by section 4192 of the*
2 *Internal Revenue Code of 1986.”.*

3 *(b) APPLICATION OF MAXIMUM FAIR PRICES AND CON-*
4 *FORMING AMENDMENTS.—*

5 *(1) UNDER MEDICARE.—*

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

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

22 *(C) APPLICATION AS NEGOTIATED PRICE*
23 *UNDER PART D.—Section 1860D–2(d)(1) of the*
24 *Social Security Act (42 U.S.C. 1395w–*
25 *102(d)(1)) is amended—*

1 (i) in subparagraph (B), by inserting
2 “, subject to subparagraph (D),” after “ne-
3 gotiated prices”; and

4 (ii) by adding at the end the following
5 new subparagraph:

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

16 (D) *INFORMATION FROM PRESCRIPTION*
17 *DRUG PLANS AND MA–PD PLANS REQUIRED.—*

18 (i) *PRESCRIPTION DRUG PLANS.—Sec-*
19 *tion 1860D–12(b) of the Social Security Act*
20 *(42 U.S.C. 1395w–112(b)) is amended by*
21 *adding at the end the following new para-*
22 *graph:*

23 “(8) *PROVISION OF INFORMATION RELATED TO*
24 *MAXIMUM FAIR PRICES.—Each contract entered into*
25 *with a PDP sponsor under this part with respect to*

1 *a prescription drug plan offered by such sponsor shall*
2 *require the sponsor to provide information to the Sec-*
3 *retary as requested by the Secretary in accordance*
4 *with section 1196(b).”.*

5 *(ii) MA–PD PLANS.—Section*
6 *1857(f)(3) of the Social Security Act (42*
7 *U.S.C. 1395w–27(f)(3)) is amended by add-*
8 *ing at the end the following new subpara-*
9 *graph:*

10 *“(E) PROVISION OF INFORMATION RELATED*
11 *TO MAXIMUM FAIR PRICES.—Section 1860D–*
12 *12(b)(8).”.*

13 *(2) UNDER GROUP HEALTH PLANS AND HEALTH*
14 *INSURANCE COVERAGE.—*

15 *(A) PHSA.—Part A of title XXVII of the*
16 *Public Health Service Act is amended by insert-*
17 *ing after section 2729 the following new section:*

18 **“SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM**
19 **AND APPLICATION OF MAXIMUM FAIR**
20 **PRICES.**

21 *“(a) IN GENERAL.—In the case of a group health plan*
22 *or health insurance issuer offering health insurance cov-*
23 *erage that is treated under section 1197 of the Social Secu-*
24 *rity Act as having in effect an agreement with the Secretary*
25 *under the Fair Price Drug Negotiation Program under part*

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

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

7 “(A) if coverage of such selected drug is pro-
8 vided under such plan or coverage if the drug is
9 furnished or dispensed at a pharmacy or by a
10 mail order service, to the plans or coverage of-
11 fered by such plan or issuer, and to the individ-
12 uals enrolled under such plans or coverage, dur-
13 ing such period, with respect to such selected
14 drug, in the same manner as such provisions
15 apply to prescription drug plans and MA–PD
16 plans, and to individuals enrolled under such
17 prescription drug plans and MA–PD plans dur-
18 ing such period; and

19 “(B) if coverage of such selected drug is pro-
20 vided under such plan or coverage if the drug is
21 furnished or administered by a hospital, physi-
22 cian, or other provider of services or supplier, to
23 the plans or coverage offered by such plan or
24 issuers, to the individuals enrolled under such
25 plans or coverage, and to hospitals, physicians,

1 *and other providers of services and suppliers*
2 *during such period, with respect to such drug in*
3 *the same manner as such provisions apply to the*
4 *Secretary, to individuals entitled to benefits*
5 *under part A of title XVIII or enrolled under*
6 *part B of such title, and to hospitals, physicians,*
7 *and other providers and suppliers participating*
8 *under title XVIII during such period;*

9 “(2) *the plan or issuer shall apply any cost-shar-*
10 *ing responsibilities under such plan or coverage, with*
11 *respect to such selected drug, by substituting an*
12 *amount not more than the maximum fair price nego-*
13 *tiated under such part E of title XI for such drug in*
14 *lieu of the drug price upon which the cost-sharing*
15 *would have otherwise applied; and*

16 “(3) *the Secretary shall apply the provisions of*
17 *such part E to such plan, issuer, and coverage, such*
18 *individuals so enrolled in such plans and coverage,*
19 *and such hospitals, physicians, and other providers*
20 *and suppliers participating in such plans and cov-*
21 *erage.*

22 “(b) *NOTIFICATION REGARDING NONPARTICIPATION IN*
23 *FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group*
24 *health plan or a health insurance issuer offering group or*
25 *individual health insurance coverage shall publicly disclose*

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

10 (B) *ERISA.*—

11 (i) *IN GENERAL.*—*Subpart B of part 7*
12 *of subtitle B of title I of the Employee Re-*
13 *tirement Income Security Act of 1974 (29*
14 *U.S.C. 1181 et. seq.) is amended by adding*
15 *at the end the following new section:*

16 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
17 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

1 *such Act) with respect to such period with respect to which*
2 *coverage is provided under such plan or coverage—*

3 “(1) *the provisions of such part shall apply to*
4 *the plans or coverage offered by such plan or issuer,*
5 *and to the individuals enrolled under such plans or*
6 *coverage, during such period, with respect to such se-*
7 *lected drug, in the same manner as such provisions*
8 *apply to prescription drug plans and MA–PD plans,*
9 *and to individuals enrolled under such prescription*
10 *drug plans and MA–PD plans;*

11 “(2) *the plan or issuer shall apply any cost-shar-*
12 *ing responsibilities under such plan or coverage, with*
13 *respect to such selected drug, by substituting the max-*
14 *imum fair price negotiated under such part for such*
15 *drug in lieu of the contracted rate under such plan*
16 *or coverage for such selected drug; and*

17 “(3) *the Secretary shall apply the provisions of*
18 *such part to such plan, issuer, and coverage, and such*
19 *individuals so enrolled in such plans.*

20 “(b) *NOTIFICATION REGARDING NONPARTICIPATION IN*
21 *FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group*
22 *health plan or a health insurance issuer offering group*
23 *health insurance coverage shall publicly disclose in a man-*
24 *ner and in accordance with a process specified by the Sec-*
25 *retary any election made under section 1197 of the Social*

1 *Security Act by the plan or issuer to not participate in*
2 *the Fair Drug Price Negotiation Program under part E*
3 *of title XI of such Act with respect to a selected drug (as*
4 *defined in section 1192(c) of such Act) for which coverage*
5 *is provided under such plan or coverage before the begin-*
6 *ning of the plan year for which such election was made.”.*

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

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

12 *(C) IRC.—*

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

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

19 *“(a) IN GENERAL.—In the case of a group health plan*
20 *that is treated under section 1197 of the Social Security*
21 *Act as having in effect an agreement with the Secretary*
22 *under the Fair Price Drug Negotiation Program under part*
23 *E of title XI of such Act, with respect to a price applica-*
24 *bility period (as defined in section 1191(b) of such Act) and*

1 *a selected drug (as defined in section 1192(c) of such Act)*
2 *with respect to such period with respect to which coverage*
3 *is provided under such plan—*

4 “(1) *the provisions of such part shall apply to*
5 *the plans offered by such plan, and to the individuals*
6 *enrolled under such plans, during such period, with*
7 *respect to such selected drug, in the same manner as*
8 *such provisions apply to prescription drug plans and*
9 *MA–PD plans, and to individuals enrolled under*
10 *such prescription drug plans and MA–PD plans;*

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

17 “(3) *the Secretary shall apply the provisions of*
18 *such part to such plan and such individuals so en-*
19 *rolled in such plan.*

20 “(b) *NOTIFICATION REGARDING NONPARTICIPATION IN*
21 *FAIR DRUG PRICE NEGOTIATION PROGRAM.—A group*
22 *health plan shall publicly disclose in a manner and in ac-*
23 *cordance with a process specified by the Secretary any elec-*
24 *tion made under section 1197 of the Social Security Act*
25 *by the plan to not participate in the Fair Drug Price Nego-*

1 *tiation Program under part E of title XI of such Act with*
2 *respect to a selected drug (as defined in section 1192(c) of*
3 *such Act) for which coverage is provided under such plan*
4 *before the beginning of the plan year for which such election*
5 *was made.”.*

6 *(ii) CLERICAL AMENDMENT.—The table*
7 *of sections for subchapter B of chapter 100*
8 *of such Code is amended by adding at the*
9 *end the following new item:*

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

10 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX IM-**
11 **POSED DURING NONCOMPLIANCE PERIODS.**

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

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

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

22 *“(1) such tax, divided by*

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

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

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

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

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

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

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

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

10 *“(c) APPLICABLE PERCENTAGE.—The term ‘applicable*
11 *percentage’ means—*

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

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

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

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

23 *“(d) DEFINITIONS.—The terms ‘selected drug publica-*
24 *tion date’ and ‘maximum fair price’ have the meaning*
25 *given such terms in section 1191 of the Social Security Act*

1 *and the term ‘selected drug’ has the meaning given such*
2 *term in section 1192 of such Act.*

3 “(e) *ANTI-ABUSE RULE.—In the case of a sale which*
4 *was timed for the purpose of avoiding the tax imposed by*
5 *this section, the Secretary may treat such sale as occurring*
6 *during a day described in subsection (b).”.*

7 (b) *NO DEDUCTION FOR EXCISE TAX PAYMENTS.—*
8 *Section 275 of the Internal Revenue Code of 1986 is amend-*
9 *ed by adding “or by section 4192” before the period at the*
10 *end of subsection (a)(6).*

11 (c) *CONFORMING AMENDMENTS.—*

12 (1) *Section 4221(a) of the Internal Revenue Code*
13 *of 1986 is amended by inserting “or 4192” after “sec-*
14 *tion 4191”.*

15 (2) *Section 6416(b)(2) of such Code is amended*
16 *by inserting “or 4192” after “section 4191”.*

17 (d) *CLERICAL AMENDMENTS.—*

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

22 (2) *The table of subchapters for chapter 32 of*
23 *such Code is amended by striking the item relating to*
24 *subchapter E and inserting the following new item:*

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

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

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

4 (e) *EFFECTIVE DATE.*—*The amendments made by this*
5 *section shall apply to sales after the date of the enactment*
6 *of this Act.*

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

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

11 (a) *IN GENERAL.*—*Section 1834 of the Social Security*
12 *Act (42 U.S.C. 1395m) is amended by adding at the end*
13 *the following new subsection:*

14 “(x) *REBATE BY MANUFACTURERS FOR SINGLE*
15 *SOURCE DRUGS WITH PRICES INCREASING FASTER THAN*
16 *INFLATION.*—

17 “(1) *REQUIREMENTS.*—

18 “(A) *SECRETARIAL PROVISION OF INFORMA-*
19 *TION.*—*Not later than 6 months after the end of*
20 *each calendar quarter beginning on or after July*
21 *1, 2021, the Secretary shall, for each part B*
22 *rebtable drug, report to each manufacturer of*
23 *such part B rebatable drug the following for such*
24 *calendar quarter:*

1 “(i) Information on the total number
2 of units of the billing and payment code de-
3 scribed in subparagraph (A)(i) of para-
4 graph (3) with respect to such drug and cal-
5 endar quarter.

6 “(ii) Information on the amount (if
7 any) of the excess average sales price in-
8 crease described in subparagraph (A)(ii) of
9 such paragraph for such drug and calendar
10 quarter.

11 “(iii) The rebate amount specified
12 under such paragraph for such part B
13 rebtable drug and calendar quarter.

14 “(B) MANUFACTURER REQUIREMENT.—For
15 each calendar quarter beginning on or after July
16 1, 2021, the manufacturer of a part B rebtable
17 drug shall, for such drug, not later than 30 days
18 after the date of receipt from the Secretary of the
19 information described in subparagraph (A) for
20 such calendar quarter, provide to the Secretary
21 a rebate that is equal to the amount specified in
22 paragraph (3) for such drug for such calendar
23 quarter.

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

1 “(A) *IN GENERAL.*—*In this subsection, the*
2 *term ‘part B rebatable drug’ means a single*
3 *source drug or biological (as defined in subpara-*
4 *graph (D) of section 1847A(c)(6)), including a*
5 *biosimilar biological product (as defined in sub-*
6 *paragraph (H) of such section), paid for under*
7 *this part, except such term shall not include such*
8 *a drug or biological—*

9 “(i) *if the average total allowed charges*
10 *for a year per individual that uses such a*
11 *drug or biological, as determined by the*
12 *Secretary, are less than, subject to subpara-*
13 *graph (B), \$100; or*

14 “(ii) *that is a vaccine described in sub-*
15 *paragraph (A) or (B) of section 1861(s)(10).*

16 “(B) *INCREASE.*—*The dollar amount ap-*
17 *plied under subparagraph (A)(i)—*

18 “(i) *for 2022, shall be the dollar*
19 *amount specified under such subparagraph*
20 *for 2021, increased by the percentage in-*
21 *crease in the consumer price index for all*
22 *urban consumers (United States city aver-*
23 *age) for the 12 month period ending with*
24 *June of the previous year; and*

1 “(ii) for a subsequent year, shall be the
2 dollar amount specified in this clause (or
3 clause (i)) for the previous year, increased
4 by the percentage increase in the consumer
5 price index for all urban consumers (United
6 States city average) for the 12 month period
7 ending with June of the previous year.

8 Any dollar amount specified under this subpara-
9 graph that is not a multiple of \$10 shall be
10 rounded to the nearest multiple of \$10.

11 “(3) REBATE AMOUNT.—

12 “(A) IN GENERAL.—For purposes of para-
13 graph (1), the amount specified in this para-
14 graph for a part B rebatable drug assigned to a
15 billing and payment code for a calendar quarter
16 is, subject to paragraph (4), the amount equal to
17 the product of—

18 “(i) subject to subparagraph (B), the
19 total number of units of the billing and
20 payment code for such part B rebatable
21 drug furnished under this part during the
22 calendar quarter; and

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

24 “(I) the payment amount under
25 subparagraph (B) or (C) of section

1 1847A(b)(1), as applicable, for such
2 part B rebatable drug during the cal-
3 endar quarter; exceeds

4 “(II) the inflation-adjusted pay-
5 ment amount determined under sub-
6 paragraph (C) for such part B
7 rebatable drug during the calendar
8 quarter.

9 “(B) *EXCLUDED UNITS*.—For purposes of
10 subparagraph (A)(i), the total number of units of
11 the billing and payment code for each part B
12 rebatable drug furnished during a calendar
13 quarter shall not include—

14 “(i) units packaged into the payment
15 for a procedure or service under section
16 1833(t) or under section 1833(i) (instead of
17 separately payable under such respective
18 section);

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

22 “(iii) units of a part B rebatable drug
23 of a manufacturer furnished to an indi-
24 vidual, if such manufacturer, with respect
25 to the furnishing of such units of such drug,

1 *provides for discounts under section 340B of*
2 *the Public Health Service Act or for rebates*
3 *under section 1927.*

4 “(C) *DETERMINATION OF INFLATION-AD-*
5 *JUSTED PAYMENT AMOUNT.—The inflation-ad-*
6 *justed payment amount determined under this*
7 *subparagraph for a part B rebatable drug for a*
8 *calendar quarter is—*

9 “(i) *the payment amount for the bill-*
10 *ing and payment code for such drug in the*
11 *payment amount benchmark quarter (as de-*
12 *fined in subparagraph (D)); increased by*

13 “(ii) *the percentage by which the rebate*
14 *period CPI-U (as defined in subparagraph*
15 *(F)) for the calendar quarter exceeds the*
16 *benchmark period CPI-U (as defined in*
17 *subparagraph (E)).*

18 “(D) *PAYMENT AMOUNT BENCHMARK QUAR-*
19 *TER.—The term ‘payment amount benchmark*
20 *quarter’ means the calendar quarter beginning*
21 *January 1, 2016.*

22 “(E) *BENCHMARK PERIOD CPI-U.—The*
23 *term ‘benchmark period CPI-U’ means the con-*
24 *sumer price index for all urban consumers*
25 *(United States city average) for July 2015.*

1 “(F) *REBATE PERIOD CPI-U*.—The term
2 ‘rebate period CPI-U’ means, with respect to a
3 calendar quarter described in subparagraph (C),
4 the greater of the benchmark period CPI-U and
5 the consumer price index for all urban con-
6 sumers (United States city average) for the first
7 month of the calendar quarter that is two cal-
8 endar quarters prior to such described calendar
9 quarter.

10 “(4) *SPECIAL TREATMENT OF CERTAIN DRUGS*
11 *AND EXEMPTION*.—

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

1 *endar quarter after the day on which the drug*
2 *was first marketed’.*

3 “(B) *TIMELINE FOR PROVISION OF REBATES*
4 *FOR SUBSEQUENTLY APPROVED DRUGS.—In the*
5 *case of a part B rebatable drug first approved or*
6 *licensed by the Food and Drug Administration*
7 *after July 1, 2015, paragraph (1)(B) shall be ap-*
8 *plied as if the reference to ‘July 1, 2021’ under*
9 *such paragraph were a reference to the later of*
10 *the 6th full calendar quarter after the day on*
11 *which the drug was first marketed or July 1,*
12 *2021.*

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

21 “(D) *SELECTED DRUGS.—In the case of a*
22 *part B rebatable drug that is a selected drug (as*
23 *defined in section 1192(c)) for a price applica-*
24 *bility period (as defined in section 1191(b)(2))*
25 *and is determined (pursuant to such section*

1 1192(c)) to no longer be a selected drug, for each
2 applicable year beginning after the price appli-
3 cability period with respect to such drug, clause
4 (i) of paragraph (3)(C) shall be applied as if the
5 term ‘payment amount benchmark quarter’ were
6 defined under paragraph (3)(D) as the calendar
7 quarter beginning January 1 of the last year be-
8 ginning during such price applicability period
9 with respect to such selected drug and clause (ii)
10 of paragraph (3)(C) shall be applied as if the
11 term ‘benchmark period CPI-U’ were defined
12 under paragraph (3)(E) as if the reference to
13 ‘July 2015’ under such paragraph were a ref-
14 erence to the July of the year preceding such last
15 year.

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

20 “(A) in computing the amount of any coin-
21 surance applicable under this title to an indi-
22 vidual with respect to such drug, the computa-
23 tion of such coinsurance shall be based on the in-
24 flation-adjusted payment amount determined

1 *under paragraph (3)(C) for such part B*
2 *rebate drug; and*

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

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

10 *“(7) CIVIL MONEY PENALTY.—If a manufacturer*
11 *of a part B rebate drug has failed to comply with*
12 *the requirements under paragraph (1)(B) for such*
13 *drug for a calendar quarter, the manufacturer shall*
14 *be subject to, in accordance with a process established*
15 *by the Secretary pursuant to regulations, a civil*
16 *money penalty in an amount equal to at least 125*
17 *percent of the amount specified in paragraph (3) for*
18 *such drug for such calendar quarter. The provisions*
19 *of section 1128A (other than subsections (a) (with re-*
20 *spect to amounts of penalties or additional assess-*
21 *ments) and (b)) shall apply to a civil money penalty*
22 *under this paragraph in the same manner as such*
23 *provisions apply to a penalty or proceeding under*
24 *section 1128A(a).*

25 *“(8) STUDY AND REPORT.—*

1 “(A) *STUDY.*—*The Secretary shall conduct*
2 *a study of the feasibility of and operational*
3 *issues involved with the following:*

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

7 “(ii) *Including drugs and biologicals*
8 *paid for under MA plans under part C in*
9 *the rebate system under this subsection.*

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

15 “(B) *REPORT.*—*Not later than 3 years after*
16 *the date of the enactment of this subsection, the*
17 *Secretary shall submit to Congress a report on*
18 *the study conducted under subparagraph (A).*

19 “(9) *APPLICATION TO MULTIPLE SOURCE*
20 *DRUGS.*—*The Secretary may, based on the report sub-*
21 *mitted under paragraph (8) and pursuant to rule-*
22 *making, apply the provisions of this subsection to*
23 *multiple source drugs (as defined in section*
24 *1847A(c)(6)(C)), including, for purposes of deter-*
25 *mining the rebate amount under paragraph (3), by*

1 *calculating manufacturer-specific average sales prices*
2 *for the benchmark period and the rebate period.”.*

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

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 insert-*
12 *ing “(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 *defined 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 quarter*
20 *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 (3)(A)(ii)(I)*
25 *of such section for such drug, and (ii) 20*

1 *percent of the inflation-adjusted payment*
2 *amount under paragraph (3)(A)(ii)(II) of*
3 *such section for such drug”;*

4 *(B) in paragraph (4), by inserting “subject*
5 *to paragraph (1)(DD),” before “the applicable*
6 *amount”;* and

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

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

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

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

1 *a covered OPD service (or group of services), shall be*
2 *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 Act*
10 *(42 U.S.C. 1395w–3a(c)(3)) is amended by inserting “or*
11 *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 U.S.C.*
15 *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 *defined in subsection (h)(1)) of a manufacturer (as de-*
24 *defined 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 sub-*
2 *section (b).*

3 *“(2) AUTHORIZING COVERAGE FOR DRUGS NOT*
4 *COVERED UNDER AGREEMENTS.—Paragraph (1) shall*
5 *not apply to the dispensing of a covered part D drug*
6 *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 begin-*
15 *ning with 2022.*

16 *“(b) AGREEMENTS.—*

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

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

1 *report to the manufacturer the following for such*
2 *year:*

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

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

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

16 “(B) *MANUFACTURER REQUIREMENTS.—*
17 *For each applicable year with respect to which*
18 *the agreement is in effect, the manufacturer of*
19 *the part D rebatable drug, for each dosage form*
20 *and strength with respect to such drug, not later*
21 *than 30 days after the date of receipt from the*
22 *Secretary of the information described in sub-*
23 *paragraph (A) for such year, shall provide to the*
24 *Secretary a rebate that is equal to the amount*
25 *specified in subsection (c) for such dosage form*

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

3 “(2) *LENGTH OF AGREEMENT.*—

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

10 “(B) *TERMINATION.*—

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

22 “(ii) *BY A MANUFACTURER.*—*A manu-*
23 *facturer may terminate an agreement under*
24 *this section for any reason. Any such termi-*

1 *nation shall be effective, with respect to a*
2 *plan year—*

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

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

11 *“(C) EFFECTIVENESS OF TERMINATION.—*
12 *Any termination under this paragraph shall not*
13 *affect rebates due under the agreement under this*
14 *section before the effective date of its termination.*

15 *“(D) DELAY BEFORE REENTRY.—In the*
16 *case of any agreement under this section with a*
17 *manufacturer that is terminated in a plan year,*
18 *the Secretary may not enter into another such*
19 *agreement with the manufacturer (or a successor*
20 *manufacturer) before the subsequent plan year,*
21 *unless the Secretary finds good cause for an ear-*
22 *lier reinstatement of such an agreement.*

23 *“(c) REBATE AMOUNT.—*

24 *“(1) IN GENERAL.—For purposes of this section,*
25 *the amount specified in this subsection for a dosage*

1 *form and strength with respect to a part D rebatable*
2 *drug and applicable year is, subject to subparagraphs*
3 *(B) and (C) of paragraph (5), the amount equal to*
4 *the product of—*

5 *“(A) the total number of units of such dos-*
6 *age form and strength with respect to such part*
7 *D rebatable drug and year; and*

8 *“(B) the amount (if any) by which—*

9 *“(i) the annual manufacturer price (as*
10 *determined in paragraph (2)) paid for such*
11 *dosage form and strength with respect to*
12 *such part D rebatable drug for the year; ex-*
13 *ceeds*

14 *“(ii) the inflation-adjusted payment*
15 *amount determined under paragraph (3) for*
16 *such dosage form and strength with respect*
17 *to such part D rebatable drug for the year.*

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

23 *“(A) the average manufacturer price (as de-*
24 *finied in subsection (h)(6)) of such dosage form*
25 *and strength, as calculated for a unit of such*

1 *drug, with respect to each of the calendar quar-*
2 *ters of such year; and*

3 *“(B) the ratio of—*

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

7 *“(ii) the total number of units of such*
8 *dosage form and strength dispensed during*
9 *such year.*

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

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

20 *“(B) the percentage by which the applicable*
21 *year CPI–U (as defined in subsection (h)(5)) for*
22 *the applicable year exceeds the benchmark period*
23 *CPI–U (as defined in subsection (h)(4)).*

24 *“(4) DETERMINATION OF BENCHMARK YEAR*
25 *MANUFACTURER PRICE.—The benchmark year manu-*

1 *facturer price determined under this paragraph for a*
2 *dosage form and strength, with respect to a part D*
3 *rebatable drug and an applicable year, is the sum of*
4 *the products of—*

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

11 *“(B) the ratio of—*

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

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

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

21 *“(A) SUBSEQUENTLY APPROVED DRUGS.—*

22 *In the case of a part D rebatable drug first ap-*
23 *proved or licensed by the Food and Drug Admin-*
24 *istration after January 1, 2016, subparagraphs*
25 *(A) and (B) of paragraph (4) shall be applied as*

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

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

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

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

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

6 “(ii) *LINE EXTENSION DEFINED.*—*In*
7 *this subparagraph, the term ‘line extension’*
8 *means, with respect to a part D rebatable*
9 *drug, a new formulation of the drug (as de-*
10 *termined by the Secretary), such as an ex-*
11 *tended release formulation, but does not in-*
12 *clude an abuse-deterrent formulation of the*
13 *drug (as determined by the Secretary), re-*
14 *gardless of whether such abuse-deterrent for-*
15 *mulation is an extended release formula-*
16 *tion.*

17 “(D) *SELECTED DRUGS.*—*In the case of a*
18 *part D rebatable drug that is a selected drug (as*
19 *defined in section 1192(c)) for a price applica-*
20 *bility period (as defined in section 1191(b)(2))*
21 *and is determined (pursuant to such section*
22 *1192(c)) to no longer be a selected drug, for each*
23 *applicable year beginning after the price appli-*
24 *cability period with respect to such drug, sub-*
25 *paragraphs (A) and (B) of paragraph (4) shall*

1 *be applied as if the term ‘payment amount*
2 *benchmark year’ were defined under subsection*
3 *(h)(3) as the last year beginning during such*
4 *price applicability period with respect to such*
5 *selected drug and subparagraph (B) of para-*
6 *graph (3) shall be applied as if the term ‘bench-*
7 *mark period CPI–U’ were defined under sub-*
8 *section (h)(4) as if the reference to ‘January*
9 *2016’ under such subsection were a reference to*
10 *January of the last year beginning during such*
11 *price applicability period with respect to such*
12 *drug.*

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

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

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

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

9 “(g) *JUDICIAL REVIEW.*—*There shall be no judicial re-*
10 *view of the following:*

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

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

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

17 “(h) *DEFINITIONS.*—*In this section:*

18 “(1) *PART D REBATABLE DRUG DEFINED.*—

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

1 *who uses such a drug or biological, as deter-*
2 *mined by the Secretary, is less than, subject to*
3 *subparagraph (B), \$100, as determined by the*
4 *Secretary using the most recent data available*
5 *or, if data is not available, as estimated by the*
6 *Secretary.*

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

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

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

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

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

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

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

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

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

1 *spect to a covered outpatient drug of a manufacturer*
2 *for a rebate period under section 1927.”.*

3 **TITLE III—PART D IMPROVE-**
4 **MENTS AND MAXIMUM OUT-**
5 **OF-POCKET CAP FOR MEDI-**
6 **CARE BENEFICIARIES**

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

8 (a) *BENEFIT STRUCTURE REDESIGN.*—Section
9 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
10 102(b)) is amended—

11 (1) *in paragraph (2)—*

12 (A) *in subparagraph (A), in the matter pre-*
13 *ceding clause (i), by inserting “for a year pre-*
14 *ceding 2022 and for costs above the annual de-*
15 *ductible specified in paragraph (1) and up to the*
16 *annual out-of-pocket threshold specified in para-*
17 *graph (4)(B) for 2022 and each subsequent year”*
18 *after “paragraph (3)”;*

19 (B) *in subparagraph (C)—*

20 (i) *in clause (i), in the matter pre-*
21 *ceding subclause (I), by inserting “for a*
22 *year preceding 2022,” after “paragraph*
23 *(4),”; and*

1 (ii) in clause (ii)(III), by striking
2 “and each subsequent year” and inserting
3 “and 2021”; and

4 (C) in subparagraph (D)—

5 (i) in clause (i)—

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

10 (II) in subclause (I)(bb), by strik-
11 ing “a year after 2018” and inserting
12 “each of years 2018 through 2021”;
13 and

14 (ii) in clause (ii)(V), by striking “2019
15 and each subsequent year” and inserting
16 “each of years 2019 through 2021”;

17 (2) in paragraph (3)(A)—

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

21 (B) in clause (ii), by striking “for a subse-
22 quent year” and inserting “for each of years
23 2007 through 2021”; and

24 (3) in paragraph (4)—

25 (A) in subparagraph (A)—

- 1 *(i) in clause (i)—*
- 2 *(I) by redesignating subclauses (I)*
3 *and (II) as items (aa) and (bb), re-*
4 *spectively, and moving the margin of*
5 *each such redesignated item 2 ems to*
6 *the right;*
- 7 *(II) in the matter preceding item*
8 *(aa), as redesignated by subclause (I),*
9 *by striking “is equal to the greater*
10 *of—” and inserting “is equal to—*
11 *“(I) for a year preceding 2022,*
12 *the greater of—”;*
- 13 *(III) by striking the period at the*
14 *end of item (bb), as redesignated by*
15 *subclause (I), and inserting “; and”;*
16 *and*
- 17 *(IV) by adding at the end the fol-*
18 *lowing:*
- 19 *“(II) for 2022 and each suc-*
20 *ceeding year, \$0.”; and*
- 21 *(ii) in clause (ii), by striking “clause*
22 *(i)(I)” and inserting “clause (i)(I)(aa)”;*
23 *(B) in subparagraph (B)—*
- 24 *(i) in clause (i)—*

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

3 (II) in subclause (VI)—

4 (aa) by striking “for a subse-
5 quent year” and inserting “for
6 2021”; and

7 (bb) by striking the period at
8 the end and inserting a semicolon;
9 and

10 (III) by adding at the end the fol-
11 lowing new subclauses:

12 “(VII) for 2022, is equal to
13 \$2,000; or

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

20 (ii) in clause (ii), by striking “clause
21 (i)(II)” and inserting “clause (i)”;

22 (C) in subparagraph (C)(i), by striking
23 “and for amounts” and inserting “and, for a
24 year preceding 2022, for amounts”; and

1 (D) in subparagraph (E), by striking “In
2 applying” and inserting “For each of years 2011
3 through 2021, in applying”.

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

9 (c) *MANUFACTURER DISCOUNT PROGRAM.*—

10 (1) *IN GENERAL.*—Part D of title XVIII of the
11 Social Security Act (42 U.S.C. 1395w–101 et seq.), as
12 amended by section 202, is further amended by insert-
13 ing after section 1860D–14B the following new sec-
14 tion:

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

16 “(a) *ESTABLISHMENT.*—The Secretary shall establish
17 a manufacturer discount program (in this section referred
18 to as the ‘program’). Under the program, the Secretary shall
19 enter into agreements described in subsection (b) with man-
20 ufacturers and provide for the performance of the duties de-
21 scribed in subsection (c). The Secretary shall establish a
22 model agreement for use under the program by not later
23 than January 1, 2021, in consultation with manufacturers,
24 and allow for comment on such model agreement.

25 “(b) *TERMS OF AGREEMENT.*—

1 “(1) *IN GENERAL.*—

2 “(A) *AGREEMENT.*—*An agreement under*
3 *this section shall require the manufacturer to*
4 *provide applicable beneficiaries access to dis-*
5 *counted prices for applicable drugs of the manu-*
6 *facturer that are dispensed on or after January*
7 *1, 2022.*

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

14 “(C) *TIMING OF AGREEMENT.*—

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

24 “(ii) *2023 AND SUBSEQUENT YEARS.*—
25 *In order for an agreement with a manufac-*

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

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

13 “(3) *COMPLIANCE WITH REQUIREMENTS FOR AD-*
14 *MINISTRATION OF PROGRAM.—Each manufacturer*
15 *with an agreement in effect under this section shall*
16 *comply with requirements imposed by the Secretary*
17 *or a third party with a contract under subsection*
18 *(d)(3), as applicable, for purposes of administering*
19 *the program, including any determination under sub-*
20 *paragraph (A) of subsection (c)(1) or procedures es-*
21 *tablished under such subsection (c)(1).*

22 “(4) *LENGTH OF AGREEMENT.—*

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

1 *matically renewed for a period of not less than*
2 *1 year unless terminated under subparagraph*
3 *(B).*

4 “(B) *TERMINATION.*—

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

20 “(ii) *BY A MANUFACTURER.*—*A manu-*
21 *facturer may terminate an agreement under*
22 *this section for any reason. Any such termi-*
23 *nation shall be effective, with respect to a*
24 *plan year—*

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

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

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

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

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

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

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

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

8 “(C) the establishment of procedures to en-
9 sure that, not later than the applicable number
10 of calendar days after the dispensing of an ap-
11 plicable drug by a pharmacy or mail order serv-
12 ice, the pharmacy or mail order service is reim-
13 bursed for an amount equal to the difference be-
14 tween—

15 “(i) the negotiated price of the applica-
16 ble drug; and

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

19 “(D) the establishment of procedures to en-
20 sure that the discounted price for an applicable
21 drug under this section is applied before any
22 coverage or financial assistance under other
23 health benefit plans or programs that provide
24 coverage or financial assistance for the purchase
25 or provision of prescription drug coverage on be-

1 *half of applicable beneficiaries as the Secretary*
2 *may specify; and*

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

8 “(2) *MONITORING COMPLIANCE.—*

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

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

18 “(3) *COLLECTION OF DATA FROM PRESCRIPTION*
19 *DRUG PLANS AND MA–PD PLANS.—The Secretary may*
20 *collect appropriate data from prescription drug plans*
21 *and MA–PD plans in a timeframe that allows for*
22 *discounted prices to be provided for applicable drugs*
23 *under this section.*

24 “(d) *ADMINISTRATION.—*

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

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

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

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

20 “(B) *receive, distribute, or facilitate the dis-*
21 *tribution of funds of manufacturers to appro-*
22 *priate individuals or entities in order to meet*
23 *the obligations of manufacturers under agree-*
24 *ments under this section;*

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

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

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

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

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

24 “(e) *ENFORCEMENT.*—

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

4 “(2) *CIVIL MONEY PENALTY.*—

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

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

17 “(ii) *25 percent of such amount.*

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

24 “(f) *CLARIFICATION REGARDING AVAILABILITY OF*
25 *OTHER COVERED PART D DRUGS.*—*Nothing in this section*

1 *shall prevent an applicable beneficiary from purchasing a*
2 *covered part D drug that is not an applicable drug (includ-*
3 *ing a generic drug or a drug that is not on the formulary*
4 *of the prescription drug plan or MA–PD plan that the ap-*
5 *plicable beneficiary is enrolled in).*

6 “(g) *DEFINITIONS.—In this section:*

7 “(1) *APPLICABLE BENEFICIARY.—The term ‘ap-*
8 *plicable beneficiary’ means an individual who, on the*
9 *date of dispensing a covered part D drug—*

10 “(A) *is enrolled in a prescription drug plan*
11 *or an MA–PD plan;*

12 “(B) *is not enrolled in a qualified retiree*
13 *prescription drug plan; and*

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

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

20 “(A) *means a covered part D drug—*

21 “(i) *approved under a new drug appli-*
22 *cation under section 505(c) of the Federal*
23 *Food, Drug, and Cosmetic Act or, in the*
24 *case of a biologic product, licensed under*

1 *section 351 of the Public Health Service*
2 *Act; and*

3 *“(ii)(I) if the PDP sponsor of the pre-*
4 *scription drug plan or the MA organization*
5 *offering the MA–PD plan uses a formulary,*
6 *which is on the formulary of the prescrip-*
7 *tion drug plan or MA–PD plan that the ap-*
8 *plicable beneficiary is enrolled in;*

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

16 *“(III) is provided through an exception*
17 *or appeal; and*

18 *“(B) does not include a selected drug (as de-*
19 *finied in section 1192(c)) during a price applica-*
20 *bility period (as defined in section 1191(b)(2))*
21 *with respect to such drug.*

22 *“(3) APPLICABLE NUMBER OF CALENDAR*
23 *DAYS.—The term ‘applicable number of calendar*
24 *days’ means—*

1 “(A) *with respect to claims for reimburse-*
2 *ment submitted electronically, 14 days; and*

3 “(B) *with respect to claims for reimburse-*
4 *ment submitted otherwise, 30 days.*

5 “(4) *DISCOUNTED PRICE.—*

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

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

16 “(ii) *who has incurred such costs in*
17 *the year that are equal to or exceed such*
18 *threshold for the year, 70 percent of the ne-*
19 *gotiated price of such drug.*

20 “(B) *CLARIFICATION.—Nothing in this sec-*
21 *tion shall be construed as affecting the responsi-*
22 *bility of an applicable beneficiary for payment*
23 *of a dispensing fee for an applicable drug.*

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

1 “(i) *CLAIMS SPANNING DEDUCTIBLE.—*

2 *In the case where the entire amount of the*
3 *negotiated price of an individual claim for*
4 *an applicable drug with respect to an ap-*
5 *plicable beneficiary does not fall at or above*
6 *the annual deductible specified in section*
7 *1860D–2(b)(1) for the year, the manufac-*
8 *turer of the applicable drug shall provide*
9 *the discounted price under this section on*
10 *only the portion of the negotiated price of*
11 *the applicable drug that falls at or above*
12 *such annual deductible.*

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

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

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

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

7 “(5) *MANUFACTURER.—The term ‘manufacturer’*
8 *means any entity which is engaged in the production,*
9 *preparation, propagation, compounding, conversion,*
10 *or processing of prescription drug products, either di-*
11 *rectly or indirectly by extraction from substances of*
12 *natural origin, or independently by means of chem-*
13 *ical synthesis, or by a combination of extraction and*
14 *chemical synthesis. Such term does not include a*
15 *wholesale distributor of drugs or a retail pharmacy li-*
16 *censed under State law.*

17 “(6) *NEGOTIATED PRICE.—The term ‘negotiated*
18 *price’ has the meaning given such term in section*
19 *423.100 of title 42, Code of Federal Regulations (or*
20 *any successor regulation), except that such negotiated*
21 *price shall not include any dispensing fee for the ap-*
22 *plicable drug.*

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

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

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

6 *(A) in subsection (a), in the first sentence,*
7 *by striking “The Secretary” and inserting “Sub-*
8 *ject to subsection (h), the Secretary”; and*

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

11 *“(h) SUNSET OF PROGRAM.—*

12 *“(1) IN GENERAL.—The program shall not apply*
13 *with respect to applicable drugs dispensed on or after*
14 *January 1, 2022, and, subject to paragraph (2),*
15 *agreements under this section shall be terminated as*
16 *of such date.*

17 *“(2) CONTINUED APPLICATION FOR APPLICABLE*
18 *DRUGS DISPENSED PRIOR TO SUNSET.—The provi-*
19 *sions of this section (including all responsibilities and*
20 *duties) shall continue to apply after January 1, 2022,*
21 *with respect to applicable drugs dispensed prior to*
22 *such date.”.*

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

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

3 *(A) in subsection (b)(2)(C)(iii)—*

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

7 *“(I) the reinsurance”; and*

8 *(ii) by adding at the end the following:*

9 *“(II) for 2022 and each subse-*
10 *quent year, the manufacturer discounts*
11 *provided under section 1860D–14C*
12 *subtracted from the actuarial value to*
13 *produce such bid; and”; and*

14 *(B) in subsection (c)(1)(C)—*

15 *(i) by striking “an actuarial valuation*
16 *of the reinsurance” and inserting “an actu-*
17 *arial valuation of—*

18 *“(i) the reinsurance”;*

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

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

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

4 (d) *CONFORMING AMENDMENTS.*—

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

7 (A) *in subsection (a)(2)(A)(i)(I), by striking*
8 *“, or an increase in the initial” and inserting*
9 *“or, for a year preceding 2022, an increase in*
10 *the initial”;*

11 (B) *in subsection (c)(1)(C)—*

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

14 (ii) *by inserting “for a year preceding*
15 *2022 or the annual out-of-pocket threshold*
16 *specified in subsection (b)(4)(B) for the year*
17 *for 2022 and each subsequent year” after*
18 *“subsection (b)(3) for the year” each place*
19 *it appears; and*

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

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

1 *amended by striking “the initial” and inserting “for*
2 *a year preceding 2022, the initial”.*

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

5 (A) *in paragraph (1)—*

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

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

12 (iii) *in subparagraph (E), by striking*
13 *“The elimination” and inserting “For a*
14 *year preceding 2022, the elimination”;* and

15 (B) *in paragraph (2)—*

16 (i) *in subparagraph (C), by striking*
17 *“The continuation” and inserting “For a*
18 *year preceding 2022, the continuation”;* and

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

22 (4) *Section 1860D–21(d)(7) of the Social Secu-*
23 *rity Act (42 U.S.C. 1395w–131(d)(7)) is amended by*
24 *striking “section 1860D–2(b)(4)(B)(i)” and inserting*
25 *“section 1860D–2(b)(4)(C)(i)”.*

1 (5) *Section 1860D–22(a)(2)(A) of the Social Se-*
2 *curity Act (42 U.S.C. 1395w–132(a)(2)(A)) is amend-*
3 *ed—*

4 (A) *by striking “the value of any discount”*
5 *and inserting the following: “the value of—*

6 *“(i) for years prior to 2022, any dis-*
7 *count”;*

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

11 (C) *by adding at the end the following new*
12 *clause:*

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

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

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

20 (B) *by inserting “for such year” before the*
21 *period.*

22 (7) *Section 1860D–43 of the Social Security Act*
23 *(42 U.S.C. 1395w–153) is amended—*

24 (A) *in subsection (a)—*

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

3 “(1) participate in—

4 “(A) for 2011 through 2021, the Medicare
5 coverage gap discount program under section
6 1860D–14A; and

7 “(B) for 2022 and each subsequent year, the
8 manufacturer discount program under section
9 1860D–14C;”;

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

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

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

16 “(B) for 2022 and each subsequent year, an
17 agreement described in subsection (b) of section
18 1860D–14C with the Secretary; and”;

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

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

23 “(A) for 2011 through 2021, a contract with
24 a third party that the Secretary has entered into

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

3 *“(B) for 2022 and each subsequent year, a*
4 *contract with a third party that the Secretary*
5 *has entered into a contract with under subsection*
6 *(d)(3) of section 1860D–14C.”; and*

7 *(B) by striking subsection (b) and inserting*
8 *the following:*

9 *“(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),*
10 *and (3)(A) of subsection (a) shall apply to covered part D*
11 *drugs dispensed under this part on or after January 1,*
12 *2011, and before January 1, 2022, and paragraphs (1)(B),*
13 *(2)(B), and (3)(B) of such subsection shall apply to covered*
14 *part D drugs dispensed under this part on or after January*
15 *1, 2022.”.*

16 *(e) EFFECTIVE DATE.—The amendments made by this*
17 *section shall apply with respect to plan year 2022 and sub-*
18 *sequent plan years.*

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

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

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

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

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

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

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

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

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

17 *(2) by adding at the end the following new para-*
18 *graph:*

19 **“(8) APPLICATION OF PHARMACY QUALITY MEAS-**
20 **URES.—**

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

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

3 “(B) *STANDARD PHARMACY QUALITY MEAS-*
4 *URES.—The Secretary shall establish or approve*
5 *standard quality measures from a consensus and*
6 *evidence-based organization for payments de-*
7 *scribed in subparagraph (A). Such measures*
8 *shall focus on patient health outcomes and be*
9 *based on proven criteria measuring pharmacy*
10 *performance.*

11 “(C) *EFFECTIVE DATE.—The requirement*
12 *under subparagraph (A) shall take effect for plan*
13 *years beginning on or after January 1, 2021, or*
14 *such earlier date specified by the Secretary if the*
15 *Secretary determines there are sufficient meas-*
16 *ures established or approved under subparagraph*
17 *(B) to meet the requirement under subparagraph*
18 *(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, the
11 dollar amount applied under this
12 clause (after application of para-
13 graph (4)(A)) for plan year 2020
14 for a drug described in subclause
15 (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 fol-
11 lowing new subclause:

12 “(II) for plan year 2021 and each
13 subsequent plan year, the copayment
14 amount applied under clause (ii) for
15 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 the
24 nearest multiple of 5 cents or 10 cents, respec-
25 tively.”;

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 year*
6 *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 following*
10 *new clause:*

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

16 (B) *in subparagraph (E)*—

17 (i) *by striking “subsection (c), the sub-*
18 *stitution for” and inserting “subsection*
19 *(c)—*

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

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

24 (iii) *by adding at the end the following*
25 *new clause:*

1 “(i) for plan year 2021, the elimi-
2 nation of any cost-sharing imposed under
3 section 1860D–2(b)(4)(A).”; and
4 (3) in paragraph (4)(A)(ii), by inserting “(before
5 2021)” after “subsequent year”.

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

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

13 “(C) INFORMATION ON PREMIUMS FOR SUB-
14 SIDY ELIGIBLE INDIVIDUALS.—

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

1 *premium that would apply if such indi-*
2 *vidual were to remain enrolled in such plan*
3 *to premiums that would apply if the indi-*
4 *vidual were to enroll in other LIS bench-*
5 *mark plans.*

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

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

17 “(II) *with respect to which the*
18 *premium would be waived as de mini-*
19 *mis pursuant to section 1860D–*
20 *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 fol-*
10 *lowing: “or through use of an intelligent assign-*
11 *ment process that is designed to maximize the*
12 *access of such individual to necessary prescrip-*
13 *tion drugs while minimizing costs to such indi-*
14 *vidual and to the program under this part to the*
15 *greatest extent possible. In the case the Secretary*
16 *enrolls such individuals through use of an intel-*
17 *ligent assignment process, such process shall take*
18 *into account the extent to which prescription*
19 *drugs necessary for the individual are covered in*
20 *the case of a PDP sponsor of a prescription drug*
21 *plan that uses a formulary, the use of prior au-*
22 *thorization or other restrictions on access to cov-*
23 *erage of such prescription drugs by such a spon-*
24 *sor, and the overall quality of a prescription*
25 *drug plan as measured by quality ratings estab-*
26 *lished by the Secretary”;* and

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

4 (2) in subparagraph (D)—

5 (A) by inserting after “PDP region” the fol-
6 lowing: “or through use of an intelligent assign-
7 ment process that is designed to maximize the
8 access of such individual to necessary prescrip-
9 tion drugs while minimizing costs to such indi-
10 vidual and to the program under this part to the
11 greatest extent possible. In the case the Secretary
12 enrolls such individuals through use of an intel-
13 ligent assignment process, such process shall take
14 into account the extent to which prescription
15 drugs necessary for the individual are covered in
16 the case of a PDP sponsor of a prescription drug
17 plan that uses a formulary, the use of prior au-
18 thorization or other restrictions on access to cov-
19 erage of such prescription drugs by such a spon-
20 sor, and the overall quality of a prescription
21 drug plan as measured by quality ratings estab-
22 lished by the Secretary”; and

23 (B) by striking “Nothing in the previous
24 sentence” and inserting “Nothing in this sub-
25 paragraph”.

1 (b) *EFFECTIVE DATE.*—*The amendments made by sub-*
2 *section (a) shall apply with respect to plan years beginning*
3 *with plan year 2022.*

4 **SEC. 404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUB-**
5 **SIDIES UNDER PART D OF THE MEDICARE**
6 **PROGRAM.**

7 *Section 1860D–14(a) of the Social Security Act (42*
8 *U.S.C. 1395w–114(a)), as amended by sections 301(d) and*
9 *401, is further amended—*

10 (1) *in the subsection heading, by striking “INDI-*
11 *VIDUALS” and all that follows through “LINE” and*
12 *inserting “CERTAIN INDIVIDUALS”;*

13 (2) *in paragraph (1)—*

14 (A) *by striking the paragraph heading and*
15 *inserting “INDIVIDUALS WITH CERTAIN LOW IN-*
16 *COMES”; and*

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

21 (3) *in paragraph (2)—*

22 (A) *by striking the paragraph heading and*
23 *inserting “OTHER LOW-INCOME INDIVIDUALS”;*
24 *and*

25 (B) *in subparagraph (A)—*

1 (i) by inserting “(or, with respect to a
2 plan year beginning on or after January 1,
3 2022, 150 percent)” after “135 percent”;
4 and

5 (ii) by inserting “(or, with respect to a
6 plan year beginning on or after January 1,
7 2022, 200 percent)” after “150 percent”;
8 and

9 (4) in paragraph (3)(A)(ii), by inserting “(or,
10 with respect to a plan year beginning on or after
11 January 1, 2022, 200 percent)” after “150 percent”.

12 **SEC. 405. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-**
13 **COME TERRITORIAL RESIDENTS FOR PRE-**
14 **MIUM AND COST-SHARING SUBSIDIES UNDER**
15 **THE MEDICARE PROGRAM; SUNSET OF EN-**
16 **HANCED ALLOTMENT PROGRAM.**

17 (a) *AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-*
18 *COME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-*
19 *SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM.—*

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

23 (A) *in subparagraph (B)(v)—*

24 (i) *in subclause (I), by striking “and”*
25 *at the end;*

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

3 (iii) by inserting after subclause (II)
4 the following new subclause:

5 “(III) with respect to plan years
6 beginning on or after January 1, 2021,
7 shall provide that any part D eligible
8 individual who is enrolled for medical
9 assistance under the State Medicaid
10 plan of a territory (as defined in sec-
11 tion 1935(f)) under title XIX (or a
12 waiver of such a plan) shall be treated
13 as a subsidy eligible individual de-
14 scribed in paragraph (1).”; and

15 (B) in subparagraph (F), by adding at the
16 end the following new sentence: “The previous
17 sentence shall not apply with respect to eligi-
18 bility determinations for premium and cost-shar-
19 ing subsidies under this section made on or after
20 January 1, 2021.”.

21 (2) CONFORMING AMENDMENT.—Section 1860D–
22 31(j)(2)(D) of the Social Security Act (42 U.S.C.
23 1395w–141(j)(2)(D)) is amended by adding at the
24 end the following new sentence: “The previous sen-
25 tence shall not apply with respect to amounts made

1 *available to a State under this paragraph on or after*
2 *January 1, 2021.”.*

3 ***(b) SUNSET OF ENHANCED ALLOTMENT PROGRAM.—***

4 ***(1) IN GENERAL.—****Section 1935(e) of the Social*
5 *Security Act (42 U.S.C. 1396u–5(e)) is amended—*

6 ***(A)*** *in paragraph (1)(A), by inserting after*
7 *“such State” the following: “before January 1,*
8 *2021”;* *and*

9 ***(B)*** *in paragraph (3)—*

10 ***(i)*** *in subparagraph (A), in the matter*
11 *preceding clause (i), by inserting after “a*
12 *year” the following: “(before 2021)”;* *and*

13 ***(ii)*** *in subparagraph (B)(iii), by strik-*
14 *ing “a subsequent year” and inserting*
15 *“each of fiscal years 2008 through 2020”.*

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

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

1 **SEC. 406. AUTOMATIC QUALIFICATION OF CERTAIN MED-**
2 **ICAID BENEFICIARIES FOR PREMIUM AND**
3 **COST-SHARING SUBSIDIES UNDER PART D OF**
4 **THE MEDICARE PROGRAM.**

5 *Clause (v) of section 1860D–14(a)(3)(B) of the Social*
6 *Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as amended*
7 *by section 405, is further amended—*

8 *(1) in subclause (II), by striking “and” at the*
9 *end;*

10 *(2) in subclause (III), by striking the period and*
11 *inserting “; and”; and*

12 *(3) by inserting after subclause (III) the fol-*
13 *lowing new subclause:*

14 *“(IV) with respect to plan years*
15 *beginning on or after January 1, 2022,*
16 *shall, notwithstanding the preceding*
17 *clauses of this subparagraph, provide*
18 *that any part D eligible individual not*
19 *described in subclause (I), (II), or (III)*
20 *who is enrolled, as of the day before the*
21 *date on which such individual attains*
22 *the age of 65, for medical assistance*
23 *under a State plan under title XIX (or*
24 *a waiver of such plan) pursuant to*
25 *clause (i)(VIII) or (ii)(XX) of section*
26 *1902(a)(10)(A), and who has income*

1 *below 200 percent of the poverty line*
2 *applicable to a family of the size in-*
3 *volved, shall be treated as a subsidy el-*
4 *igible individual described in para-*
5 *graph (1) for a limited period of time,*
6 *as specified by the Secretary.”.*

7 **SEC. 407. ELIMINATING THE RESOURCE REQUIREMENT**
8 **WITH RESPECT TO SUBSIDY ELIGIBLE INDI-**
9 **VIDUALS UNDER PART D OF THE MEDICARE**
10 **PROGRAM.**

11 *Section 1860D–14(a)(3)(A)(iii) of the Social Security*
12 *Act (42 U.S.C. 1395w–114(a)(3)(A)(iii)) is amended by in-*
13 *serting “in the case of a plan year beginning before Janu-*
14 *ary 1, 2022,” before “meets”.*

15 **TITLE V—DRUG PRICE**
16 **TRANSPARENCY**

17 **SEC. 501. DRUG PRICE TRANSPARENCY.**

18 *Part A of title XI of the Social Security Act is amend-*
19 *ed by adding at the end the following new sections:*

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

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

22 **“(1) MANUFACTURER.—The term ‘manufacturer’**
23 **means the person—**

24 **“(A) that holds the application for a drug**
25 **approved under section 505 of the Federal Food,**

1 *Drug, and Cosmetic Act or licensed under section*
2 *351 of the Public Health Service Act; or*

3 *“(B) who is responsible for setting the*
4 *wholesale acquisition cost for the drug.*

5 *“(2) QUALIFYING DRUG.—The term ‘qualifying*
6 *drug’ means any drug that is approved under sub-*
7 *section (c) or (j) of section 505 of the Federal Food,*
8 *Drug, and Cosmetic Act or licensed under subsection*
9 *(a) or (k) of section 351 of the Public Health Service*
10 *Act—*

11 *“(A) that has a wholesale acquisition cost of*
12 *\$100 or more, adjusted for inflation occurring*
13 *after the date of enactment of this section, for a*
14 *month’s supply or a typical course of treatment*
15 *that lasts less than a month, and is—*

16 *“(i) subject to section 503(b)(1) of the*
17 *Federal Food, Drug, and Cosmetic Act; and*

18 *“(ii) not a preventative vaccine; and*

19 *“(B) for which, during the previous cal-*
20 *endar year, at least 1 dollar of the total amount*
21 *of sales were for individuals enrolled under the*
22 *Medicare program under title XVIII or under a*
23 *State Medicaid plan under title XIX or under a*
24 *waiver of such plan.*

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

4 “(b) *REPORT.*—

5 “(1) *REPORT REQUIRED.*—*The manufacturer of*
6 *a qualifying drug shall submit a report to the Sec-*
7 *retary if, with respect to the qualifying drug—*

8 “(A) *there is an increase in the price of the*
9 *qualifying drug that results in an increase in the*
10 *wholesale acquisition cost of that drug that is*
11 *equal to—*

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

15 “(ii) *25 percent or more within a 36-*
16 *month period beginning on or after Janu-*
17 *ary 1, 2019; or*

18 “(B) *the estimated price of the qualifying*
19 *drug or spending per individual or per user of*
20 *such drug (as estimated by the Secretary) for the*
21 *applicable year (or per course of treatment in*
22 *such applicable year as determined by the Sec-*
23 *retary) is at least \$26,000 beginning on or after*
24 *January 1, 2021.*

1 “(2) *REPORT DEADLINE.*—Each report described
2 in paragraph (1) shall be submitted to the Sec-
3 retary—

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

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

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

21 “(c) *CONTENTS.*—A report under subsection (b), con-
22 sistent with the standard for disclosures described in section
23 213.3(d) of title 12, Code of Federal Regulations (as in effect
24 on the date of enactment of this section), shall, at a min-
25 imum, include—

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

2 “(A) the percentage by which the manufac-
3 turer will raise the wholesale acquisition cost of
4 the drug within the 12-month period or 36-
5 month period as described in subsection
6 (b)(1)(A)(i) or (b)(1)(A)(ii), and the effective
7 date of such price increase or the cost associated
8 with a qualifying drug if such drug meets the
9 criteria under subsection (b)(1)(B) and the effec-
10 tive date at which such drug meets such criteria;

11 “(B) an explanation for, and description of,
12 each price increase for such drug that will occur
13 during the 12-month period or the 36-month pe-
14 riod described in subsection (b)(1)(A)(i) or
15 (b)(1)(A)(ii), as applicable;

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

20 “(D) if known and different from the manu-
21 facturer of the qualifying drug, the identity of—

22 “(i) the sponsor or sponsors of any in-
23 vestigational new drug applications under
24 section 505(i) of the Federal Food, Drug,
25 and Cosmetic Act for clinical investigations

1 *with respect to such drug, for which the full*
2 *reports are submitted as part of the appli-*
3 *cation—*

4 *“(I) for approval of the drug*
5 *under section 505 of such Act; or*

6 *“(II) for licensure of the drug*
7 *under section 351 of the Public Health*
8 *Service Act; and*

9 *“(ii) the sponsor of an application for*
10 *the drug approved under such section 505 of*
11 *the Federal Food, Drug, and Cosmetic Act*
12 *or licensed under section 351 of the Public*
13 *Health Service Act;*

14 *“(E) a description of the history of the*
15 *manufacturer’s price increases for the drug since*
16 *the approval of the application for the drug*
17 *under section 505 of the Federal Food, Drug,*
18 *and Cosmetic Act or the issuance of the license*
19 *for the drug under section 351 of the Public*
20 *Health Service Act, or since the manufacturer*
21 *acquired such approved application or license, if*
22 *applicable;*

23 *“(F) the current wholesale acquisition cost*
24 *of the drug;*

1 “(G) the total expenditures of the manufac-
2 turer on—

3 “(i) materials and manufacturing for
4 such drug;

5 “(ii) acquiring patents and licensing
6 for such drug; and

7 “(iii) purchasing or acquiring such
8 drug from another manufacturer, if appli-
9 cable;

10 “(H) the percentage of total expenditures of
11 the manufacturer on research and development
12 for such drug that was derived from Federal
13 funds;

14 “(I) the total expenditures of the manufac-
15 turer on research and development for such drug
16 that is necessary to demonstrate that it meets
17 applicable statutory standards for approval
18 under section 505 of the Federal Food, Drug,
19 and Cosmetic Act or licensure under section 351
20 of the Public Health Service Act, as applicable;

21 “(J) the total expenditures of the manufac-
22 turer on pursuing new or expanded indications
23 or dosage changes for such drug under section
24 505 of the Federal Food, Drug, and Cosmetic Act
25 or section 351 of the Public Health Service Act;

1 “(K) the total expenditures of the manufac-
2 turer on carrying out postmarket requirements
3 related to such drug, including under section
4 505(o)(3) of the Federal Food, Drug, and Cos-
5 metic Act;

6 “(L) the total revenue and the net profit
7 generated from the qualifying drug for each cal-
8 endar year since the approval of the application
9 for the drug under section 505 of the Federal
10 Food, Drug, and Cosmetic Act or the issuance of
11 the license for the drug under section 351 of the
12 Public Health Service Act, or since the manufac-
13 turer acquired such approved application or li-
14 cense; and

15 “(M) the total costs associated with mar-
16 keting and advertising for the qualifying drug;
17 “(2) with respect to the manufacturer—

18 “(A) the total revenue and the net profit of
19 the manufacturer for each of the 12-month period
20 described in subsection (b)(1)(A)(i) or the 36-
21 month period described in subsection
22 (b)(1)(A)(ii), as applicable;

23 “(B) all stock-based performance metrics
24 used by the manufacturer to determine executive
25 compensation for each of the 12-month periods

1 *described in subsection (b)(1)(A)(i) or the 36-*
2 *month periods described in subsection*
3 *(b)(1)(A)(ii), as applicable; and*

4 *“(C) any additional information the manu-*
5 *facturer chooses to provide related to drug pric-*
6 *ing decisions, such as total expenditures on—*

7 *“(i) drug research and development; or*

8 *“(ii) clinical trials, including on drugs*
9 *that failed to receive approval by the Food*
10 *and Drug Administration; and*

11 *“(3) such other related information as the Sec-*
12 *retary considers appropriate and as specified by the*
13 *Secretary.*

14 *“(d) INFORMATION PROVIDED.—The manufacturer of*
15 *a qualifying drug that is required to submit a report under*
16 *subsection (b), shall ensure that such report and any expla-*
17 *nation for, and description of, each price increase described*
18 *in subsection (c)(1) shall be truthful, not misleading, and*
19 *accurate.*

20 *“(e) CIVIL MONETARY PENALTY.—Any manufacturer*
21 *of a qualifying drug that fails to submit a report for the*
22 *drug as required by this section, following notification by*
23 *the Secretary to the manufacturer that the manufacturer*
24 *is not in compliance with this section, shall be subject to*

1 *a civil monetary penalty of \$75,000 for each day on which*
2 *the violation continues.*

3 “(f) *FALSE INFORMATION.*—*Any manufacturer that*
4 *submits a report for a drug as required by this section that*
5 *knowingly provides false information in such report is sub-*
6 *ject to a civil monetary penalty in an amount not to exceed*
7 *\$100,000 for each item of false information.*

8 “(g) *PUBLIC POSTING.*—

9 “(1) *IN GENERAL.*—*Subject to paragraph (4), the*
10 *Secretary shall post each report submitted under sub-*
11 *section (b) on the public website of the Department of*
12 *Health and Human Services the day the price in-*
13 *crease of a qualifying drug is scheduled to go into ef-*
14 *fect.*

15 “(2) *FORMAT.*—*In developing the format in*
16 *which reports will be publicly posted under para-*
17 *graph (1), the Secretary shall consult with stake-*
18 *holders, including beneficiary groups, and shall seek*
19 *feedback from consumer advocates and readability ex-*
20 *perts on the format and presentation of the content of*
21 *such reports to ensure that such reports are—*

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

23 “(B) *written in plain language that con-*
24 *sumers can readily understand.*

1 “(3) *LIST.*—*In addition to the reports submitted*
2 *under subsection (b), the Secretary shall also post a*
3 *list of each qualifying drug with respect to which the*
4 *manufacturer was required to submit such a report in*
5 *the preceding year and whether such manufacturer*
6 *was required to submit such report based on a quali-*
7 *fying price increase or whether such drug meets the*
8 *criteria under subsection (b)(1)(B).*

9 “(4) *PROTECTED INFORMATION.*—*In carrying*
10 *out this section, the Secretary shall enforce applicable*
11 *law concerning the protection of confidential commer-*
12 *cial information and trade secrets.*

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

14 “(a) *IN GENERAL.*—*Subject to subsection (b), the Sec-*
15 *retary shall submit to the Committees on Energy and Com-*
16 *merce and Ways and Means of the House of Representatives*
17 *and the Committees on Health, Education, Labor, and Pen-*
18 *sions and Finance of the Senate, and post on the public*
19 *website of the Department of Health and Human Services*
20 *in a way that is user-friendly to the public and written*
21 *in plain language that consumers can readily understand,*
22 *an annual report—*

23 “(1) *summarizing the information reported pur-*
24 *suant to section 1150C;*

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

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

7 “(4) explaining how the Department of Health
8 and Human Services is improving consumer and pro-
9 vider information about drug value and drug price
10 transparency.

11 “(b) *PROTECTED INFORMATION*.—In carrying out this
12 section, the Secretary shall enforce applicable law con-
13 cerning the protection of confidential commercial informa-
14 tion and trade secrets.”.

15 **TITLE VI—MISCELLANEOUS**

16 **SEC. 601. TEMPORARY INCREASE IN MEDICARE PART B PAY-** 17 **MENT FOR CERTAIN BIOSIMILAR BIOLOGICAL** 18 **PRODUCTS.**

19 Section 1847A(b)(8) of the Social Security Act (42
20 U.S.C. 1395w–3a(b)(8)) is amended—

21 (1) by redesignating subparagraphs (A) and (B)
22 as clauses (i) and (ii), respectively, and moving the
23 margin of each such redesignated clause 2 ems to the
24 right;

1 (2) *by striking “PRODUCT.—The amount” and*
2 *inserting the following: “PRODUCT.—*

3 *“(A) IN GENERAL.—Subject to subpara-*
4 *graph (B), the amount”;* and

5 (3) *by adding at the end the following new sub-*
6 *paragraph:*

7 *“(B) TEMPORARY PAYMENT INCREASE.—*

8 *“(i) IN GENERAL.—In the case of a*
9 *qualifying biosimilar biological product*
10 *that is furnished during the applicable 5-*
11 *year period for such product, the amount*
12 *specified in this paragraph for such product*
13 *with respect to such period is the sum deter-*
14 *mined under subparagraph (A), except that*
15 *clause (ii) of such subparagraph shall be*
16 *applied by substituting ‘8 percent’ for ‘6*
17 *percent’.*

18 *“(ii) APPLICABLE 5-YEAR PERIOD.—*
19 *For purposes of clause (i), the applicable 5-*
20 *year period for a biosimilar biological prod-*
21 *uct is—*

22 *“(I) in the case of such a product*
23 *for which payment was made under*
24 *this paragraph as of December 31,*

1 2019, the 5-year period beginning on
2 January 1, 2020; and

3 “*(II) in the case of such a product*
4 *for which payment is first made under*
5 *this paragraph during a calendar*
6 *quarter during the period beginning*
7 *January 1, 2020, and ending Decem-*
8 *ber 31, 2024, the 5-year period begin-*
9 *ning on the first day of such calendar*
10 *quarter during which such payment is*
11 *first made.*

12 “*(iii) QUALIFYING BIOSIMILAR BIO-*
13 *LOGICAL PRODUCT DEFINED.—For purposes*
14 *of this subparagraph, the term ‘qualifying*
15 *biosimilar biological product’ means a bio-*
16 *similar biological product described in*
17 *paragraph (1)(C) with respect to which—*

18 “*(I) in the case of a product de-*
19 *scribed in clause (ii)(I), the average*
20 *sales price is not more than the aver-*
21 *age sales price for the reference biologi-*
22 *cal product; and*

23 “*(II) in the case of a product de-*
24 *scribed in clause (ii)(II), the wholesale*
25 *acquisition cost is not more than the*

1 *wholesale acquisition cost for the ref-*
2 *erence biological product.”.*