

Union Calendar No. 264

116TH CONGRESS
1ST SESSION

H. R. 3

[Report No. 116-324, Parts I, II and III]

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

DECEMBER 6, 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 italic]

DECEMBER 6, 2019

Reported from the Committee on Ways and Means with an amendment
[Strike out all after the enacting clause and insert the part printed in boldface roman]

DECEMBER 6, 2019

Referral to the Committee on Education and Labor extended for a period ending not later than December 9, 2019

DECEMBER 9, 2019

Additional sponsors: Mr. LARSON of Connecticut, Ms. KUSTER of New Hampshire, Ms. DEGETTE, Mr. RUSH, Ms. SHALALA, Mr. RYAN, Mr. MORELLE, Mr. SABLAN, Mr. CASE, Mr. ENGEL, Ms. CASTOR of Florida, Ms. FRANKEL, Mr. EVANS, Mr. COURTNEY, Mr. NORCROSS, Ms. MOORE, Mr. KILDEE, Ms. NORTON, Mr. MCGOVERN, Mr. VISCLOSKY, Mr. CARBAJAL, Mr. PAPPAS, Ms. BONAMICI, Ms. HILL of California, Mrs. HAYES, Mr. CARTWRIGHT, Mr. MCNERNEY, Ms. BLUNT ROCHESTER, Mr. KIM, Mr. TRONE, Mr. ALLRED, Mr. ROSE of New York, Mr. THOMPSON of California, Ms. MENG, Mr. COHEN, Mr. SUOZZI, Ms. WILD, Ms. ESHOO, Mr. SOTO, Mr. HORSFORD, Mr. VELA, Mrs. BEATTY, Ms. WASSERMAN SCHULTZ, Mr. KEATING, Mr. GOLDEN, Mr. SCHIFF, Ms. CRAIG, Mr. WELCH, Mr. MICHAEL F. DOYLE of Pennsylvania, Ms. GARCIA of Texas, Mr. DANNY K. DAVIS of Illinois, Mr. RUIZ, Ms. MATSUI, Ms. SLOTKIN, Ms. WILSON of Florida, Mr. LOEBSACK, Mr. CRIST, Mrs. BUSTOS, Ms. MUCARSEL-POWELL, Mr. CASTEN of Illinois, Ms. SCHRIER, Mr. CUELLAR, Ms. WEXTON, Mr. CLEAVER, Ms. SCHAKOWSKY, Mr. SARBANES, Mr. SEAN PATRICK MALONEY of New York, Mr. LAWSON of Florida, Mr. PHILLIPS, Mr. SCHNEIDER, Mr. MEEKS, Mr. ESPAILLAT, Mr. LYNCH, Mr. HIGGINS of New York, Mr. LANGEVIN, Ms. JUDY CHU of California, Ms. STEVENS, Mr. PERLMUTTER, Ms. DAVIDS of Kansas, Mrs. AXNE, Mr. HASTINGS, Mr. BEYER, Mrs. LOWEY, Mr. MCEACHIN, Mrs. TORRES of California, Mr. PAYNE, Ms. SCANLON, Mr. DEUTCH, Mr. YARMUTH, Ms. SPANBERGER, Mr. JEFFRIES, Mrs. MCBATH, Mrs. DINGELL, Ms. FINKENAUER, Mr. GARAMENDI, Ms. MCCOLLUM, Mr. VEASEY, Mr. CASTRO of Texas, Mr. GONZALEZ of Texas, Ms. BASS, Mr. BISHOP of Georgia, Mr. SMITH of Washington, Mr. LOWENTHAL, and Mrs. FLETCHER

DECEMBER 9, 2019

Reported from the Committee on Education and Labor with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in boldface italic]

[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 *gible 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-ELIGI-
12 ble 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 “(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 rebtable 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 rebatable 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 rebatable
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 REBATABLE 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 *rebtable 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 rebtable 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.”.*

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

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

6 (a) *BENEFIT STRUCTURE REDESIGN.*—Section
 7 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
 8 102(b)) is amended—

9 (1) in paragraph (2)—

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

17 (B) in subparagraph (C)—

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

22 (ii) in clause (ii)(III), by striking
 23 “and each subsequent year” and inserting
 24 “and 2021”; and

25 (C) in subparagraph (D)—

1 (i) in clause (i)—

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

6 (II) in subclause (I)(bb), by strik-
7 ing “a year after 2018” and inserting
8 “each of years 2018 through 2021”;
9 and

10 (ii) in clause (ii)(V), by striking “2019
11 and each subsequent year” and inserting
12 “each of years 2019 through 2021”;

13 (2) in paragraph (3)(A)—

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

17 (B) in clause (ii), by striking “for a subse-
18 quent year” and inserting “for each of years
19 2007 through 2021”; and

20 (3) in paragraph (4)—

21 (A) in subparagraph (A)—

22 (i) in clause (i)—

23 (I) by redesignating subclauses (I)
24 and (II) as items (aa) and (bb), re-
25 spectively, and moving the margin of

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

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

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

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

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

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

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

19 (B) in subparagraph (B)—

20 (i) in clause (i)—

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

23 (II) in subclause (VI)—

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

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

7 (III) by adding at the end the fol-
8 lowing new subclauses:

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

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

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

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

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

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

6 (c) *MANUFACTURER DISCOUNT PROGRAM.*—

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

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

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

22 “(b) *TERMS OF AGREEMENT.*—

23 “(1) *IN GENERAL.*—

24 “(A) *AGREEMENT.*—*An agreement under*
25 *this section shall require the manufacturer to*

1 *provide applicable beneficiaries access to dis-*
2 *counted prices for applicable drugs of the manu-*
3 *facturer that are dispensed on or after January*
4 *1, 2022.*

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

11 “(C) *TIMING OF AGREEMENT.—*

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

21 “(ii) *2023 AND SUBSEQUENT YEARS.—*
22 *In order for an agreement with a manufac-*
23 *turer to be in effect under this section with*
24 *respect to plan year 2023 or a subsequent*
25 *plan year, the manufacturer shall enter into*

1 *such agreement (or such agreement shall be*
2 *renewed under paragraph (4)(A)) not later*
3 *than January 30 of the preceding year.*

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

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

19 “(4) *LENGTH OF AGREEMENT.—*

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

1 “(B) *TERMINATION.*—

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

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

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

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

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

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

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

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

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

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

1 *ble beneficiaries at pharmacies or by mail order*
2 *service at the point-of-sale of an applicable drug;*

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

10 “(i) *the negotiated price of the applica-*
11 *ble drug; and*

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

14 “(D) *the establishment of procedures to en-*
15 *sure that the discounted price for an applicable*
16 *drug under this section is applied before any*
17 *coverage or financial assistance under other*
18 *health benefit plans or programs that provide*
19 *coverage or financial assistance for the purchase*
20 *or provision of prescription drug coverage on be-*
21 *half of applicable beneficiaries as the Secretary*
22 *may specify; and*

23 “(E) *providing a reasonable dispute resolu-*
24 *tion mechanism to resolve disagreements between*
25 *manufacturers, applicable beneficiaries, and the*

1 *third party with a contract under subsection*
2 *(d)(3).*

3 “(2) *MONITORING COMPLIANCE.*—

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

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

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

19 “(d) *ADMINISTRATION.*—

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

24 “(2) *LIMITATION.*—*In providing for the imple-*
25 *mentation of this section, the Secretary shall not re-*

1 *ceive or distribute any funds of a manufacturer under*
2 *the program.*

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

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

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

19 *“(C) provide adequate and timely informa-*
20 *tion to manufacturers, consistent with the agree-*
21 *ment with the manufacturer under this section,*
22 *as necessary for the manufacturer to fulfill its*
23 *obligations under this section; and*

24 *“(D) permit manufacturers to conduct peri-*
25 *odic audits, directly or through contracts, of the*

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

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

10 “(5) *IMPLEMENTATION.*—*Notwithstanding any*
11 *other provision of law, the Secretary may implement*
12 *the program under this section by program instruc-*
13 *tion or otherwise.*

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

17 “(e) *ENFORCEMENT.*—

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

21 “(2) *CIVIL MONEY PENALTY.*—

22 “(A) *IN GENERAL.*—*The Secretary may im-*
23 *pose a civil money penalty on a manufacturer*
24 *that fails to provide applicable beneficiaries dis-*
25 *counts for applicable drugs of the manufacturer*

1 *in accordance with such agreement for each such*
2 *failure in an amount the Secretary determines is*
3 *equal to the sum of—*

4 “(i) *the amount that the manufacturer*
5 *would have paid with respect to such dis-*
6 *counts under the agreement, which will then*
7 *be used to pay the discounts which the man-*
8 *ufacturer had failed to provide; and*

9 “(ii) *25 percent of such amount.*

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

16 “(f) *CLARIFICATION REGARDING AVAILABILITY OF*
17 *OTHER COVERED PART D DRUGS.—Nothing in this section*
18 *shall prevent an applicable beneficiary from purchasing a*
19 *covered part D drug that is not an applicable drug (includ-*
20 *ing a generic drug or a drug that is not on the formulary*
21 *of the prescription drug plan or MA–PD plan that the ap-*
22 *plicable beneficiary is enrolled in).*

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

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

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

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

8 “(C) *has incurred costs for covered part D*
9 *drugs in the year that are equal to or exceed the*
10 *annual deductible specified in section 1860D–*
11 *2(b)(1) for such year.*

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

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

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

21 “(ii)(I) *if the PDP sponsor of the pre-*
22 *scription drug plan or the MA organization*
23 *offering the MA–PD plan uses a formulary,*
24 *which is on the formulary of the prescrip-*

1 *tion drug plan or MA–PD plan that the ap-*
 2 *plicable beneficiary is enrolled in;*

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

10 *“(III) is provided through an exception*
 11 *or appeal; and*

12 *“(B) does not include a selected drug (as de-*
 13 *efined in section 1192(c)) during a price applica-*
 14 *bility period (as defined in section 1191(b)(2))*
 15 *with respect to such drug.*

16 *“(3) APPLICABLE NUMBER OF CALENDAR*
 17 *DAYS.—The term ‘applicable number of calendar*
 18 *days’ means—*

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

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

23 *“(4) DISCOUNTED PRICE.—*

24 *“(A) IN GENERAL.—The term ‘discounted*
 25 *price’ means, with respect to an applicable drug*

1 *of a manufacturer furnished during a year to an*
2 *applicable beneficiary—*

3 “(i) *who has not incurred costs for cov-*
4 *ered part D drugs in the year that are*
5 *equal to or exceed the annual out-of-pocket*
6 *threshold specified in section 1860D-*
7 *2(b)(4)(B)(i) for the year, 90 percent of the*
8 *negotiated price of such drug; and*

9 “(ii) *who has incurred such costs in*
10 *the year that are equal to or exceed such*
11 *threshold for the year, 70 percent of the ne-*
12 *gotiated price of such drug.*

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

17 “(C) *SPECIAL CASE FOR CERTAIN*
18 *CLAIMS.—*

19 “(i) *CLAIMS SPANNING DEDUCTIBLE.—*
20 *In the case where the entire amount of the*
21 *negotiated price of an individual claim for*
22 *an applicable drug with respect to an ap-*
23 *plicable beneficiary does not fall at or above*
24 *the annual deductible specified in section*
25 *1860D-2(b)(1) for the year, the manufac-*

1 *turer of the applicable drug shall provide*
2 *the discounted price under this section on*
3 *only the portion of the negotiated price of*
4 *the applicable drug that falls at or above*
5 *such annual deductible.*

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

16 *“(I) in accordance with subpara-*
17 *graph (A)(i) on the portion of the ne-*
18 *gotiated price of the applicable drug*
19 *that falls below such threshold; and*

20 *“(II) in accordance with subpara-*
21 *graph (A)(ii) on the portion of such*
22 *price of such drug that falls at or*
23 *above such threshold.*

24 *“(5) MANUFACTURER.—The term ‘manufacturer’*
25 *means any entity which is engaged in the production,*

1 *preparation, propagation, compounding, conversion,*
2 *or processing of prescription drug products, either di-*
3 *rectly or indirectly by extraction from substances of*
4 *natural origin, or independently by means of chem-*
5 *ical synthesis, or by a combination of extraction and*
6 *chemical synthesis. Such term does not include a*
7 *wholesale distributor of drugs or a retail pharmacy li-*
8 *censed under State law.*

9 “(6) *NEGOTIATED PRICE.*—*The term ‘negotiated*
10 *price’ has the meaning given such term in section*
11 *423.100 of title 42, Code of Federal Regulations (or*
12 *any successor regulation), except that such negotiated*
13 *price shall not include any dispensing fee for the ap-*
14 *plicable drug.*

15 “(7) *QUALIFIED RETIREE PRESCRIPTION DRUG*
16 *PLAN.*—*The term ‘qualified retiree prescription drug*
17 *plan’ has the meaning given such term in section*
18 *1860D–22(a)(2).”.*

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

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

1 (B) by adding at the end the following new
2 subsection:

3 “(h) *SUNSET OF PROGRAM.*—

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

9 “(2) *CONTINUED APPLICATION FOR APPLICABLE*
10 *DRUGS DISPENSED PRIOR TO SUNSET.*—The provi-
11 sions of this section (including all responsibilities and
12 duties) shall continue to apply after January 1, 2022,
13 with respect to applicable drugs dispensed prior to
14 such date.”.

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

19 (A) in subsection (b)(2)(C)(iii)—

20 (i) by striking “assumptions regarding
21 the reinsurance” and inserting “assump-
22 tions regarding—

23 “(I) the reinsurance”; and

24 (ii) by adding at the end the following:

1 “(II) for 2022 and each subse-
 2 quent year, the manufacturer discounts
 3 provided under section 1860D–14C
 4 subtracted from the actuarial value to
 5 produce such bid; and”;

6 (B) in subsection (c)(1)(C)—

7 (i) by striking “an actuarial valuation
 8 of the reinsurance” and inserting “an actu-
 9 arial valuation of—

10 “(i) the reinsurance”;

11 (ii) in clause (i), as inserted by clause
 12 (i) of this subparagraph, by adding “and”
 13 at the end; and

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

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

19 (d) CONFORMING AMENDMENTS.—

20 (1) Section 1860D–2 of the Social Security Act
 21 (42 U.S.C. 1395w–102) is amended—

22 (A) in subsection (a)(2)(A)(i)(I), by striking
 23 “, or an increase in the initial” and inserting
 24 “or, for a year preceding 2022, an increase in
 25 the initial”;

1 (B) in subsection (c)(1)(C)—

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

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

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

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

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

19 (A) in paragraph (1)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (A) in subsection (a)—

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

17 “(1) participate in—

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

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

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

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

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

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

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

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

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

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

20 (B) by striking subsection (b) and inserting
21 the following:

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

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

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

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

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

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

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

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

1 *individual enrolled with such plan for such plan*
2 *year who is not a subsidy eligible individual (as*
3 *defined in section 1860D–14(a)(3)) and with re-*
4 *spect to whom the plan projects that the dis-*
5 *persing of the first fill of a covered part D drug*
6 *to such individual will result in the individual*
7 *incurring costs that are equal to or above the an-*
8 *nuual out-of-pocket threshold specified in para-*
9 *graph (4)(B) for such plan year, provide such*
10 *individual with the option to make the coinsur-*
11 *ance payment required under subparagraph (A)*
12 *(for the portion of such costs that are not above*
13 *such annual out-of-pocket threshold) in the form*
14 *of periodic installments over the remainder of*
15 *such plan year.”.*

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

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

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

24 *(2) by adding at the end the following new para-*
25 *graph:*

1 “(8) *APPLICATION OF PHARMACY QUALITY MEAS-*
2 *URES.—*

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

10 “(B) *STANDARD PHARMACY QUALITY MEAS-*
11 *URES.—The Secretary shall establish or approve*
12 *standard quality measures from a consensus and*
13 *evidence-based organization for payments de-*
14 *scribed in subparagraph (A). Such measures*
15 *shall focus on patient health outcomes and be*
16 *based on proven criteria measuring pharmacy*
17 *performance.*

18 “(C) *EFFECTIVE DATE.—The requirement*
19 *under subparagraph (A) shall take effect for plan*
20 *years beginning on or after January 1, 2021, or*
21 *such earlier date specified by the Secretary if the*
22 *Secretary determines there are sufficient meas-*
23 *ures established or approved under subparagraph*
24 *(B) to meet the requirement under subparagraph*
25 *(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.”.*

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

4 **(a) SHORT TITLE.—This Act may be cited as**
 5 **the “Elijah E. Cummings Lower Drug Costs**
 6 **Now Act”.**

7 **(b) TABLE OF CONTENTS.—The table of con-**
 8 **tents is as follows:**

Sec. 1. Short title; table of contents.

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

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

Sec. 102. Selected drug manufacturer excise tax imposed dur-
ing 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 cir-
cumstances.

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 reduc-
tions for low-income individuals.

Sec. 402. Dissemination to Medicare part D subsidy eligible in-
dividuals of information comparing premiums of
certain prescription drug plans.

Sec. 403. Providing for intelligent assignment of certain sub-
sidy eligible individuals auto-enrolled under
Medicare prescription drug plans and MA-PD
plans.

- Sec. 404. Expanding eligibility for low-income subsidies under part D of the Medicare program.
- Sec. 405. Automatic eligibility of certain low-income territorial residents for premium and cost-sharing subsidies under the Medicare program; Sunset of enhanced allotment program.
- Sec. 406. Automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program.
- Sec. 407. Eliminating the resource requirement with respect to subsidy eligible individuals under part D of the Medicare program.
- Sec. 408. Providing for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program.

TITLE V—DRUG PRICE TRANSPARENCY

- Sec. 501. Drug price transparency.

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

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

6 **(a) PROGRAM TO LOWER PRICES FOR CER-**
 7 **TAIN HIGH-PRICED SINGLE SOURCE DRUGS.—**

8 **Title XI of the Social Security Act (42 U.S.C.**
 9 **1301 et seq.) is amended by adding at the end**
 10 **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 es-**
 16 **tablish a Fair Price Negotiation Program (in**

1 **this part referred to as the ‘program’). Under**
2 **the program, with respect to each price appli-**
3 **cability period, the Secretary shall—**

4 **“(1) publish a list of selected drugs in**
5 **accordance with section 1192;**

6 **“(2) enter into agreements with man-**
7 **ufacturers of selected drugs with respect**
8 **to such period, in accordance with sec-**
9 **tion 1193;**

10 **“(3) negotiate and, if applicable, re-**
11 **negotiate maximum fair prices for such**
12 **selected drugs, in accordance with sec-**
13 **tion 1194; and**

14 **“(4) carry out the administrative du-**
15 **ties described in section 1196.**

16 **“(b) DEFINITIONS RELATING TO TIMING.—For**
17 **purposes of this part:**

18 **“(1) INITIAL PRICE APPLICABILITY**
19 **YEAR.—The term ‘initial price applica-**
20 **bility year’ means a plan year (beginning**
21 **with plan year 2023) or, if agreed to in an**
22 **agreement under section 1193 by the Sec-**
23 **retary and manufacturer involved, a pe-**
24 **riod of more than one plan year (begin-**
25 **ning on or after January 1, 2023).**

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

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

15 **“(4) VOLUNTARY NEGOTIATION PERIOD.—**
16 **The term ‘voluntary negotiation period’**
17 **means, with respect to an initial price ap-**
18 **plicability year with respect to a selected**
19 **drug, the period—**

20 **“(A) beginning on the sooner of—**

21 **“(i) the date on which the**
22 **manufacturer of the drug and the**
23 **Secretary enter into an agree-**
24 **ment under section 1193 with re-**
25 **spect to such drug; or**

1 “(ii) June 15 following the se-
2 lected drug publication date with
3 respect to such selected drug; and

4 “(B) ending on March 31 of the
5 year that begins one year prior to the
6 initial price applicability year.

7 “(c) OTHER DEFINITIONS.—For purposes of
8 this part:

9 “(1) FAIR PRICE ELIGIBLE INDIVIDUAL.—
10 The term ‘fair price eligible individual’
11 means, with respect to a selected drug—

12 “(A) in the case such drug is fur-
13 nished or dispensed to the individual
14 at a pharmacy or by a mail order
15 service—

16 “(i) an individual who is en-
17 rolled under a prescription drug
18 plan under part D of title XVIII or
19 an MA-PD plan under part C of
20 such title under which coverage
21 is provided for such drug; and

22 “(ii) an individual who is en-
23 rolled under a group health plan
24 or health insurance coverage of-
25 fered in the group or individual

1 market (as such terms are defined
2 in section 2791 of the Public
3 Health Service Act) with respect
4 to which there is in effect an
5 agreement with the Secretary
6 under section 1197 with respect
7 to such selected drug as so fur-
8 nished or dispensed; and

9 “(B) in the case such drug is fur-
10 nished or administered to the indi-
11 vidual by a hospital, physician, or
12 other provider of services or sup-
13 plier—

14 “(i) an individual who is enti-
15 tled to benefits under part A of
16 title XVIII or enrolled under part
17 B of such title if such selected
18 drug is covered under the respec-
19 tive part; and

20 “(ii) an individual who is en-
21 rolled under a group health plan
22 or health insurance coverage of-
23 fered in the group or individual
24 market (as such terms are defined
25 in section 2791 of the Public

1 **Health Service Act) with respect**
2 **to which there is in effect an**
3 **agreement with the Secretary**
4 **under section 1197 with respect**
5 **to such selected drug as so fur-**
6 **nished or administered.**

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

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

17 **“(A) IN GENERAL.—The terms ‘aver-**
18 **age international market price’ and**
19 **‘AIM price’ mean, with respect to a**
20 **drug, the average price (which shall**
21 **be the net average price, if prac-**
22 **ticable, and volume-weighted, if prac-**
23 **ticable) for a unit (as defined in para-**
24 **graph (4)) of the drug for sales of**
25 **such drug (calculated across different**

1 dosage forms and strengths of the
2 drug and not based on the specific
3 formulation or package size or pack-
4 age type), as computed (as of the date
5 of publication of such drug as a se-
6 lected drug under section 1192(a)) in
7 all countries described in clause (ii)
8 of subparagraph (B) that are applica-
9 ble countries (as described in clause
10 (i) of such subparagraph) with re-
11 spect to such drug.

12 “(B) APPLICABLE COUNTRIES.—

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

22 “(ii) COUNTRIES DESCRIBED.—

23 For purposes of this paragraph,
24 the following are countries de-
25 scribed in this clause:

1 **“(I) Australia.**

2 **“(II) Canada.**

3 **“(III) France.**

4 **“(IV) Germany.**

5 **“(V) Japan.**

6 **“(VI) The United Kingdom.**

7 **“(4) UNIT.—The term ‘unit’ means,**
8 **with respect to a drug, the lowest identi-**
9 **fiable quantity (such as a capsule or tab-**
10 **let, milligram of molecules, or grams) of**
11 **the drug that is dispensed.**

12 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
13 **AS SELECTED DRUGS.**

14 **“(a) IN GENERAL.—Not later than the se-**
15 **lected drug publication date with respect to**
16 **an initial price applicability year, the Sec-**
17 **retary shall select and publish in the Federal**
18 **Register a list of—**

19 **“(1)(A) with respect to an initial price**
20 **applicability year during the period be-**
21 **ginning with 2023 and ending with 2027,**
22 **at least 25 negotiation-eligible drugs de-**
23 **scribed in subparagraphs (A) and (B), but**
24 **not subparagraph (C), of subsection (d)(1)**
25 **(or, with respect to an initial price appli-**

1 **capability year during such period begin-**
2 **ning after 2023, the maximum number (if**
3 **such number is less than 25) of such ne-**
4 **gotiation-eligible drugs for the year) with**
5 **respect to such year;**

6 **“(B) with respect to an initial price**
7 **applicability year during the period be-**
8 **ginning with 2028 and ending with 2032,**
9 **at least 30 negotiation-eligible drugs de-**
10 **scribed in subparagraphs (A) and (B), but**
11 **not subparagraph (C), of subsection (d)(1)**
12 **(or, with respect to an initial price appli-**
13 **cability year during such period, the**
14 **maximum number (if such number is less**
15 **than 30) of such negotiation-eligible**
16 **drugs for the year) with respect to such**
17 **year; and**

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

1 **than 35) of such negotiation-eligible**
2 **drugs for the year) with respect to such**
3 **year;**

4 **“(2) all negotiation-eligible drugs de-**
5 **scribed in subparagraph (C) of such sub-**
6 **section with respect to such year; and**

7 **“(3) all new-entrant negotiation-eli-**
8 **ble drugs (as defined in subsection (g)(1))**
9 **with respect to such year.**

10 **Each drug published on the list pursuant to**
11 **the previous sentence shall be subject to the**
12 **negotiation process under section 1194 for the**
13 **voluntary negotiation period with respect to**
14 **such initial price applicability year (and the**
15 **renegotiation process under such section as**
16 **applicable for any subsequent year during the**
17 **applicable price applicability period). In ap-**
18 **plying this subsection, any negotiation-eli-**
19 **ble drug that is selected under this subsection**
20 **for an initial price applicability year shall not**
21 **count toward the required minimum amount**
22 **of drugs to be selected under paragraph (1)**
23 **for any subsequent year, including such a**
24 **drug so selected that is subject to renegoti-**
25 **ation under section 1194.**

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

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

1 each subsequent plan year beginning before
2 the first plan year beginning after the date on
3 which the Secretary determines two or more
4 drug products—

5 “(1) are approved or licensed (as ap-
6 plicable)—

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

10 “(B) under section 351(k) of the
11 Public Health Service Act using such
12 drug as the reference product; and

13 “(2) continue to be marketed.

14 “(d) NEGOTIATION-ELIGIBLE DRUG.—

15 “(1) IN GENERAL.—For purposes of this
16 part, the term ‘negotiation-eligible drug’
17 means, with respect to the selected drug
18 publication date with respect to an initial
19 price applicability year, a qualifying sin-
20 gle source drug, as defined in subsection
21 (e), that meets any of the following cri-
22 teria:

23 “(A) COVERED PART D DRUGS.—The
24 drug is among the 125 covered part D
25 drugs (as defined in section 1860D-

1 **2(e)) for which there was an esti-**
2 **ated greatest net spending under**
3 **parts C and D of title XVIII, as deter-**
4 **mined by the Secretary, during the**
5 **most recent plan year prior to such**
6 **drug publication date for which data**
7 **are available.**

8 **“(B) OTHER DRUGS.—The drug is**
9 **among the 125 drugs for which there**
10 **was an estimated greatest net spend-**
11 **ing in the United States (including**
12 **the 50 States, the District of Colum-**
13 **bia, and the territories of the United**
14 **States), as determined by the Sec-**
15 **retary, during the most recent plan**
16 **year prior to such drug publication**
17 **date for which data are available.**

18 **“(C) INSULIN.—The drug is a quali-**
19 **ifying single source drug described in**
20 **subsection (e)(3).**

21 **“(2) CLARIFICATION.—In determining**
22 **whether a qualifying single source drug**
23 **satisfies any of the criteria described in**
24 **paragraph (1), the Secretary shall, to the**
25 **extent practicable, use data that is aggre-**

1 gated across dosage forms and strengths
2 of the drug and not based on the specific
3 formulation or package size or package
4 type of the drug.

5 “(3) PUBLICATION.—Not later than the
6 selected drug publication date with re-
7 spect to an initial price applicability
8 year, the Secretary shall publish in the
9 Federal Register a list of negotiation-eli-
10 gible drugs with respect to such selected
11 drug publication date.

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

16 “(1) DRUG PRODUCTS.—A drug that—

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

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

1 **“(2) BIOLOGICAL PRODUCTS.—A biological**
2 **cal product that—**

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

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

17 **“(3) INSULIN PRODUCT.—Notwith-**
18 **standing paragraphs (1) and (2), any insu-**
19 **lin product that is approved under sub-**
20 **section (c) or (j) of section 505 of the Fed-**
21 **eral Food, Drug, and Cosmetic Act or li-**
22 **censed under subsection (a) or (k) of sec-**
23 **tion 351 of the Public Health Service Act**
24 **and continues to be marketed under such**
25 **section 505 or 351, including any insulin**

1 product that has been deemed to be li-
2 censed under section 351(a) of the Public
3 Health Service Act pursuant to section
4 7002(e)(4) of the Biologics Price Competi-
5 tion and Innovation Act of 2009 and con-
6 tinues to be marketed pursuant to such
7 licensure.

8 For purposes of applying paragraphs (1) and
9 (2), a drug or biological product that is mar-
10 keted by the same sponsor or manufacturer
11 (or an affiliate thereof or a cross-licensed pro-
12 ducer or distributor) as the listed drug or ref-
13 erence product described in such respective
14 paragraph shall not be taken into consider-
15 ation.

16 “(f) INFORMATION ON INTERNATIONAL DRUG
17 PRICES.—For purposes of determining which
18 negotiation-eligible drugs to select under sub-
19 section (a) and, in the case of such drugs that
20 are selected drugs, to determine the max-
21 imum fair price for such a drug and whether
22 such maximum fair price should be renegoti-
23 ated under section 1194, the Secretary shall
24 use data relating to the AIM price with re-
25 spect to such drug as available or provided to

1 the Secretary and shall on an ongoing basis
2 request from manufacturers of selected drugs
3 information on the AIM price of such a drug.

4 “(g) NEW-ENTRANT NEGOTIATION-ELIGIBLE
5 DRUGS.—

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

12 “(A) that is first approved or li-
13 censed, as described in paragraph (1),
14 (2), or (3) of subsection (e), as applica-
15 ble, during the year preceding such
16 selected drug publication date; and

17 “(B) that the Secretary deter-
18 mines under paragraph (2) is likely to
19 be included as a negotiation-eligible
20 drug with respect to the subsequent
21 selected drug publication date.

22 “(2) DETERMINATION.—In the case of a
23 qualifying single source drug that meets
24 the criteria described in subparagraph
25 (A) of paragraph (1), with respect to an

1 **initial price applicability year, if the**
2 **wholesale acquisition cost at which such**
3 **drug is first marketed in the United**
4 **States is equal to or greater than the me-**
5 **dian household income (as determined**
6 **according to the most recent data col-**
7 **lected by the United States Census Bu-**
8 **reau), the Secretary shall determine be-**
9 **fore the selected drug publication date**
10 **with respect to the initial price applica-**
11 **bility year, if the drug is likely to be in-**
12 **cluded as a negotiation-eligible drug with**
13 **respect to the subsequent selected drug**
14 **publication date, based on the projected**
15 **spending under title XVIII or in the**
16 **United States on such drug. For purposes**
17 **of this paragraph the term ‘United States’**
18 **includes the 50 States, the District of Co-**
19 **lumbia, and the territories of the United**
20 **States.**

21 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

22 **“(a) IN GENERAL.—For purposes of section**
23 **1191(a)(2), the Secretary shall enter into**
24 **agreements with manufacturers of selected**
25 **drugs with respect to a price applicability pe-**

1 riod, by not later than June 15 following the
2 selected drug publication date with respect to
3 such selected drug, under which—

4 “(1) during the voluntary negotiation
5 period for the initial price applicability
6 year for the selected drug, the Secretary
7 and manufacturer, in accordance with
8 section 1194, negotiate to determine (and,
9 by not later than the last date of such pe-
10 riod and in accordance with subsection
11 (c), agree to) a maximum fair price for
12 such selected drug of the manufacturer
13 in order to provide access to such price—

14 “(A) to fair price eligible individ-
15 uals who with respect to such drug
16 are described in subparagraph (A) of
17 section 1191(c)(1) and are furnished
18 or dispensed such drug during, sub-
19 ject to subparagraph (2), the price ap-
20 plicability period; and

21 “(B) to hospitals, physicians, and
22 other providers of services and sup-
23 pliers with respect to fair price eligi-
24 ble individuals who with respect to
25 such drug are described in subpara-

1 **graph (B) of such section and are fur-**
2 **nished or administered such drug**
3 **during, subject to subparagraph (2),**
4 **the price applicability period;**

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

20 **“(A) to fair price eligible individ-**
21 **uals who with respect to such drug**
22 **are described in subparagraph (A) of**
23 **section 1191(c)(1) and are furnished**
24 **or dispensed such drug during any**
25 **year during the price applicability**

1 **period (beginning after such renego-**
2 **tiation) with respect to such selected**
3 **drug; and**

4 **“(B) to hospitals, physicians, and**
5 **other providers of services and sup-**
6 **pliers with respect to fair price eligi-**
7 **ble individuals who with respect to**
8 **such drug are described in subpara-**
9 **graph (B) of such section and are fur-**
10 **nished or administered such drug**
11 **during any year described in sub-**
12 **paragraph (A);**

13 **“(3) the maximum fair price (includ-**
14 **ing as renegotiated pursuant to para-**
15 **graph (2)), with respect to such a selected**
16 **drug, shall be provided to fair price eligi-**
17 **ble individuals, who with respect to such**
18 **drug are described in subparagraph (A)**
19 **of section 1191(c)(1), at the pharmacy or**
20 **by a mail order service at the point-of-**
21 **sale of such drug;**

22 **“(4) the manufacturer, subject to sub-**
23 **section (d), submits to the Secretary, in a**
24 **form and manner specified by the Sec-**
25 **retary—**

1 “(A) for the voluntary negotiation
2 period for the price applicability pe-
3 riod (and, if applicable, before any
4 period of renegotiation specified pur-
5 suant to paragraph (2)) with respect
6 to such drug all information that the
7 Secretary requires to carry out the
8 negotiation (or renegotiation process)
9 under this part, including informa-
10 tion described in section 1192(f) and
11 section 1194(d)(1); and

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

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

1 “(6) the manufacturer complies with
2 requirements imposed by the Secretary
3 for purposes of administering the pro-
4 gram, including with respect to the du-
5 ties described in section 1196.

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

12 “(c) SPECIAL RULE FOR CERTAIN SELECTED
13 DRUGS WITHOUT AIM PRICE.—

14 “(1) IN GENERAL.—In the case of a se-
15 lected drug for which there is no AIM
16 price available with respect to the initial
17 price applicability year for such drug and
18 for which an AIM price becomes avail-
19 able beginning with respect to a subse-
20 quent plan year during the price applica-
21 bility period for such drug, if the Sec-
22 retary determines that the amount de-
23 scribed in paragraph (2)(A) for a unit of
24 such drug is greater than the amount de-
25 scribed in paragraph (2)(B) for a unit of

1 such drug, then by not later than one
2 year after the date of such determination,
3 the manufacturer of such selected drug
4 shall pay to the Treasury an amount
5 equal to the product of—

6 “(A) the difference between such
7 amount described in paragraph (2)(A)
8 for a unit of such drug and such
9 amount described in paragraph (2)(B)
10 for a unit of such drug; and

11 “(B) the number of units of such
12 drug sold in the United States, in-
13 cluding the 50 States, the District of
14 Columbia, and the territories of the
15 United States, during the period de-
16 scribed in paragraph (2)(B).

17 “(2) AMOUNTS DESCRIBED.—

18 “(A) WEIGHTED AVERAGE PRICE BE-
19 FORE AIM PRICE AVAILABLE.—For pur-
20 poses of paragraph (1), the amount
21 described in this subparagraph for a
22 selected drug described in such para-
23 graph, is the amount equal to the
24 weighted average manufacturer price
25 (as defined in section 1927(k)(1)) for

1 such dosage strength and form for
2 the drug during the period beginning
3 with the first plan year for which the
4 drug is included on the list of nego-
5 tiation-eligible drugs published under
6 section 1192(d) and ending with the
7 last plan year during the price appli-
8 cability period for such drug with re-
9 spect to which there is no AIM price
10 available for such drug.

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

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

1 **facturer (as determined by the Secretary)**
2 **may be used only by the Secretary or dis-**
3 **closed to and used by the Comptroller Gen-**
4 **eral of the United States or the Medicare Pay-**
5 **ment Advisory Commission for purposes of**
6 **carrying out this part.**

7 **“(e) REGULATIONS.—**

8 **“(1) IN GENERAL.—The Secretary shall,**
9 **pursuant to rulemaking, specify, in ac-**
10 **cordance with paragraph (2), the infor-**
11 **mation that must be submitted under**
12 **subsection (a)(4).**

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

1 **appropriate officials of the government of**
2 **the foreign country involved.**

3 **“(f) COMPLIANCE WITH REQUIREMENTS FOR**
4 **ADMINISTRATION OF PROGRAM.—Each manufac-**
5 **turer with an agreement in effect under this**
6 **section shall comply with requirements im-**
7 **posed by the Secretary or a third party with**
8 **a contract under section 1196(c)(1), as appli-**
9 **cable, for purposes of administering the pro-**
10 **gram.**

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

12 **“(a) IN GENERAL.—For purposes of this**
13 **part, under an agreement under section 1193**
14 **between the Secretary and a manufacturer of**
15 **a selected drug, with respect to the period for**
16 **which such agreement is in effect and in ac-**
17 **cordance with subsections (b) and (c), the Sec-**
18 **retary and the manufacturer—**

19 **“(1) shall during the voluntary nego-**
20 **tiation period with respect to the initial**
21 **price applicability year for such drug, in**
22 **accordance with this section, negotiate a**
23 **maximum fair price for such drug for the**
24 **purpose described in section 1193(a)(1);**
25 **and**

1 “(2) as applicable pursuant to section
2 1193(a)(2) and in accordance with the
3 process specified pursuant to such sec-
4 tion, renegotiate such maximum fair
5 price for such drug for the purpose de-
6 scribed in such section.

7 “(b) **NEGOTIATING METHODOLOGY AND OB-**
8 **JECTIVE.—**

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

17 “(2) **PRIORITIZING FACTORS.—**In consid-
18 ering the factors described in subsection
19 (d) in negotiating (and, as applicable, re-
20 negotiating) the maximum fair price for a
21 selected drug, the Secretary shall, to the
22 extent practicable, consider all of the
23 available factors listed but shall
24 prioritize the following factors:

1 **“(A) RESEARCH AND DEVELOPMENT**
2 **COSTS.—The factor described in para-**
3 **graph (1)(A) of subsection (d).**

4 **“(B) MARKET DATA.—The factor de-**
5 **scribed in paragraph (1)(B) of such**
6 **subsection.**

7 **“(C) UNIT COSTS OF PRODUCTION**
8 **AND DISTRIBUTION.—The factor de-**
9 **scribed in paragraph (1)(C) of such**
10 **subsection.**

11 **“(D) COMPARISON TO EXISTING**
12 **THERAPEUTIC ALTERNATIVES.—The fac-**
13 **tor described in paragraph (2)(A) of**
14 **such subsection.**

15 **“(3) REQUIREMENT.—**

16 **“(A) IN GENERAL.—In negotiating**
17 **the maximum fair price of a selected**
18 **drug, with respect to an initial price**
19 **applicability year for the selected**
20 **drug, and, as applicable, in renegoti-**
21 **ating the maximum fair price for**
22 **such drug, with respect to a subse-**
23 **quent year during the price applica-**
24 **bility period for such drug, in the**
25 **case that the manufacturer of the se-**

1 lected drug offers under the negotia-
2 tion or renegotiation, as applicable, a
3 price for such drug that is not more
4 than the target price described in
5 subparagraph (B) for such drug for
6 the respective year, the Secretary
7 shall agree under such negotiation or
8 renegotiation, respectively, to such
9 offered price as the maximum fair
10 price.

11 “(B) TARGET PRICE.—

12 “(i) IN GENERAL.—Subject to
13 clause (ii), the target price de-
14 scribed in this subparagraph for a
15 selected drug with respect to a
16 year, is the average price (which
17 shall be the net average price, if
18 practicable, and volume-weighted,
19 if practicable) for a unit of such
20 drug for sales of such drug, as
21 computed (across different dosage
22 forms and strengths of the drug
23 and not based on the specific for-
24 mulation or package size or pack-
25 age type of the drug) in the appli-

1 cable country described in sec-
2 tion 1191(c)(3)(B) with respect to
3 such drug that, with respect to
4 such year, has the lowest average
5 price for such drug as compared
6 to the average prices (as so com-
7 puted) of such drug with respect
8 to such year in the other applica-
9 ble countries described in such
10 section with respect to such drug.

11 “(ii) **SELECTED DRUGS WITHOUT**
12 **AIM PRICE.—In applying this para-**
13 **graph in the case of negotiating**
14 **the maximum fair price of a se-**
15 **lected drug for which there is no**
16 **AIM price available with respect**
17 **to the initial price applicability**
18 **year for such drug, or, as applica-**
19 **ble, renegotiating the maximum**
20 **fair price for such drug with re-**
21 **spect to a subsequent year during**
22 **the price applicability period for**
23 **such drug before the first plan**
24 **year for which there is an AIM**
25 **price available for such drug, the**

1 target price described in this sub-
2 paragraph for such drug and re-
3 spective year is the amount that
4 is 80 percent of the average man-
5 ufacturer price (as defined in sec-
6 tion 1927(k)(1)) for such drug and
7 year.

8 “(4) ANNUAL REPORT.—After the com-
9 pletion of each voluntary negotiation pe-
10 riod, the Secretary shall submit to Con-
11 gress a report on the maximum fair
12 prices negotiated (or, as applicable, re-
13 negotiated) for such period. Such report
14 shall include information on how such
15 prices so negotiated (or renegotiated)
16 meet the requirements of this part, in-
17 cluding the requirements of this sub-
18 section.

19 “(c) LIMITATION.—

20 “(1) IN GENERAL.—Subject to para-
21 graph (2), the maximum fair price nego-
22 tiated (including as renegotiated) under
23 this section for a selected drug, with re-
24 spect to each plan year during a price ap-
25 plicability period for such drug, shall not

1 exceed 120 percent of the AIM price ap-
2 plicable to such drug with respect to
3 such year.

4 “(2) **SELECTED DRUGS WITHOUT AIM**
5 **PRICE.**—In the case of a selected drug for
6 which there is no AIM price available
7 with respect to the initial price applica-
8 bility year for such drug, for each plan
9 year during the price applicability period
10 before the first plan year for which there
11 is an AIM price available for such drug,
12 the maximum fair price negotiated (in-
13 cluding as renegotiated) under this sec-
14 tion for the selected drug shall not ex-
15 ceed the amount equal to 85 percent of
16 the average manufacturer price for the
17 drug with respect to such year.

18 “(d) **CONSIDERATIONS.**—For purposes of ne-
19 gotiating and, as applicable, renegotiating (in-
20 cluding for purposes of determining whether
21 to renegotiate) the maximum fair price of a
22 selected drug under this part with the manu-
23 facturer of the drug, the Secretary shall, con-
24 sistent with subsection (b)(2), take into con-
25 sideration the following factors:

1 **“(1) MANUFACTURER-SPECIFIC INFORMA-**
2 **TION.—The following information, includ-**
3 **ing as submitted by the manufacturer:**

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

9 **“(B) Market data for the drug, in-**
10 **cluding the distribution of sales**
11 **across different programs and pur-**
12 **chasers and projected future reve-**
13 **nues for the drug.**

14 **“(C) Unit costs of production and**
15 **distribution of the drug.**

16 **“(D) Prior Federal financial sup-**
17 **port for novel therapeutic discovery**
18 **and development with respect to the**
19 **drug.**

20 **“(E) Data on patents and on exist-**
21 **ing and pending exclusivity for the**
22 **drug.**

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

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

5 **“(2) INFORMATION ON ALTERNATIVE**
6 **PRODUCTS.—The following information:**

7 **“(A) The extent to which the drug**
8 **represents a therapeutic advance as**
9 **compared to existing therapeutic al-**
10 **ternatives and, to the extent such in-**
11 **formation is available, the costs of**
12 **such existing therapeutic alter-**
13 **natives.**

14 **“(B) Information on approval by**
15 **the Food and Drug Administration of**
16 **alternative drug products.**

17 **“(C) Information on comparative**
18 **effectiveness analysis for such prod-**
19 **ucts, taking into consideration the ef-**
20 **fects of such products on specific**
21 **populations, such as individuals with**
22 **disabilities, the elderly, terminally ill,**
23 **children, and other patient popu-**
24 **lations.**

1 **In considering information described in**
2 **subparagraph (C), the Secretary shall not**
3 **use evidence or findings from compara-**
4 **tive clinical effectiveness research in a**
5 **manner that treats extending the life of**
6 **an elderly, disabled, or terminally ill indi-**
7 **vidual as of lower value than extending**
8 **the life of an individual who is younger,**
9 **nondisabled, or not terminally ill. Noth-**
10 **ing in the previous sentence shall affect**
11 **the application or consideration of an**
12 **AIM price for a selected drug.**

13 **“(3) FOREIGN SALES INFORMATION.—To**
14 **the extent available on a timely basis, in-**
15 **cluding as provided by a manufacturer of**
16 **the selected drug or otherwise, informa-**
17 **tion on sales of the selected drug in each**
18 **of the countries described in section**
19 **1191(c)(3)(B).**

20 **“(4) ADDITIONAL INFORMATION.—Infor-**
21 **mation submitted to the Secretary, in ac-**
22 **cordance with a process specified by the**
23 **Secretary, by other parties that are af-**
24 **ected by the establishment of a max-**
25 **imum fair price for the selected drug.**

1 “(e) **REQUEST FOR INFORMATION.—For pur-**
2 **poses of negotiating and, as applicable, re-**
3 **negotiating (including for purposes of deter-**
4 **mining whether to renegotiate) the maximum**
5 **fair price of a selected drug under this part**
6 **with the manufacturer of the drug, with re-**
7 **spect to a price applicability period, and**
8 **other relevant data for purposes of this sec-**
9 **tion—**

10 “(1) **the Secretary shall, not later than**
11 **the selected drug publication date with**
12 **respect to the initial price applicability**
13 **year of such period, request drug pricing**
14 **information from the manufacturer of**
15 **such selected drug, including information**
16 **described in subsection (d)(1); and**

17 “(2) **by not later than October 1 fol-**
18 **lowing the selected drug publication**
19 **date, the manufacturer of such selected**
20 **drug shall submit to the Secretary such**
21 **requested information in such form and**
22 **manner as the Secretary may require.**

23 **The Secretary shall request, from the manu-**
24 **facturer or others, such additional informa-**
25 **tion as may be needed to carry out the nego-**

1 **tiation and renegotiation process under this**
2 **section.**

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

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

12 **“(b) UPDATES.—**

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

21 **“(A) subject to subparagraph (B),**
22 **the amount equal to the maximum**
23 **fair price published for such drug for**
24 **the previous year, increased by the**
25 **annual percentage increase in the**

1 **consumer price index for all urban**
2 **consumers (all items; U.S. city aver-**
3 **age) as of September of such previous**
4 **year; or**

5 **“(B) in the case the maximum fair**
6 **price for such drug was renegotiated,**
7 **for the first year for which such price**
8 **as so renegotiated applies, such re-**
9 **negotiated maximum fair price.**

10 **“(2) PRICES NEGOTIATED AFTER DEAD-**
11 **LINE.—In the case of a selected drug with**
12 **respect to an initial price applicability**
13 **year for which the maximum fair price is**
14 **determined under this part after the date**
15 **of publication under this section, the Sec-**
16 **retary shall publish such maximum fair**
17 **price in the Federal Register by not later**
18 **than 30 days after the date such max-**
19 **imum price is so determined.**

20 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
21 **VISIONS.**

22 **“(a) ADMINISTRATIVE DUTIES.—**

23 **“(1) IN GENERAL.—For purposes of sec-**
24 **tion 1191, the administrative duties de-**
25 **scribed in this section are the following:**

1 **“(A) The establishment of proce-**
2 **dures (including through agreements**
3 **with manufacturers under this part,**
4 **contracts with prescription drug**
5 **plans under part D of title XVIII and**
6 **MA–PD plans under part C of such**
7 **title, and agreements under section**
8 **1197 with group health plans and**
9 **health insurance issuers of health in-**
10 **surance coverage offered in the indi-**
11 **vidual or group market) under which**
12 **the maximum fair price for a selected**
13 **drug is provided to fair price eligible**
14 **individuals, who with respect to such**
15 **drug are described in subparagraph**
16 **(A) of section 1191(c)(1), at phar-**
17 **macies or by mail order service at the**
18 **point-of-sale of the drug for the appli-**
19 **cable price period for such drug and**
20 **providing that such maximum fair**
21 **price is used for determining cost-**
22 **sharing under such plans or coverage**
23 **for the selected drug.**

24 **“(B) The establishment of proce-**
25 **dures (including through agreements**

1 with manufacturers under this part
2 and contracts with hospitals, physi-
3 cians, and other providers of services
4 and suppliers and agreements under
5 section 1197 with group health plans
6 and health insurance issuers of
7 health insurance coverage offered in
8 the individual or group market)
9 under which, in the case of a selected
10 drug furnished or administered by
11 such a hospital, physician, or other
12 provider of services or supplier to
13 fair price eligible individuals (who
14 with respect to such drug are de-
15 scribed in subparagraph (B) of sec-
16 tion 1191(c)(1)), the maximum fair
17 price for the selected drug is pro-
18 vided to such hospitals, physicians,
19 and other providers of services and
20 suppliers (as applicable) with respect
21 to such individuals and providing
22 that such maximum fair price is used
23 for determining cost-sharing under
24 the respective part, plan, or coverage
25 for the selected drug.

1 **“(C) The establishment of proce-**
2 **dures (including through agreements**
3 **and contracts described in subpara-**
4 **graphs (A) and (B)) to ensure that,**
5 **not later than 90 days after the dis-**
6 **persing of a selected drug to a fair**
7 **price eligible individual by a phar-**
8 **macy or mail order service, the phar-**
9 **macy or mail order service is reim-**
10 **bursed for an amount equal to the**
11 **difference between—**

12 **“(i) the lesser of—**

13 **“(I) the wholesale acquisi-**
14 **tion cost of the drug;**

15 **“(II) the national average**
16 **drug acquisition cost of the**
17 **drug; and**

18 **“(III) any other similar de-**
19 **termination of pharmacy ac-**
20 **quisition costs of the drug, as**
21 **determined by the Secretary;**
22 **and**

23 **“(ii) the maximum fair price**
24 **for the drug.**

1 **“(D) The establishment of proce-**
2 **dures to ensure that the maximum**
3 **fair price for a selected drug is ap-**
4 **plied before—**

5 **“(i) any coverage or financial**
6 **assistance under other health**
7 **benefit plans or programs that**
8 **provide coverage or financial as-**
9 **sistance for the purchase or pro-**
10 **vision of prescription drug cov-**
11 **erage on behalf of fair price eligi-**
12 **ble individuals as the Secretary**
13 **may specify; and**

14 **“(ii) any other discounts.**

15 **“(E) The establishment of proce-**
16 **dures to enter into appropriate agree-**
17 **ments and protocols for the ongoing**
18 **computation of AIM prices for se-**
19 **lected drugs, including, to the extent**
20 **possible, to compute the AIM price**
21 **for selected drugs and including by**
22 **providing that the manufacturer of**
23 **such a selected drug should provide**
24 **information for such computation not**
25 **later than 3 months after the first**

1 **date of the voluntary negotiation pe-**
2 **riod for such selected drug.**

3 **“(F) The establishment of proce-**
4 **dures to compute and apply the max-**
5 **imum fair price across different**
6 **strengths and dosage forms of a se-**
7 **lected drug and not based on the spe-**
8 **cific formulation or package size or**
9 **package type of the drug.**

10 **“(G) The establishment of proce-**
11 **dures to negotiate and apply the max-**
12 **imum fair price in a manner that**
13 **does not include any dispensing or**
14 **similar fee.**

15 **“(H) The establishment of proce-**
16 **dures to carry out the provisions of**
17 **this part, as applicable, with respect**
18 **to—**

19 **“(i) fair price eligible individ-**
20 **uals who are enrolled under a**
21 **prescription drug plan under part**
22 **D of title XVIII or an MA-PD plan**
23 **under part C of such title;**

24 **“(ii) fair price eligible individ-**
25 **uals who are enrolled under a**

1 **group health plan or health insur-**
2 **ance coverage offered by a health**
3 **insurance issuer in the individual**
4 **or group market with respect to**
5 **which there is an agreement in ef-**
6 **fect under section 1197; and**

7 **“(iii) fair price eligible indi-**
8 **viduals who are entitled to bene-**
9 **fits under part A of title XVIII or**
10 **enrolled under part B of such**
11 **title.**

12 **“(I) The establishment of a nego-**
13 **tiation process and renegotiation**
14 **process in accordance with section**
15 **1194, including a process for acquir-**
16 **ing information described in sub-**
17 **section (d) of such section and deter-**
18 **mining amounts described in sub-**
19 **section (b) of such section.**

20 **“(J) The provision of a reasonable**
21 **dispute resolution mechanism to re-**
22 **solve disagreements between manu-**
23 **facturers, fair price eligible individ-**
24 **uals, and the third party with a con-**
25 **tract under subsection (c)(1).**

1 **“(2) MONITORING COMPLIANCE.—**

2 **“(A) IN GENERAL.—The Secretary**
3 **shall monitor compliance by a manu-**
4 **facturer with the terms of an agree-**
5 **ment under section 1193, including by**
6 **establishing a mechanism through**
7 **which violations of such terms may**
8 **be reported.**

9 **“(B) NOTIFICATION.—If a third**
10 **party with a contract under sub-**
11 **section (c)(1) determines that the**
12 **manufacturer is not in compliance**
13 **with such agreement, the third party**
14 **shall notify the Secretary of such**
15 **noncompliance for appropriate en-**
16 **forcement under section 4192 of the**
17 **Internal Revenue Code of 1986 or sec-**
18 **tion 1198, as applicable.**

19 **“(b) COLLECTION OF DATA.—**

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

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

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

11 “(c) CONTRACT WITH THIRD PARTIES.—

12 “(1) IN GENERAL.—The Secretary may
13 enter into a contract with 1 or more third
14 parties to administer the requirements
15 established by the Secretary in order to
16 carry out this part. At a minimum, the
17 contract with a third party under the
18 preceding sentence shall require that the
19 third party—

20 “(A) receive and transmit infor-
21 mation between the Secretary, manu-
22 facturers, and other individuals or
23 entities the Secretary determines ap-
24 propriate;

1 **“(B) receive, distribute, or facili-**
2 **tate the distribution of funds of man-**
3 **ufacturers to appropriate individuals**
4 **or entities in order to meet the obli-**
5 **gations of manufacturers under**
6 **agreements under this part;**

7 **“(C) provide adequate and timely**
8 **information to manufacturers, con-**
9 **sistent with the agreement with the**
10 **manufacturer under this part, as nec-**
11 **essary for the manufacturer to fulfill**
12 **its obligations under this part; and**

13 **“(D) permit manufacturers to con-**
14 **duct periodic audits, directly or**
15 **through contracts, of the data and in-**
16 **formation used by the third party to**
17 **determine discounts for applicable**
18 **drugs of the manufacturer under the**
19 **program.**

20 **“(2) PERFORMANCE REQUIREMENTS.—**

21 **The Secretary shall establish perform-**
22 **ance requirements for a third party with**
23 **a contract under paragraph (1) and safe-**
24 **guards to protect the independence and**
25 **integrity of the activities carried out by**

1 **the third party under the program under**
2 **this part.**

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

5 **“(a) AGREEMENT TO PARTICIPATE UNDER**
6 **PROGRAM.—**

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

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

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

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

22 **“(b) PUBLICATION OF ELECTION.—With re-**
23 **spect to each price applicability period and**
24 **each selected drug with respect to such pe-**
25 **riod, the Secretary and the Secretary of Labor**

1 and the Secretary of the Treasury, as applica-
2 ble, shall make public a list of each group
3 health plan and each issuer of health insur-
4 ance coverage, with respect to which cov-
5 erage is provided under such plan or cov-
6 erage for such drug, that has elected under
7 subsection (a) not to participate under the
8 program with respect to such period and
9 drug.

10 “SEC. 1198. CIVIL MONETARY PENALTY.

11 “(a) VIOLATIONS RELATING TO OFFERING OF
12 MAXIMUM FAIR PRICE.—Any manufacturer of a
13 selected drug that has entered into an agree-
14 ment under section 1193, with respect to a
15 plan year during the price applicability pe-
16 riod for such drug, that does not provide ac-
17 cess to a price that is not more than the max-
18 imum fair price (or a lesser price) for such
19 drug for such year—

20 “(1) to a fair price eligible individual
21 who with respect to such drug is de-
22 scribed in subparagraph (A) of section
23 1191(c)(1) and who is furnished or dis-
24 pensed such drug during such year; or

1 “(2) to a hospital, physician, or other
2 provider of services or supplier with re-
3 spect to fair price eligible individuals
4 who with respect to such drug is de-
5 scribed in subparagraph (B) of such sec-
6 tion and is furnished or administered
7 such drug by such hospital, physician, or
8 provider or supplier during such year;
9 shall be subject to a civil monetary penalty
10 equal to ten times the amount equal to the dif-
11 ference between the price for such drug made
12 available for such year by such manufacturer
13 with respect to such individual or hospital,
14 physician, provider, or supplier and the max-
15 imum fair price for such drug for such year.

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

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

7 **“SEC. 1199. MISCELLANEOUS PROVISIONS.**

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

11 **“(b) NATIONAL ACADEMY OF MEDICINE**
12 **STUDY.—Not later than December 31, 2025, the**
13 **National Academy of Medicine shall conduct**
14 **a study, and submit to Congress a report, on**
15 **recommendations for improvements to the**
16 **program under this part, including the deter-**
17 **mination of the limits applied under section**
18 **1194(c).**

19 **“(c) MEDPAC STUDY.—Not later than De-**
20 **cember 31, 2025, the Medicare Payment Advi-**
21 **sory Commission shall conduct a study, and**
22 **submit to Congress a report, on the program**
23 **under this part with respect to the Medicare**
24 **program under title XVIII, including with re-**
25 **spect to the effect of the program on individ-**

1 uals entitled to benefits or enrolled under
2 such title.

3 **“(d) LIMITATION ON JUDICIAL REVIEW.—The**
4 **following shall not be subject to judicial re-**
5 **view:**

6 **“(1) The selection of drugs for publi-**
7 **cation under section 1192(a).**

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

11 **“(3) The determination of the max-**
12 **imum fair price of a selected drug under**
13 **section 1194.**

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

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

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

1 **information as is necessary to determine the**
2 **tax imposed by section 4192 of the Internal**
3 **Revenue Code of 1986.”.**

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

6 **(1) UNDER MEDICARE.—**

7 **(A) APPLICATION TO PAYMENTS**
8 **UNDER PART B.—Section 1847A(b)(1)(B)**
9 **of the Social Security Act (42 U.S.C.**
10 **1395w-3a(b)(1)(B)) is amended by in-**
11 **serting “or in the case of such a drug**
12 **or biological that is a selected drug**
13 **(as defined in section 1192(c)), with**
14 **respect to a price applicability period**
15 **(as defined in section 1191(b)(2)), 106**
16 **percent of the maximum fair price (as**
17 **defined in section 1191(c)(2) applica-**
18 **ble for such drug and a plan year**
19 **during such period” after “paragraph**
20 **(4)”.**

21 **(B) EXCEPTION TO PART D NON-IN-**
22 **TERFERENCE.—Section 1860D-11(i) of**
23 **the Social Security Act (42 U.S.C.**
24 **1395w-111(i)) is amended by inserting**

1 **“, except as provided under part E of**
2 **title XI” after “the Secretary”.**

3 **(C) APPLICATION AS NEGOTIATED**
4 **PRICE UNDER PART D.—Section 1860D-**
5 **2(d)(1) of the Social Security Act (42**
6 **U.S.C. 1395w-102(d)(1) is amended—**

7 **(i) in subparagraph (B), by in-**
8 **serting “, subject to subparagraph**
9 **(D),” after “negotiated prices”;**
10 **and**

11 **(ii) by adding at the end the**
12 **following new subparagraph:**

13 **“(D) APPLICATION OF MAXIMUM FAIR**
14 **PRICE FOR SELECTED DRUGS.—In apply-**
15 **ing this section, in the case of a cov-**
16 **ered part D drug that is a selected**
17 **drug (as defined in section 1192(c)),**
18 **with respect to a price applicability**
19 **period (as defined in section**
20 **1191(b)(2)), the negotiated prices used**
21 **for payment (as described in this sub-**
22 **section) shall be the maximum fair**
23 **price (as defined in section 1191(c)(2))**
24 **for such drug and for each plan year**
25 **during such period.”.**

1 **(D) INFORMATION FROM PRESCRIP-**
2 **TION DRUG PLANS AND MA-PD PLANS RE-**
3 **QUIRED.—**

4 **(i) PRESCRIPTION DRUG**
5 **PLANS.—Section 1860D-12(b) of**
6 **the Social Security Act (42 U.S.C.**
7 **1395w-112(b)) is amended by add-**
8 **ing at the end the following new**
9 **paragraph:**

10 **“(8) PROVISION OF INFORMATION RE-**
11 **LATED TO MAXIMUM FAIR PRICES.—Each**
12 **contract entered into with a PDP sponsor**
13 **under this part with respect to a pre-**
14 **scription drug plan offered by such spon-**
15 **sor shall require the sponsor to provide**
16 **information to the Secretary as requested**
17 **by the Secretary in accordance with sec-**
18 **tion 1196(b).”.**

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

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

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

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

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

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

1 “(1) the provisions of such part shall
2 apply to the plans or coverage offered by
3 such plan or issuer, and to the individ-
4 uals enrolled under such plans or cov-
5 erage, during such period, with respect
6 to such selected drug, in the same man-
7 ner as such provisions apply to prescrip-
8 tion drug plans and MA-PD plans, and to
9 individuals enrolled under such prescrip-
10 tion drug plans and MA-PD plans;

11 “(2) the plan or issuer shall apply any
12 cost-sharing responsibilities under such
13 plan or coverage, with respect to such se-
14 lected drug, by substituting the maximum
15 fair price negotiated under such part for
16 such drug in lieu of the contracted rate
17 under such plan or coverage for such se-
18 lected drug; and

19 “(3) the Secretary shall apply the pro-
20 visions of such part to such plan, issuer,
21 and coverage, and such individuals so en-
22 rolled in such plans.

23 “(b) NOTIFICATION REGARDING NONPARTICI-
24 PATION IN FAIR DRUG PRICE NEGOTIATION PRO-
25 GRAM.—A group health plan or a health insur-

1 **ance issuer offering group or individual**
2 **health insurance coverage shall publicly dis-**
3 **close in a manner and in accordance with a**
4 **process specified by the Secretary any elec-**
5 **tion made under section 1197 of the Social Se-**
6 **curity Act by the plan or issuer to not partici-**
7 **pate in the Fair Drug Price Negotiation Pro-**
8 **gram under part E of title XI of such Act with**
9 **respect to a selected drug (as defined in sec-**
10 **tion 1192(c) of such Act) for which coverage**
11 **is provided under such plan or coverage be-**
12 **fore the beginning of the plan year for which**
13 **such election was made.”.**

14 **(B) ERISA.—**

15 **(i) IN GENERAL.—Subpart B of**
16 **part 7 of subtitle B of title I of the**
17 **Employee Retirement Income Se-**
18 **curity Act of 1974 (29 U.S.C. 1181**
19 **et. seq.) is amended by adding at**
20 **the end the following new section:**

21 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
22 **APPLICATION OF MAXIMUM FAIR PRICES.**

23 **“(a) IN GENERAL.—In the case of a group**
24 **health plan or health insurance issuer offer-**
25 **ing group health insurance coverage that is**

1 treated under section 1197 of the Social Secu-
2 rity Act as having in effect an agreement with
3 the Secretary under the Fair Price Drug Ne-
4 gotiation Program under part E of title XI of
5 such Act, with respect to a price applicability
6 period (as defined in section 1191(b) of such
7 Act) and a selected drug (as defined in section
8 1192(c) of such Act) with respect to such pe-
9 riod with respect to which coverage is pro-
10 vided under such plan or coverage—

11 “(1) the provisions of such part shall
12 apply to the plans or coverage offered by
13 such plan or issuer, and to the individ-
14 uals enrolled under such plans or cov-
15 erage, during such period, with respect
16 to such selected drug, in the same man-
17 ner as such provisions apply to prescrip-
18 tion drug plans and MA–PD plans, and to
19 individuals enrolled under such prescrip-
20 tion drug plans and MA–PD plans;

21 “(2) the plan or issuer shall apply any
22 cost-sharing responsibilities under such
23 plan or coverage, with respect to such se-
24 lected drug, by substituting the maximum
25 fair price negotiated under such part for

1 **such drug in lieu of the contracted rate**
2 **under such plan or coverage for such se-**
3 **lected drug; and**

4 **“(3) the Secretary shall apply the pro-**
5 **visions of such part to such plan, issuer,**
6 **and coverage, and such individuals so en-**
7 **rolled in such plans.**

8 **“(b) NOTIFICATION REGARDING NONPARTICI-**
9 **PATION IN FAIR DRUG PRICE NEGOTIATION PRO-**
10 **GRAM.—A group health plan or a health insur-**
11 **ance issuer offering group health insurance**
12 **coverage shall publicly disclose in a manner**
13 **and in accordance with a process specified by**
14 **the Secretary any election made under sec-**
15 **tion 1197 of the Social Security Act by the**
16 **plan or issuer to not participate in the Fair**
17 **Drug Price Negotiation Program under part E**
18 **of title XI of such Act with respect to a se-**
19 **lected drug (as defined in section 1192(c) of**
20 **such Act) for which coverage is provided**
21 **under such plan or coverage before the begin-**
22 **ning of the plan year for which such election**
23 **was made.”.**

24 **(ii) CLERICAL AMENDMENT.—**
25 **The table of sections for part 7 of**

1 subtitle B of title I of the Em-
2 ployee Retirement Income Secu-
3 rity Act of 1974 is amended by
4 adding at the end the following:

“Sec. 716. Fair Price Drug Negotiation Program and applica-
tion of maximum fair prices.”.

5 (C) IRC.—

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

11 “SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM
12 AND APPLICATION OF MAXIMUM FAIR
13 PRICES.

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

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

3 **“(A) if coverage of such selected**
4 **drug is provided under such plan if**
5 **the drug is furnished or dispensed at**
6 **a pharmacy or by a mail order serv-**
7 **ice, to the plan, and to the individuals**
8 **enrolled under such plan during such**
9 **period, with respect to such selected**
10 **drug, in the same manner as such**
11 **provisions apply to prescription drug**
12 **plans and MA-PD plans, and to indi-**
13 **viduals enrolled under such prescrip-**
14 **tion drug plans and MA-PD plans**
15 **during such period; and**

16 **“(B) if coverage of such selected**
17 **drug is provided under such plan if**
18 **the drug is furnished or administered**
19 **by a hospital, physician, or other pro-**
20 **vider of services or supplier, to the**
21 **plan, to the individuals enrolled**
22 **under such plan, and to hospitals,**
23 **physicians, and other providers of**
24 **services and suppliers during such**
25 **period, with respect to such drug in**

1 **the same manner as such provisions**
2 **apply to the Secretary, to individuals**
3 **entitled to benefits under part A of**
4 **title XVIII or enrolled under part B of**
5 **such title, and to hospitals, physi-**
6 **cians, and other providers and sup-**
7 **pliers participating under title XVIII**
8 **during such period;**

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

18 **“(3) the Secretary shall apply the pro-**
19 **visions of such part E to such plan and**
20 **such individuals so enrolled in such plan.**

21 **“(b) NOTIFICATION REGARDING NONPARTICI-**
22 **PATION IN FAIR DRUG PRICE NEGOTIATION PRO-**
23 **GRAM.—A group health plan shall publicly dis-**
24 **close in a manner and in accordance with a**
25 **process specified by the Secretary any elec-**

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

9 (ii) APPLICATION TO RETIREE
10 AND CERTAIN SMALL GROUP HEALTH
11 PLANS.—Section 9831(a)(2) of the
12 Internal Revenue Code of 1986 is
13 amended by inserting “other than
14 with respect to section 9816,” be-
15 fore “any group health plan”.

16 (iii) CLERICAL AMENDMENT.—
17 The table of sections for sub-
18 chapter B of chapter 100 of such
19 Code is amended by adding at the
20 end the following new item:

“Sec. 9816. Fair Price Drug Negotiation Program and applica-
tion of maximum fair prices.”.

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

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

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

10 **“(a) IN GENERAL.—There is hereby im-**
11 **posed on the sale by the manufacturer, pro-**
12 **ducer, or importer of any selected drug dur-**
13 **ing a day described in subsection (b) a tax in**
14 **an amount such that the applicable percent-**
15 **age is equal to the ratio of—**

16 **“(1) such tax, divided by**

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

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

23 **“(1) The period beginning on the**
24 **June 16th immediately following the se-**
25 **lected drug publication date and ending**
26 **on the first date during which the manu-**

1 **facturer of the drug has in place an**
2 **agreement described in subsection (a) of**
3 **section 1193 of the Social Security Act**
4 **with respect to such drug.**

5 **“(2) The period beginning on the**
6 **April 1st immediately following the June**
7 **16th described in paragraph (1) and end-**
8 **ing on the first date during which the**
9 **manufacturer of the drug has agreed to a**
10 **maximum fair price under such agree-**
11 **ment.**

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

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

1 ning on the date on which such Secretary
2 certifies that such information is overdue
3 and ending on the date that such infor-
4 mation is so submitted.

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

13 “(c) **APPLICABLE PERCENTAGE.**—For pur-
14 poses of this section, the term ‘applicable per-
15 centage’ means—

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

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

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

1 **day described in subsection (b) with re-**
2 **spect to such drug, 85 percent, and**

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

5 **“(d) SELECTED DRUG.—For purposes of this**
6 **section—**

7 **“(1) IN GENERAL.—The term ‘selected**
8 **drug’ means any selected drug (within**
9 **the meaning of section 1192 of the Social**
10 **Security Act) which is manufactured or**
11 **produced in the United States or entered**
12 **into the United States for consumption,**
13 **use, or warehousing.**

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

17 **“(3) COORDINATION WITH RULES FOR**
18 **POSSESSIONS OF THE UNITED STATES.—Rules**
19 **similar to the rules of paragraphs (2) and**
20 **(4) of section 4132(c) shall apply for pur-**
21 **poses of this section.**

22 **“(e) OTHER DEFINITIONS.—For purposes of**
23 **this section, the terms ‘selected drug publica-**
24 **tion date’ and ‘maximum fair price’ have the**

1 meaning given such terms in section 1191 of
2 the Social Security Act.

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

8 (b) NO DEDUCTION FOR EXCISE TAX PAY-
9 MENTS.—Section 275 of the Internal Revenue
10 Code of 1986 is amended by adding “or by sec-
11 tion 4192” before the period at the end of sub-
12 section (a)(6).

13 (c) CONFORMING AMENDMENTS.—

14 (1) Section 4221(a) of the Internal
15 Revenue Code of 1986 is amended by in-
16 sserting “or 4192” after “section 4191”.

17 (2) Section 6416(b)(2) of such Code is
18 amended by inserting “or 4192” after
19 “section 4191”.

20 (d) CLERICAL AMENDMENTS.—

21 (1) The heading of subchapter E of
22 chapter 32 of the Internal Revenue Code
23 of 1986 is amended by striking “Medical
24 Devices” and inserting “Other Medical
25 Products”.

1 **(2) The table of subchapters for chap-**
 2 **ter 32 of such Code is amended by strik-**
 3 **ing the item relating to subchapter E and**
 4 **inserting the following new item:**

 “SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

5 **(3) The table of sections for sub-**
 6 **chapter E of chapter 32 of such Code is**
 7 **amended by adding at the end the fol-**
 8 **lowing new item:**

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

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

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

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

16 **(a) IN GENERAL.—Section 1834 of the So-**
 17 **cial Security Act (42 U.S.C. 1395m) is amended**
 18 **by adding at the end the following new sub-**
 19 **section:**

20 **“(x) REBATE BY MANUFACTURERS FOR SIN-**
 21 **GLE SOURCE DRUGS WITH PRICES INCREASING**
 22 **FASTER THAN INFLATION.—**

23 **“(1) REQUIREMENTS.—**

1 **“(A) SECRETARIAL PROVISION OF IN-**
2 **FORMATION.—Not later than 6 months**
3 **after the end of each calendar quar-**
4 **ter beginning on or after July 1, 2021,**
5 **the Secretary shall, for each part B**
6 **rebatable drug, report to each manu-**
7 **facturer of such part B rebatable**
8 **drug the following for such calendar**
9 **quarter:**

10 **“(i) Information on the total**
11 **number of units of the billing and**
12 **payment code described in sub-**
13 **paragraph (A)(i) of paragraph (3)**
14 **with respect to such drug and cal-**
15 **endar quarter.**

16 **“(ii) Information on the**
17 **amount (if any) of the excess av-**
18 **erage sales price increase de-**
19 **scribed in subparagraph (A)(ii) of**
20 **such paragraph for such drug and**
21 **calendar quarter.**

22 **“(iii) The rebate amount speci-**
23 **fied under such paragraph for**
24 **such part B rebatable drug and**
25 **calendar quarter.**

1 **“(B) MANUFACTURER REQUIRE-**
2 **MENT.—For each calendar quarter be-**
3 **ginning on or after July 1, 2021, the**
4 **manufacturer of a part B rebatable**
5 **drug shall, for such drug, not later**
6 **than 30 days after the date of receipt**
7 **from the Secretary of the information**
8 **described in subparagraph (A) for**
9 **such calendar quarter, provide to the**
10 **Secretary a rebate that is equal to the**
11 **amount specified in paragraph (3) for**
12 **such drug for such calendar quarter.**

13 **“(2) PART B REBATABLE DRUG DE-**
14 **FINED.—**

15 **“(A) IN GENERAL.—In this sub-**
16 **section, the term ‘part B rebatable**
17 **drug’ means a single source drug or**
18 **biological (as defined in subpara-**
19 **graph (D) of section 1847A(c)(6)), in-**
20 **cluding a biosimilar biological prod-**
21 **uct (as defined in subparagraph (H)**
22 **of such section), paid for under this**
23 **part, except such term shall not in-**
24 **clude such a drug or biological—**

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

7 “(ii) that is a vaccine de-
8 scribed in subparagraph (A) or
9 (B) of section 1861(s)(10).

10 “(B) INCREASE.—The dollar
11 amount applied under subparagraph
12 (A)(i)—

13 “(i) for 2022, shall be the dol-
14 lar amount specified under such
15 subparagraph for 2021, increased
16 by the percentage increase in the
17 consumer price index for all
18 urban consumers (United States
19 city average) for the 12 month pe-
20 riod ending with June of the pre-
21 vious year; and

22 “(ii) for a subsequent year,
23 shall be the dollar amount speci-
24 fied in this clause (or clause (i))
25 for the previous year, increased

1 by the percentage increase in the
2 consumer price index for all
3 urban consumers (United States
4 city average) for the 12 month pe-
5 riod ending with June of the pre-
6 vious year.

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

11 “(3) REBATE AMOUNT.—

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

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

1 “(ii) the amount (if any) by
2 which—

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

9 “(II) the inflation-adjusted
10 payment amount determined
11 under subparagraph (C) for
12 such part B rebatable drug
13 during the calendar quarter.

14 “(B) EXCLUDED UNITS.—For pur-
15 poses of subparagraph (A)(i), the total
16 number of units of the billing and
17 payment code for each part B
18 rebatable drug furnished during a
19 calendar quarter shall not include—

20 “(i) units packaged into the
21 payment for a procedure or serv-
22 ice under section 1833(t) or under
23 section 1833(i) (instead of sepa-
24 rately payable under such respec-
25 tive section);

1 “(ii) units included under the
2 single payment system for renal
3 dialysis services under section
4 1881(b)(14); or

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

14 “(C) DETERMINATION OF INFLATION-
15 ADJUSTED PAYMENT AMOUNT.—The in-
16 flation-adjusted payment amount de-
17 termined under this subparagraph
18 for a part B rebatable drug for a cal-
19 endar quarter is—

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

1 “(ii) the percentage by which
2 the rebate period CPI-U (as de-
3 fined in subparagraph (F)) for the
4 calendar quarter exceeds the
5 benchmark period CPI-U (as de-
6 fined in subparagraph (E)).

7 “(D) PAYMENT AMOUNT BENCHMARK
8 QUARTER.—The term ‘payment amount
9 benchmark quarter’ means the cal-
10 endar quarter beginning January 1,
11 2016.

12 “(E) BENCHMARK PERIOD CPI-U.—
13 The term ‘benchmark period CPI-U’
14 means the consumer price index for
15 all urban consumers (United States
16 city average) for July 2015.

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

1 endar quarters prior to such de-
2 scribed calendar quarter.

3 “(G) COUNTING UNITS.—

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

18 “(ii) COUNTING UNITS FOR
19 CLAIMS PROCESSED AFTER CUT-OFF
20 PERIOD.—If the Secretary uses a
21 cut-off period pursuant to clause
22 (i), in the case of units of a part B
23 rebatable drug furnished during a
24 quarter but pursuant to applica-
25 tion of such cut-off period ex-

1 cluded for purposes of subpara-
2 graph (A)(i) from the total num-
3 ber of billing units for the drug
4 for such quarter, the Secretary
5 shall count such units of such
6 drug so furnished in the total
7 number of billing units for such
8 drug for a subsequent quarter, as
9 the Secretary determines appro-
10 priate.

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

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

1 term ‘benchmark period CPI-U’ were
2 defined under paragraph (3)(E) as if
3 the reference to ‘July 2015’ under
4 such paragraph were a reference to
5 ‘the first month of the first full cal-
6 endar quarter after the day on which
7 the drug was first marketed’.

8 “(B) TIMELINE FOR PROVISION OF
9 REBATES FOR SUBSEQUENTLY APPROVED
10 DRUGS.—In the case of a part B
11 rebatable drug first approved or li-
12 censed by the Food and Drug Admin-
13 istration after July 1, 2015, paragraph
14 (1)(B) shall be applied as if the ref-
15 erence to ‘July 1, 2021’ under such
16 paragraph were a reference to the
17 later of the 6th full calendar quarter
18 after the day on which the drug was
19 first marketed or July 1, 2021.

20 “(C) EXEMPTION FOR SHORTAGES.—
21 The Secretary may reduce or waive
22 the rebate amount under paragraph
23 (1)(B) with respect to a part B
24 rebatable drug that is described as
25 currently in shortage on the shortage

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

6 “(D) SELECTED DRUGS.—In the case
7 of a part B rebatable drug that is a
8 selected drug (as defined in section
9 1192(c)) for a price applicability pe-
10 riod (as defined in section 1191(b)(2))
11 and is determined (pursuant to such
12 section 1192(c)) to no longer be a se-
13 lected drug, for each applicable year
14 beginning after the price applica-
15 bility period with respect to such
16 drug, clause (i) of paragraph (3)(C)
17 shall be applied as if the term ‘pay-
18 ment amount benchmark quarter’
19 were defined under paragraph (3)(D)
20 as the calendar quarter beginning
21 January 1 of the last year beginning
22 during such price applicability period
23 with respect to such selected drug
24 and clause (ii) of paragraph (3)(C)
25 shall be applied as if the term ‘bench-

1 **mark period CPI-U’ were defined**
2 **under paragraph (3)(E) as if the ref-**
3 **erence to ‘July 2015’ under such para-**
4 **graph were a reference to the July of**
5 **the year preceding such last year.**

6 **“(5) APPLICATION TO BENEFICIARY COIN-**
7 **SURANCE.—In the case of a part B**
8 **rebatable drug, if the payment amount**
9 **for a quarter exceeds the inflation ad-**
10 **justed payment for such quarter—**

11 **“(A) in computing the amount of**
12 **any coinsurance applicable under**
13 **this title to an individual with re-**
14 **spect to such drug, the computation**
15 **of such coinsurance shall be based on**
16 **the inflation-adjusted payment**
17 **amount determined under paragraph**
18 **(3)(C) for such part B rebatable drug;**
19 **and**

20 **“(B) the amount of such coinsur-**
21 **ance is equal to 20 percent of such in-**
22 **flation-adjusted payment amount so**
23 **determined.**

24 **“(6) REBATE DEPOSITS.—Amounts paid**
25 **as rebates under paragraph (1)(B) shall**

1 be deposited into the Federal Supple-
2 mentary Medical Insurance Trust Fund
3 established under section 1841.

4 “(7) CIVIL MONEY PENALTY.—If a manu-
5 facturer of a part B rebatable drug has
6 failed to comply with the requirements
7 under paragraph (1)(B) for such drug for
8 a calendar quarter, the manufacturer
9 shall be subject to, in accordance with a
10 process established by the Secretary pur-
11 suant to regulations, a civil money pen-
12 alty in an amount equal to at least 125
13 percent of the amount specified in para-
14 graph (3) for such drug for such calendar
15 quarter. The provisions of section 1128A
16 (other than subsections (a) (with respect
17 to amounts of penalties or additional as-
18 sessments) and (b)) shall apply to a civil
19 money penalty under this paragraph in
20 the same manner as such provisions
21 apply to a penalty or proceeding under
22 section 1128A(a).

23 “(8) STUDY AND REPORT.—

24 “(A) STUDY.—The Secretary shall
25 conduct a study of the feasibility of

1 **and operational issues involved with**
2 **the following:**

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

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

11 **“(iii) Including drugs ex-**
12 **cluded under paragraph (2)(A)**
13 **and units of the billing and pay-**
14 **ment code of the drugs excluded**
15 **under paragraph (3)(B) in the re-**
16 **bate system under this sub-**
17 **section.**

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

24 **“(9) APPLICATION TO MULTIPLE SOURCE**
25 **DRUGS.—The Secretary may, based on the**

1 report submitted under paragraph (8)
2 and pursuant to rulemaking, apply the
3 provisions of this subsection to multiple
4 source drugs (as defined in section
5 1847A(c)(6)(C)), including, for purposes of
6 determining the rebate amount under
7 paragraph (3), by calculating manufac-
8 turer-specific average sales prices for the
9 benchmark period and the rebate pe-
10 riod.”.

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

14 (1) in subsection (a)—

15 (A) in paragraph (1)—

16 (i) in subparagraph (S), by
17 striking “with respect to” and in-
18 sserting “subject to subparagraph
19 (DD), with respect to”;

20 (ii) by striking “and (CC)” and
21 inserting “(CC)”; and

22 (iii) by inserting before the
23 semicolon at the end the fol-
24 lowing: “, and (DD) with respect
25 to a part B rebatable drug (as de-

1 **fin**ed in paragraph (2) of section
2 **1834(x))** for which the payment
3 **amount** for a calendar quarter
4 **under** paragraph (3)(A)(ii)(I) of
5 **such** section for such quarter ex-
6 **ceeds** the inflation-adjusted pay-
7 **ment** **under** **paragraph**
8 **(3)(A)(ii)(II)** of such section for
9 **such** quarter, the amounts paid
10 **shall** be the difference between (i)
11 **the** payment amount under para-
12 **graph** (3)(A)(ii)(I) of such section
13 **for** such drug, and (ii) 20 percent
14 **of** the inflation-adjusted payment
15 **amount** **under** **paragraph**
16 **(3)(A)(ii)(II)** of such section for
17 **such** drug”;

18 **(B)** by adding at the end of the
19 **flush** left matter following paragraph
20 **(9)**, the following:

21 **“For** purposes of applying paragraph (1)(DD),
22 **subsections** (i)(9) and (t)(3)(H), and section
23 **1834(x)(5)**, the Secretary shall make such esti-
24 **mates** and use such data as the Secretary de-
25 **termines** appropriate, and notwithstanding

1 any other provision of law, may do so by pro-
2 gram instruction or otherwise.”;

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

5 “(9) In the case of a part B rebatable drug
6 (as defined in paragraph (2) of section
7 1834(x)) furnished on or after July 1, 2021,
8 under the system under this subsection, in
9 lieu of calculation of coinsurance and the
10 amount of payment otherwise applicable
11 under this subsection, the provisions of sec-
12 tion 1834(x)(5), paragraph (1)(DD) of sub-
13 section (a), and the flush left matter following
14 paragraph (9) of subsection (a), shall, as deter-
15 mined appropriate by the Secretary, apply
16 under this subsection in the same manner as
17 such provisions of section 1834(x)(5) and sub-
18 section (a) apply under such section and sub-
19 section.”; and

20 (3) in subsection (t)(3), by adding at
21 the end the following new subparagraph:

22 “(H) PART B REBATABLE DRUGS.—In
23 the case of a part B rebatable drug
24 (as defined in paragraph (2) of sec-
25 tion 1834(x)) furnished on or after

1 **July 1, 2021, under the system under**
2 **this subsection, in lieu of calculation**
3 **of coinsurance and the amount of**
4 **payment otherwise applicable under**
5 **this subsection, the provisions of sec-**
6 **tion 1834(x)(5), paragraph (1)(DD) of**
7 **subsection (a), and the flush left mat-**
8 **ter following paragraph (9) of sub-**
9 **section (a), shall, as determined ap-**
10 **propriate by the Secretary, apply**
11 **under this subsection in the same**
12 **manner as such provisions of section**
13 **1834(x)(5) and subsection (a) apply**
14 **under such section and subsection.”.**

15 **(c) CONFORMING AMENDMENT TO PART B**
16 **ASP CALCULATION.—Section 1847A(c)(3) of the**
17 **Social Security Act (42 U.S.C. 1395w–3a(c)(3))**
18 **is amended by inserting “or section 1834(x)”**
19 **after “section 1927”.**

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

21 **(a) IN GENERAL.—Part D of title XVIII of**
22 **the Social Security Act is amended by insert-**
23 **ing after section 1860D–14A (42 U.S.C. 1395w–**
24 **114a) the following new section:**

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

4 **“(a) IN GENERAL.—**

5 **“(1) IN GENERAL.—Subject to the provi-**
6 **sions of this section, in order for cov-**
7 **erage to be available under this part for**
8 **a part D rebatable drug (as defined in**
9 **subsection (h)(1)) of a manufacturer (as**
10 **defined in section 1927(k)(5)) dispensed**
11 **during an applicable year, the manufac-**
12 **turer must have entered into and have in**
13 **effect an agreement described in sub-**
14 **section (b).**

15 **“(2) AUTHORIZING COVERAGE FOR DRUGS**
16 **NOT COVERED UNDER AGREEMENTS.—Para-**
17 **graph (1) shall not apply to the dis-**
18 **persing of a covered part D drug if—**

19 **“(A) the Secretary has made a de-**
20 **termination that the availability of**
21 **the drug is essential to the health of**
22 **beneficiaries under this part; or**

23 **“(B) the Secretary determines**
24 **that in the period beginning on Janu-**
25 **ary 1, 2022, and ending on December**

1 **31, 2022, there were extenuating cir-**
2 **cumstances.**

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

6 **“(b) AGREEMENTS.—**

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

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

20 **“(i) Information on the total**
21 **number of units (as defined in**
22 **subsection (h)(2)) for each dosage**
23 **form and strength with respect to**
24 **such part D rebatable drug and**
25 **year.**

1 “(ii) Information on the
2 amount (if any) of the excess av-
3 erage manufacturer price in-
4 crease described in subsection
5 (c)(1)(B) for each dosage form and
6 strength with respect to such
7 drug and year.

8 “(iii) The rebate amount speci-
9 fied under subsection (c) for each
10 dosage form and strength with re-
11 spect to such drug and year.

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

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

3 **“(2) LENGTH OF AGREEMENT.—**

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

12 **“(B) TERMINATION.—**

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

1 **delay the effective date of the ter-**
2 **mination.**

3 **“(ii) BY A MANUFACTURER.—A**
4 **manufacturer may terminate an**
5 **agreement under this section for**
6 **any reason. Any such termination**
7 **shall be effective, with respect to**
8 **a plan year—**

9 **“(I) if the termination oc-**
10 **curs before January 30 of the**
11 **plan year, as of the day after**
12 **the end of the plan year; and**

13 **“(II) if the termination oc-**
14 **curs on or after January 30 of**
15 **the plan year, as of the day**
16 **after the end of the suc-**
17 **ceeding plan year.**

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

24 **“(D) DELAY BEFORE REENTRY.—In**
25 **the case of any agreement under this**

1 section with a manufacturer that is
2 terminated in a plan year, the Sec-
3 retary may not enter into another
4 such agreement with the manufac-
5 turer (or a successor manufacturer)
6 before the subsequent plan year, un-
7 less the Secretary finds good cause
8 for an earlier reinstatement of such
9 an agreement.

10 **“(c) REBATE AMOUNT.—**

11 **“(1) IN GENERAL.—**For purposes of this
12 section, the amount specified in this sub-
13 section for a dosage form and strength
14 with respect to a part D rebatable drug
15 and applicable year is, subject to sub-
16 paragraphs (B) and (C) of paragraph (5),
17 the amount equal to the product of—

18 **“(A) the total number of units of**
19 **such dosage form and strength with**
20 **respect to such part D rebatable drug**
21 **and year; and**

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

24 **“(i) the annual manufacturer**
25 **price (as determined in para-**

1 **graph (2)) paid for such dosage**
2 **form and strength with respect to**
3 **such part D rebatable drug for**
4 **the year; exceeds**

5 **“(ii) the inflation-adjusted**
6 **payment amount determined**
7 **under paragraph (3) for such dos-**
8 **age form and strength with re-**
9 **spect to such part D rebatable**
10 **drug for the year.**

11 **“(2) DETERMINATION OF ANNUAL MANU-**
12 **FACTURER PRICE.—The annual manufac-**
13 **turer price determined under this para-**
14 **graph for a dosage form and strength,**
15 **with respect to a part D rebatable drug**
16 **and an applicable year, is the sum of the**
17 **products of—**

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

24 **“(B) the ratio of—**

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

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

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

16 “(A) the benchmark year manu-
17 facturer price determined under
18 paragraph (4) for such dosage form
19 and strength with respect to such
20 drug and an applicable year; in-
21 creased by

22 “(B) the percentage by which the
23 applicable year CPI-U (as defined in
24 subsection (h)(5)) for the applicable
25 year exceeds the benchmark period

1 CPI-U (as defined in subsection
2 (h)(4)).

3 “(4) DETERMINATION OF BENCHMARK
4 YEAR MANUFACTURER PRICE.—The bench-
5 mark year manufacturer price deter-
6 mined under this paragraph for a dosage
7 form and strength, with respect to a part
8 D rebatable drug and an applicable year,
9 is the sum of the products of—

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

18 “(B) the ratio of—

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

24 “(ii) the total number of units
25 of such dosage form and strength

1 dispensed during the payment
2 amount benchmark year.

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

5 “(A) SUBSEQUENTLY APPROVED
6 DRUGS.—In the case of a part D
7 rebatable drug first approved or li-
8 censed by the Food and Drug Admin-
9 istration after January 1, 2016, sub-
10 paragraphs (A) and (B) of paragraph
11 (4) shall be applied as if the term
12 ‘payment amount benchmark year’
13 were defined under subsection (h)(3)
14 as the first calendar year beginning
15 after the day on which the drug was
16 first marketed by any manufacturer
17 and subparagraph (B) of paragraph
18 (3) shall be applied as if the term
19 ‘benchmark period CPI-U’ were de-
20 fined under subsection (h)(4) as if the
21 reference to ‘January 2016’ under
22 such subsection were a reference to
23 ‘January of the first year beginning
24 after the date on which the drug was
25 first marketed by any manufacturer’.

1 **“(B) EXEMPTION FOR SHORTAGES.—**
2 **The Secretary may reduce or waive**
3 **the rebate under paragraph (1) with**
4 **respect to a part D rebatable drug**
5 **that is described as currently in**
6 **shortage on the shortage list in effect**
7 **under section 506E of the Federal**
8 **Food, Drug, and Cosmetic Act or in**
9 **the case of other exigent cir-**
10 **cumstances, as determined by the**
11 **Secretary.**

12 **“(C) TREATMENT OF NEW FORMULA-**
13 **TIONS.—**

14 **“(i) IN GENERAL.—In the case**
15 **of a part D rebatable drug that is**
16 **a line extension of a part D**
17 **rebatable drug that is an oral**
18 **solid dosage form, the Secretary**
19 **shall establish a formula for de-**
20 **termining the amount specified in**
21 **this subsection with respect to**
22 **such part D rebatable drug and**
23 **an applicable year with consider-**
24 **ation of the original part D**
25 **rebatable drug.**

1 “(ii) **LINE EXTENSION DE-**
2 **FINED.—In this subparagraph, the**
3 **term ‘line extension’ means, with**
4 **respect to a part D rebatable**
5 **drug, a new formulation of the**
6 **drug (as determined by the Sec-**
7 **retary), such as an extended re-**
8 **lease formulation, but does not in-**
9 **clude an abuse-deterrent formula-**
10 **tion of the drug (as determined**
11 **by the Secretary), regardless of**
12 **whether such abuse-deterrent for-**
13 **mulation is an extended release**
14 **formulation.**

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

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

16 “(d) **REBATE DEPOSITS.**—Amounts paid as
17 rebates under subsection (c) shall be depos-
18 ited into the Medicare Prescription Drug Ac-
19 count in the Federal Supplementary Medical
20 Insurance Trust Fund established under sec-
21 tion 1841.

22 “(e) **INFORMATION.**—For purposes of car-
23 rying out this section, the Secretary shall use
24 information submitted by manufacturers
25 under section 1927(b)(3).

1 **“(f) CIVIL MONEY PENALTY.—In the case of**
2 **a manufacturer of a part D rebatable drug**
3 **with an agreement in effect under this section**
4 **who has failed to comply with the terms of the**
5 **agreement under subsection (b)(1)(B) with re-**
6 **spect to such drug for an applicable year, the**
7 **Secretary may impose a civil money penalty**
8 **on such manufacturer in an amount equal to**
9 **125 percent of the amount specified in sub-**
10 **section (c) for such drug for such year. The**
11 **provisions of section 1128A (other than sub-**
12 **sections (a) (with respect to amounts of pen-**
13 **alties or additional assessments) and (b)) shall**
14 **apply to a civil money penalty under this sub-**
15 **section in the same manner as such provi-**
16 **sions apply to a penalty or proceeding under**
17 **section 1128A(a).**

18 **“(g) JUDICIAL REVIEW.—There shall be no**
19 **judicial review of the following:**

20 **“(1) The determination of units under**
21 **this section.**

22 **“(2) The determination of whether a**
23 **drug is a part D rebatable drug under**
24 **this section.**

1 **“(3) The calculation of the rebate**
2 **amount under this section.**

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

4 **“(1) PART D REBATABLE DRUG DE-**
5 **FINED.—**

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

22 **“(B) INCREASE.—The dollar**
23 **amount applied under subparagraph**
24 **(A)—**

1 “(i) for 2023, shall be the dol-
2 lar amount specified under such
3 subparagraph for 2022, increased
4 by the percentage increase in the
5 consumer price index for all
6 urban consumers (United States
7 city average) for the 12-month pe-
8 riod beginning with January of
9 2022; and

10 “(ii) for a subsequent year,
11 shall be the dollar amount speci-
12 fied in this subparagraph for the
13 previous year, increased by the
14 percentage increase in the con-
15 sumer price index for all urban
16 consumers (United States city av-
17 erage) for the 12-month period be-
18 ginning with January of the pre-
19 vious year.

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

24 “(2) UNIT DEFINED.—The term ‘unit’
25 means, with respect to a part D rebatable

1 **drug, the lowest identifiable quantity**
2 **(such as a capsule or tablet, milligram of**
3 **molecules, or grams) of the part D**
4 **rebatable drug that is dispensed to indi-**
5 **viduals under this part.**

6 **“(3) PAYMENT AMOUNT BENCHMARK**
7 **YEAR.—The term ‘payment amount bench-**
8 **mark year’ means the year beginning**
9 **January 1, 2016.**

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

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

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

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

4 **(b) CONFORMING AMENDMENT TO PART B**
5 **ASP CALCULATION.—Section 1847A(c)(3) of the**
6 **Social Security Act (42 U.S.C. 1395w–3a(c)(3)),**
7 **as amended by section 201(c), is further**
8 **amended by striking “section 1927 or section**
9 **1834(x)” and inserting “section 1927, section**
10 **1834(x), or section 1860D–14B”.**

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

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

16 **(a) BENEFIT STRUCTURE REDESIGN.—Sec-**
17 **tion 1860D–2(b) of the Social Security Act (42**
18 **U.S.C. 1395w–102(b)) is amended—**

19 **(1) in paragraph (2)—**

20 **(A) in subparagraph (A), in the**
21 **matter preceding clause (i), by insert-**
22 **ing “for a year preceding 2022 and for**
23 **costs above the annual deductible**
24 **specified in paragraph (1) and up to**
25 **the annual out-of-pocket threshold**

1 specified in paragraph (4)(B) for 2022
2 and each subsequent year” after
3 “paragraph (3)”;

4 (B) in subparagraph (C)—

5 (i) in clause (i), in the matter
6 preceding subclause (I), by insert-
7 ing “for a year preceding 2022,”
8 after “paragraph (4),”; and

9 (ii) in clause (ii)(III), by strik-
10 ing “and each subsequent year”
11 and inserting “and 2021”; and

12 (C) in subparagraph (D)—

13 (i) in clause (i)—

14 (I) in the matter pre-
15 ceding subclause (I), by in-
16 serting “for a year preceding
17 2022,” after “paragraph (4),”;
18 and

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

23 (ii) in clause (ii)(V), by strik-
24 ing “2019 and each subsequent

1 **year” and inserting “each of years**
2 **2019 through 2021”;**

3 **(2) in paragraph (3)(A)—**

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

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

10 **(3) in paragraph (4)—**

11 **(A) in subparagraph (A)—**

12 **(i) in clause (i)—**

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

19 **(II) in the matter pre-**
20 **ceding item (aa), as redesign-**
21 **ated by subclause (I), by**
22 **striking “is equal to the great-**
23 **er of—” and inserting “is**
24 **equal to—**

- 1 **“(I) for a year preceding**
2 **2022, the greater of—”;**
- 3 **(III) by striking the period**
4 **at the end of item (bb), as re-**
5 **designated by subclause (I),**
6 **and inserting “; and”; and**
- 7 **(IV) by adding at the end**
8 **the following:**
- 9 **“(II) for 2022 and each**
10 **succeeding year, \$0.”; and**
- 11 **(ii) in clause (ii), by striking**
12 **“clause (i)(I)” and inserting**
13 **“clause (i)(I)(aa)”;**
- 14 **(B) in subparagraph (B)—**
- 15 **(i) in clause (i)—**
- 16 **(I) in subclause (V), by**
17 **striking “or” at the end;**
- 18 **(II) in subclause (VI)—**
- 19 **(aa) by striking “for a**
20 **subsequent year” and in-**
21 **serting “for 2021”; and**
- 22 **(bb) by striking the**
23 **period at the end and in-**
24 **serting a semicolon; and**

1 (III) by adding at the end
2 the following new subclauses:

3 “(VII) for 2022, is equal to
4 \$2,000; or

5 “(VIII) for a subsequent
6 year, is equal to the amount
7 specified in this subpara-
8 graph for the previous year,
9 increased by the annual per-
10 centage increase described in
11 paragraph (6) for the year in-
12 volved.”; and

13 (ii) in clause (ii), by striking
14 “clause (i)(II)” and inserting
15 “clause (i)”;

16 (C) in subparagraph (C)(i), by
17 striking “and for amounts” and in-
18 serting “and, for a year preceding
19 2022, for amounts”; and

20 (D) in subparagraph (E), by strik-
21 ing “In applying” and inserting “For
22 each of years 2011 through 2021, in
23 applying”.

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

1 **Security Act (42 U.S.C. 1395w-115(b)(1)) is**
2 **amended by inserting after “80 percent” the**
3 **following: “(or, with respect to a coverage**
4 **year after 2021, 20 percent)”.**

5 **(c) MANUFACTURER DISCOUNT PROGRAM.—**

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

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

13 **“(a) ESTABLISHMENT.—The Secretary shall**
14 **establish a manufacturer discount program**
15 **(in this section referred to as the ‘program’).**
16 **Under the program, the Secretary shall enter**
17 **into agreements described in subsection (b)**
18 **with manufacturers and provide for the per-**
19 **formance of the duties described in sub-**
20 **section (c). The Secretary shall establish a**
21 **model agreement for use under the program**
22 **by not later than January 1, 2021, in consulta-**
23 **tion with manufacturers, and allow for com-**
24 **ment on such model agreement.**

25 **“(b) TERMS OF AGREEMENT.—**

1 **“(1) IN GENERAL.—**

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

9 **“(B) PROVISION OF DISCOUNTED**
10 **PRICES AT THE POINT-OF-SALE.—The dis-**
11 **counted prices described in subpara-**
12 **graph (A) shall be provided to the ap-**
13 **licable beneficiary at the pharmacy**
14 **or by the mail order service at the**
15 **point-of-sale of an applicable drug.**

16 **“(C) TIMING OF AGREEMENT.—**

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

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

3 “(ii) 2023 AND SUBSEQUENT
4 YEARS.—In order for an agreement
5 with a manufacturer to be in ef-
6 fect under this section with re-
7 spect to plan year 2023 or a subse-
8 quent plan year, the manufac-
9 turer shall enter into such agree-
10 ment (or such agreement shall be
11 renewed under paragraph (4)(A))
12 not later than January 30 of the
13 preceding year.

14 “(2) PROVISION OF APPROPRIATE DATA.—
15 Each manufacturer with an agreement in
16 effect under this section shall collect and
17 have available appropriate data, as deter-
18 mined by the Secretary, to ensure that it
19 can demonstrate to the Secretary compli-
20 ance with the requirements under the
21 program.

22 “(3) COMPLIANCE WITH REQUIREMENTS
23 FOR ADMINISTRATION OF PROGRAM.—Each
24 manufacturer with an agreement in ef-
25 fect under this section shall comply with

1 requirements imposed by the Secretary
2 or a third party with a contract under
3 subsection (d)(3), as applicable, for pur-
4 poses of administering the program, in-
5 cluding any determination under sub-
6 paragraph (A) of subsection (c)(1) or pro-
7 cedures established under such sub-
8 section (c)(1).

9 “(4) LENGTH OF AGREEMENT.—

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

17 “(B) TERMINATION.—

18 “(i) BY THE SECRETARY.—The
19 Secretary may provide for termi-
20 nation of an agreement under this
21 section for a knowing and willful
22 violation of the requirements of
23 the agreement or other good
24 cause shown. Such termination
25 shall not be effective earlier than

1 **30 days after the date of notice to**
2 **the manufacturer of such termi-**
3 **nation. The Secretary shall pro-**
4 **vide, upon request, a manufac-**
5 **turer with a hearing concerning**
6 **such a termination, and such**
7 **hearing shall take place prior to**
8 **the effective date of the termi-**
9 **nation with sufficient time for**
10 **such effective date to be repealed**
11 **if the Secretary determines ap-**
12 **propriate.**

13 **“(ii) BY A MANUFACTURER.—A**
14 **manufacturer may terminate an**
15 **agreement under this section for**
16 **any reason. Any such termination**
17 **shall be effective, with respect to**
18 **a plan year—**

19 **“(I) if the termination oc-**
20 **curs before January 30 of a**
21 **plan year, as of the day after**
22 **the end of the plan year; and**

23 **“(II) if the termination oc-**
24 **curs on or after January 30 of**
25 **a plan year, as of the day**

1 **after the end of the suc-**
2 **ceeding plan year.**

3 **“(iii) EFFECTIVENESS OF TERMI-**
4 **NATION.—Any termination under**
5 **this subparagraph shall not affect**
6 **discounts for applicable drugs of**
7 **the manufacturer that are due**
8 **under the agreement before the**
9 **effective date of its termination.**

10 **“(iv) NOTICE TO THIRD PARTY.—**
11 **The Secretary shall provide no-**
12 **tice of such termination to a third**
13 **party with a contract under sub-**
14 **section (d)(3) within not less than**
15 **30 days before the effective date**
16 **of such termination.**

17 **“(c) DUTIES DESCRIBED.—The duties de-**
18 **scribed in this subsection are the following:**

19 **“(1) ADMINISTRATION OF PROGRAM.—Ad-**
20 **ministering the program, including—**

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

24 **“(B) the establishment of proce-**
25 **dures under which discounted prices**

1 are provided to applicable bene-
2 ficiaries at pharmacies or by mail
3 order service at the point-of-sale of
4 an applicable drug;

5 “(C) the establishment of proce-
6 dures to ensure that, not later than
7 the applicable number of calendar
8 days after the dispensing of an appli-
9 cable drug by a pharmacy or mail
10 order service, the pharmacy or mail
11 order service is reimbursed for an
12 amount equal to the difference be-
13 tween—

14 “(i) the negotiated price of the
15 applicable drug; and

16 “(ii) the discounted price of
17 the applicable drug;

18 “(D) the establishment of proce-
19 dures to ensure that the discounted
20 price for an applicable drug under
21 this section is applied before any cov-
22 erage or financial assistance under
23 other health benefit plans or pro-
24 grams that provide coverage or finan-
25 cial assistance for the purchase or

1 provision of prescription drug cov-
2 erage on behalf of applicable bene-
3 ficiaries as the Secretary may specify;
4 and

5 “(E) providing a reasonable dis-
6 pute resolution mechanism to resolve
7 disagreements between manufactur-
8 ers, applicable beneficiaries, and the
9 third party with a contract under
10 subsection (d)(3).

11 “(2) MONITORING COMPLIANCE.—

12 “(A) IN GENERAL.—The Secretary
13 shall monitor compliance by a manu-
14 facturer with the terms of an agree-
15 ment under this section.

16 “(B) NOTIFICATION.—If a third
17 party with a contract under sub-
18 section (d)(3) determines that the
19 manufacturer is not in compliance
20 with such agreement, the third party
21 shall notify the Secretary of such
22 noncompliance for appropriate en-
23 forcement under subsection (e).

24 “(3) COLLECTION OF DATA FROM PRE-
25 SCRIPTIION DRUG PLANS AND MA-PD PLANS.—

1 **The Secretary may collect appropriate**
2 **data from prescription drug plans and**
3 **MA-PD plans in a timeframe that allows**
4 **for discounted prices to be provided for**
5 **applicable drugs under this section.**

6 **“(d) ADMINISTRATION.—**

7 **“(1) IN GENERAL.—Subject to para-**
8 **graph (2), the Secretary shall provide for**
9 **the implementation of this section, in-**
10 **cluding the performance of the duties de-**
11 **scribed in subsection (c).**

12 **“(2) LIMITATION.—In providing for the**
13 **implementation of this section, the Sec-**
14 **retary shall not receive or distribute any**
15 **funds of a manufacturer under the pro-**
16 **gram.**

17 **“(3) CONTRACT WITH THIRD PARTIES.—**
18 **The Secretary shall enter into a contract**
19 **with 1 or more third parties to admin-**
20 **ister the requirements established by the**
21 **Secretary in order to carry out this sec-**
22 **tion. At a minimum, the contract with a**
23 **third party under the preceding sentence**
24 **shall require that the third party—**

1 “(A) receive and transmit infor-
2 mation between the Secretary, manu-
3 facturers, and other individuals or
4 entities the Secretary determines ap-
5 propriate;

6 “(B) receive, distribute, or facili-
7 tate the distribution of funds of man-
8 ufacturers to appropriate individuals
9 or entities in order to meet the obli-
10 gations of manufacturers under
11 agreements under this section;

12 “(C) provide adequate and timely
13 information to manufacturers, con-
14 sistent with the agreement with the
15 manufacturer under this section, as
16 necessary for the manufacturer to ful-
17 fill its obligations under this section;
18 and

19 “(D) permit manufacturers to con-
20 duct periodic audits, directly or
21 through contracts, of the data and in-
22 formation used by the third party to
23 determine discounts for applicable
24 drugs of the manufacturer under the
25 program.

1 **“(4) PERFORMANCE REQUIREMENTS.—**
2 **The Secretary shall establish perform-**
3 **ance requirements for a third party with**
4 **a contract under paragraph (3) and safe-**
5 **guards to protect the independence and**
6 **integrity of the activities carried out by**
7 **the third party under the program under**
8 **this section.**

9 **“(5) IMPLEMENTATION.—Notwith-**
10 **standing any other provision of law, the**
11 **Secretary may implement the program**
12 **under this section by program instruc-**
13 **tion or otherwise.**

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

17 **“(e) ENFORCEMENT.—**

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

22 **“(2) CIVIL MONEY PENALTY.—**

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

1 applicable beneficiaries discounts for
2 applicable drugs of the manufacturer
3 in accordance with such agreement
4 for each such failure in an amount
5 the Secretary determines is equal to
6 the sum of—

7 “(i) the amount that the man-
8 ufacturer would have paid with
9 respect to such discounts under
10 the agreement, which will then be
11 used to pay the discounts which
12 the manufacturer had failed to
13 provide; and

14 “(ii) 25 percent of such
15 amount.

16 “(B) APPLICATION.—The provisions
17 of section 1128A (other than sub-
18 sections (a) and (b)) shall apply to a
19 civil money penalty under this para-
20 graph in the same manner as such
21 provisions apply to a penalty or pro-
22 ceeding under section 1128A(a).

23 “(f) CLARIFICATION REGARDING AVAIL-
24 ABILITY OF OTHER COVERED PART D DRUGS.—
25 Nothing in this section shall prevent an appli-

1 cable beneficiary from purchasing a covered
2 part D drug that is not an applicable drug (in-
3 cluding a generic drug or a drug that is not
4 on the formulary of the prescription drug
5 plan or MA-PD plan that the applicable bene-
6 ficiary is enrolled in).

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

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

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

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

16 **“(C) has incurred costs for cov-**
17 **ered part D drugs in the year that are**
18 **equal to or exceed the annual deduct-**
19 **ible specified in section 1860D-2(b)(1)**
20 **for such year.**

21 **“(2) APPLICABLE DRUG.—The term ‘ap-**
22 **plicable drug’, with respect to an applica-**
23 **ble beneficiary—**

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

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

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

16 “(II) if the PDP sponsor of the
17 prescription drug plan or the MA
18 organization offering the MA-PD
19 plan does not use a formulary, for
20 which benefits are available
21 under the prescription drug plan
22 or MA-PD plan that the applica-
23 ble beneficiary is enrolled in; or

24 “(III) is provided through an
25 exception or appeal; and

1 “(B) does not include a selected
2 drug (as defined in section 1192(c))
3 during a price applicability period (as
4 defined in section 1191(b)(2)) with re-
5 spect to such drug.

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

9 “(A) with respect to claims for re-
10 imbursement submitted electroni-
11 cally, 14 days; and

12 “(B) with respect to claims for re-
13 imbursement submitted otherwise, 30
14 days.

15 “(4) DISCOUNTED PRICE.—

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

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

1 **1860D-2(b)(4)(B)(i) for the year, 90**
2 **percent of the negotiated price of**
3 **such drug; and**

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

9 **“(B) CLARIFICATION.—Nothing in**
10 **this section shall be construed as af-**
11 **fecting the responsibility of an appli-**
12 **cable beneficiary for payment of a**
13 **dispensing fee for an applicable drug.**

14 **“(C) SPECIAL CASE FOR CERTAIN**
15 **CLAIMS.—**

16 **“(i) CLAIMS SPANNING DEDUCT-**
17 **IBLE.—In the case where the en-**
18 **tire amount of the negotiated**
19 **price of an individual claim for**
20 **an applicable drug with respect**
21 **to an applicable beneficiary does**
22 **not fall at or above the annual de-**
23 **ductible specified in section**
24 **1860D-2(b)(1) for the year, the**
25 **manufacturer of the applicable**

1 **drug shall provide the discounted**
2 **price under this section on only**
3 **the portion of the negotiated**
4 **price of the applicable drug that**
5 **falls at or above such annual de-**
6 **ductible.**

7 **“(ii) CLAIMS SPANNING OUT-OF-**
8 **POCKET THRESHOLD.—In the case**
9 **where the entire amount of the**
10 **negotiated price of an individual**
11 **claim for an applicable drug with**
12 **respect to an applicable bene-**
13 **ficiary does not fall entirely**
14 **below or entirely above the an-**
15 **annual out-of-pocket threshold spec-**
16 **ified in section 1860D-2(b)(4)(B)(i)**
17 **for the year, the manufacturer of**
18 **the applicable drug shall provide**
19 **the discounted price—**

20 **“(I) in accordance with**
21 **subparagraph (A)(i) on the**
22 **portion of the negotiated**
23 **price of the applicable drug**
24 **that falls below such thresh-**
25 **old; and**

1 “(II) in accordance with
2 subparagraph (A)(ii) on the
3 portion of such price of such
4 drug that falls at or above
5 such threshold.

6 “(5) MANUFACTURER.—The term ‘manu-
7 facturer’ means any entity which is en-
8 gaged in the production, preparation,
9 propagation, compounding, conversion,
10 or processing of prescription drug prod-
11 ucts, either directly or indirectly by ex-
12 traction from substances of natural ori-
13 gin, or independently by means of chem-
14 ical synthesis, or by a combination of ex-
15 traction and chemical synthesis. Such
16 term does not include a wholesale dis-
17 tributor of drugs or a retail pharmacy li-
18 censed under State law.

19 “(6) NEGOTIATED PRICE.—The term ‘ne-
20 gotiated price’ has the meaning given
21 such term in section 423.100 of title 42,
22 Code of Federal Regulations (or any suc-
23 cessor regulation), except that, with re-
24 spect to an applicable drug, such nego-

1 **tiated price shall not include any dis-**
2 **persing fee for the applicable drug.**

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

8 **(2) SUNSET OF MEDICARE COVERAGE GAP**
9 **DISCOUNT PROGRAM.—Section 1860D-14A**
10 **of the Social Security Act (42 U.S.C. 1395-**
11 **114a) is amended—**

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

16 **(B) by adding at the end the fol-**
17 **lowing new subsection:**

18 **“(h) SUNSET OF PROGRAM.—**

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

1 **“(2) CONTINUED APPLICATION FOR AP-**
2 **PLICABLE DRUGS DISPENSED PRIOR TO SUN-**
3 **SET.—The provisions of this section (in-**
4 **cluding all responsibilities and duties)**
5 **shall continue to apply after January 1,**
6 **2022, with respect to applicable drugs**
7 **dispensed prior to such date.”.**

8 **(3) INCLUSION OF ACTUARIAL VALUE OF**
9 **MANUFACTURER DISCOUNTS IN BIDS.—Sec-**
10 **tion 1860D–11 of the Social Security Act**
11 **(42 U.S.C. 1395w–111) is amended—**

12 **(A) in subsection (b)(2)(C)(iii)—**

13 **(i) by striking “assumptions**
14 **regarding the reinsurance” and**
15 **inserting “assumptions regard-**
16 **ing—**

17 **“(I) the reinsurance”; and**

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

20 **“(II) for 2022 and each**
21 **subsequent year, the manu-**
22 **facturer discounts provided**
23 **under section 1860D–14C sub-**
24 **tracted from the actuarial**

1 value to produce such bid;
2 and”;

3 **(B) in subsection (c)(1)(C)—**

4 **(i) by striking “an actuarial**
5 **valuation of the reinsurance” and**
6 **inserting “an actuarial valuation**
7 **of—**

8 **“(i) the reinsurance”;**

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

12 **(iii) by adding at the end the**
13 **following:**

14 **“(ii) for 2022 and each subse-**
15 **quent year, the manufacturer dis-**
16 **counts provided under section**
17 **1860D-14C;”.**

18 **(d) CONFORMING AMENDMENTS.—**

19 **(1) Section 1860D-2 of the Social Se-**
20 **curity Act (42 U.S.C. 1395w-102) is**
21 **amended—**

22 **(A) in subsection (a)(2)(A)(i)(I), by**
23 **striking “, or an increase in the ini-**
24 **tial” and inserting “or, for a year pre-**

1 ceding 2022, an increase in the ini-
2 tial”;

3 **(B) in subsection (c)(1)(C)—**

4 **(i) in the subparagraph head-**
5 **ing, by striking “AT INITIAL COV-**
6 **ERAGE LIMIT”;** and

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

15 **(C) in subsection (d)(1)(A), by**
16 **striking “or an initial” and inserting**
17 **“or, for a year preceding 2022, an ini-**
18 **tial”.**

19 **(2) Section 1860D–4(a)(4)(B)(i) of the**
20 **Social Security Act (42 U.S.C. 1395w–**
21 **104(a)(4)(B)(i)) is amended by striking**
22 **“the initial” and inserting “for a year pre-**
23 **ceding 2022, the initial”.**

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

4 **(A) in paragraph (1)—**

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

9 **(ii) in subparagraph (D)(iii),**
10 **by striking “1860D-2(b)(4)(A)(i)(I)”**
11 **and inserting “1860D-**
12 **2(b)(4)(A)(i)(I)(aa)”;** and

13 **(iii) in subparagraph (E), by**
14 **striking “The elimination” and in-**
15 **serting “For a year preceding**
16 **2022, the elimination”;** and

17 **(B) in paragraph (2)—**

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

22 **(ii) in subparagraph (E), by**
23 **striking “1860D-2(b)(4)(A)(i)(I)”**
24 **and inserting “1860D-**
25 **2(b)(4)(A)(i)(I)(aa)”.**

1 **(4) Section 1860D-21(d)(7) of the So-**
2 **cial Security Act (42 U.S.C. 1395w-**
3 **131(d)(7)) is amended by striking “section**
4 **1860D-2(b)(4)(B)(i)” and inserting “sec-**
5 **tion 1860D-2(b)(4)(C)(i)”.**

6 **(5) Section 1860D-22(a)(2)(A) of the**
7 **Social Security Act (42 U.S.C. 1395w-**
8 **132(a)(2)(A)) is amended—**

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

12 **“(i) for years prior to 2022,**
13 **any discount”;**

14 **(B) in clause (i), as inserted by**
15 **subparagraph (A) of this paragraph,**
16 **by striking the period at the end and**
17 **inserting “; and”; and**

18 **(C) by adding at the end the fol-**
19 **lowing new clause:**

20 **“(ii) for 2022 and each subse-**
21 **quent year, any discount pro-**
22 **vided pursuant to section 1860D-**
23 **14C.”.**

1 **(6) Section 1860D–41(a)(6) of the So-**
2 **cial Security Act (42 U.S.C. 1395w–**
3 **151(a)(6)) is amended—**

4 **(A) by inserting “for a year before**
5 **2022” after “1860D–2(b)(3)”;** and

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

8 **(7) Section 1860D–43 of the Social Se-**
9 **curity Act (42 U.S.C. 1395w–153) is**
10 **amended—**

11 **(A) in subsection (a)—**

12 **(i) by striking paragraph (1)**
13 **and inserting the following:**

14 **“(1) participate in—**

15 **“(A) for 2011 through 2021, the**
16 **Medicare coverage gap discount pro-**
17 **gram under section 1860D–14A; and**

18 **“(B) for 2022 and each subsequent**
19 **year, the manufacturer discount pro-**
20 **gram under section 1860D–14C;”;**

21 **(ii) by striking paragraph (2)**
22 **and inserting the following:**

23 **“(2) have entered into and have in ef-**
24 **fect—**

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

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

9 (iii) by striking paragraph (3)
10 and inserting the following:

11 “(3) have entered into and have in ef-
12 fect, under terms and conditions speci-
13 fied by the Secretary—

14 “(A) for 2011 through 2021, a con-
15 tract with a third party that the Sec-
16 retary has entered into a contract
17 with under subsection (d)(3) of sec-
18 tion 1860D–14A; and

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

24 (B) by striking subsection (b) and
25 inserting the following:

1 “(b) **EFFECTIVE DATE.**—Paragraphs (1)(A),
2 (2)(A), and (3)(A) of subsection (a) shall apply
3 to covered part D drugs dispensed under this
4 part on or after January 1, 2011, and before
5 January 1, 2022, and paragraphs (1)(B), (2)(B),
6 and (3)(B) of such subsection shall apply to
7 covered part D drugs dispensed under this
8 part on or after January 1, 2022.”.

9 (e) **EFFECTIVE DATE.**—The amendments
10 made by this section shall apply with respect
11 to plan year 2022 and subsequent plan years.

12 **SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
13 **TION DRUGS PLANS AND MA-PD PLANS**
14 **UNDER MEDICARE PROGRAM TO SPREAD**
15 **OUT COST-SHARING UNDER CERTAIN CIR-**
16 **CUMSTANCES.**

17 Section 1860D–2(b)(2) of the Social Secu-
18 rity Act (42 U.S.C. 1395w–102(b)(2)), as amend-
19 ed by section 301, is further amended—

20 (1) in subparagraph (A), by striking
21 “Subject to subparagraphs (C) and (D)”
22 and inserting “Subject to subparagraphs
23 (C), (D), and (E)”; and

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

1 **“(E) ENROLLEE OPTION REGARDING**
2 **SPREADING COST-SHARING.—The Sec-**
3 **retary shall establish by regulation a**
4 **process under which, with respect to**
5 **plan year 2022 and subsequent plan**
6 **years, a prescription drug plan or an**
7 **MA-PD plan shall, in the case of a**
8 **part D eligible individual enrolled**
9 **with such plan for such plan year**
10 **who is not a subsidy eligible indi-**
11 **vidual (as defined in section 1860D-**
12 **14(a)(3)) and with respect to whom**
13 **the plan projects that the dispensing**
14 **of the first fill of a covered part D**
15 **drug to such individual will result in**
16 **the individual incurring costs that**
17 **are equal to or above the annual out-**
18 **of-pocket threshold specified in para-**
19 **graph (4)(B) for such plan year, pro-**
20 **vide such individual with the option**
21 **to make the coinsurance payment re-**
22 **quired under subparagraph (A) (for**
23 **the portion of such costs that are not**
24 **above such annual out-of-pocket**
25 **threshold) in the form of periodic in-**

1 **stallments over the remainder of such**
2 **plan year.”.**

3 **SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEAS-**
4 **URES UNDER MEDICARE PART D.**

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

7 **(1) by redesignating the paragraph**
8 **(6), as added by section 50354 of division**
9 **E of the Bipartisan Budget Act of 2018**
10 **(Public Law 115–123), as paragraph (7);**
11 **and**

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

14 **“(8) APPLICATION OF PHARMACY QUALITY**
15 **MEASURES.—**

16 **“(A) IN GENERAL.—A PDP sponsor**
17 **that implements incentive payments**
18 **to a pharmacy or price concessions**
19 **paid by a pharmacy based on quality**
20 **measures shall use measures estab-**
21 **lished or approved by the Secretary**
22 **under subparagraph (B) with respect**
23 **to payment for covered part D drugs**
24 **dispensed by such pharmacy.**

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

11 **“(C) EFFECTIVE DATE.—The re-**
12 **quirement under subparagraph (A)**
13 **shall take effect for plan years begin-**
14 **ning on or after January 1, 2021, or**
15 **such earlier date specified by the Sec-**
16 **retary if the Secretary determines**
17 **there are sufficient measures estab-**
18 **lished or approved under subpara-**
19 **graph (B) to meet the requirement**
20 **under subparagraph (A).”.**

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

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

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

10 **(1) in paragraph (1)—**

11 **(A) in subparagraph (D)—**

12 **(i) in clause (ii)—**

13 **(I) by striking “that does**
14 **not exceed \$1 for” and all that**
15 **follows through the period at**
16 **the end and inserting “that**
17 **does not exceed—**

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

20 **“(aa) for a generic**
21 **drug or a preferred drug**
22 **that is a multiple source**
23 **drug (as defined in sec-**
24 **tion 1927(k)(7)(A)(i)), \$1**
25 **or, if less, the copayment**

1 amount applicable to an
2 individual under clause
3 (iii); and

4 “(bb) for any other
5 drug, \$3 or, if less, the co-
6 payment amount applica-
7 ble to an individual under
8 clause (iii); and”;

9 (II) by adding at the end
10 the following new subclauses:

11 “(II) for plan year 2021—

12 “(aa) for a generic
13 drug, \$0; and

14 “(bb) for any other
15 drug, the dollar amount
16 applied under this clause
17 (after application of para-
18 graph (4)(A)) for plan year
19 2020 for a drug described
20 in subclause (I)(bb); and

21 “(III) for a subsequent
22 year, the dollar amount ap-
23 plied under this clause for the
24 previous year for the drug, in-
25 creased by the annual per-

1 centage increase in the con-
2 sumer price index (all items;
3 U.S. city average) as of Sep-
4 tember of such previous
5 year.”; and

6 (ii) in clause (iii)—

7 (I) by striking “does not
8 exceed the copayment amount
9 specified under” and inserting
10 “does not exceed—

11 “(I) for plan years begin-
12 ning before plan year 2021,
13 the copayment amount speci-
14 fied under”;

15 (II) by striking the period
16 at the end and inserting “;
17 and”; and

18 (III) by adding at the end
19 the following new subclause:

20 “(II) for plan year 2021
21 and each subsequent plan
22 year, the copayment amount
23 applied under clause (ii) for
24 the drug and year involved.”;
25 and

1 **(B) by adding at the end the fol-**
2 **lowing new subparagraph:**

3 **“(F) ROUNDING.—Any amount es-**
4 **tablished under clause (ii) of subpara-**
5 **graph (D), including as applied under**
6 **clause (iii) of such subparagraph or**
7 **paragraph (2)(D), that is based on an**
8 **increase of \$3, that is not a multiple**
9 **of 5 cents or 10 cents, respectively,**
10 **shall be rounded to the nearest mul-**
11 **tiiple of 5 cents or 10 cents, respec-**
12 **tively.”;**

13 **(2) in paragraph (2)—**

14 **(A) in subparagraph (D)—**

15 **(i) by striking “of coinsurance**
16 **of” and inserting “of—**

17 **“(i) for plan years before plan**
18 **year 2021, coinsurance of”;**

19 **(ii) by striking the period at**
20 **the end and inserting “; and”;** and

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

23 **“(ii) for plan year 2021 and**
24 **each subsequent plan year, a co-**
25 **payment amount that does not ex-**

1 **ceed the copayment amount ap-**
2 **plied under paragraph (1)(D)(ii)**
3 **for the drug and year involved.”;**
4 **and**
5 **(B) in subparagraph (E)—**
6 **(i) by striking “subsection (c),**
7 **the substitution for” and insert-**
8 **ing “subsection (c)—**
9 **“(i) for plan years before plan**
10 **year 2021, the substitution for”;**
11 **(ii) by striking the period at**
12 **the end and inserting “; and”; and**
13 **(iii) by adding at the end the**
14 **following new clause:**
15 **“(ii) for plan year 2021, the**
16 **elimination of any cost-sharing**
17 **imposed under section 1860D-**
18 **2(b)(4)(A).”;** and
19 **(3) in paragraph (4)(A)(ii), by insert-**
20 **ing “(before 2021)” after “subsequent**
21 **year”.**

1 **SEC. 402. DISSEMINATION TO MEDICARE PART D SUBSIDY**
2 **ELIGIBLE INDIVIDUALS OF INFORMATION**
3 **COMPARING PREMIUMS OF CERTAIN PRE-**
4 **SCRIPTION DRUG PLANS.**

5 **Section 1860D–1(c)(3) of the Social Secu-**
6 **rity Act (42 U.S.C. 1395w–101(c)(3)) is amend-**
7 **ed by adding at the end the following new**
8 **subparagraph:**

9 **“(C) INFORMATION ON PREMIUMS**
10 **FOR SUBSIDY ELIGIBLE INDIVIDUALS.—**

11 **“(i) IN GENERAL.—For plan**
12 **year 2022 and each subsequent**
13 **plan year, the Secretary shall dis-**
14 **seminate to each subsidy eligible**
15 **individual (as defined in section**
16 **1860D–14(a)(3)) information under**
17 **this paragraph comparing pre-**
18 **miums that would apply to such**
19 **individual for prescription drug**
20 **coverage under LIS benchmark**
21 **plans, including, in the case of an**
22 **individual enrolled in a prescrip-**
23 **tion drug plan under this part, in-**
24 **formation that compares the pre-**
25 **mium that would apply if such in-**
26 **dividual were to remain enrolled**

1 in such plan to premiums that
2 would apply if the individual
3 were to enroll in other LIS bench-
4 mark plans.

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

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

19 “(II) with respect to which
20 the premium would be waived
21 as de minimis pursuant to sec-
22 tion 1860D-14(a)(5) for such
23 individual.”.

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

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

8 (1) in subparagraph (C)—

9 (A) by inserting after “PDP re-
10 gion” the following: “or through use
11 of an intelligent assignment process
12 that is designed to maximize the ac-
13 cess of such individual to necessary
14 prescription drugs while minimizing
15 costs to such individual and to the
16 program under this part to the great-
17 est extent possible. In the case the
18 Secretary enrolls such individuals
19 through use of an intelligent assign-
20 ment process, such process shall take
21 into account the extent to which pre-
22 scription drugs necessary for the in-
23 dividual are covered in the case of a
24 PDP sponsor of a prescription drug
25 plan that uses a formulary, the use of
26 prior authorization or other restric-

1 **tions on access to coverage of such**
2 **prescription drugs by such a sponsor,**
3 **and the overall quality of a prescrip-**
4 **tion drug plan as measured by qual-**
5 **ity ratings established by the Sec-**
6 **retary”;** and

7 **(B) by striking “Nothing in the**
8 **previous sentence” and inserting**
9 **“Nothing in this subparagraph”;** and
10 **(2) in subparagraph (D)—**

11 **(A) by inserting after “PDP re-**
12 **gion” the following: “or through use**
13 **of an intelligent assignment process**
14 **that is designed to maximize the ac-**
15 **cess of such individual to necessary**
16 **prescription drugs while minimizing**
17 **costs to such individual and to the**
18 **program under this part to the great-**
19 **est extent possible. In the case the**
20 **Secretary enrolls such individuals**
21 **through use of an intelligent assign-**
22 **ment process, such process shall take**
23 **into account the extent to which pre-**
24 **scription drugs necessary for the in-**
25 **dividual are covered in the case of a**

1 **PDP sponsor of a prescription drug**
2 **plan that uses a formulary, the use of**
3 **prior authorization or other restric-**
4 **tions on access to coverage of such**
5 **prescription drugs by such a sponsor,**
6 **and the overall quality of a prescrip-**
7 **tion drug plan as measured by qual-**
8 **ity ratings established by the Sec-**
9 **retary”; and**

10 **(B) by striking “Nothing in the**
11 **previous sentence” and inserting**
12 **“Nothing in this subparagraph”.**

13 **(b) EFFECTIVE DATE.—The amendments**
14 **made by subsection (a) shall apply with re-**
15 **spect to plan years beginning with plan year**
16 **2022.**

17 **SEC. 404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUB-**
18 **SIDIES UNDER PART D OF THE MEDICARE**
19 **PROGRAM.**

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

23 **(1) in the subsection heading, by**
24 **striking “INDIVIDUALS” and all that fol-**

1 **lows through “LINE” and inserting “CER-**
2 **TAIN INDIVIDUALS”;**

3 **(2) in paragraph (1)—**

4 **(A) by striking the paragraph**
5 **heading and inserting “INDIVIDUALS**
6 **WITH CERTAIN LOW INCOMES”;** and

7 **(B) in the matter preceding sub-**
8 **paragraph (A), by inserting “(or, with**
9 **respect to a plan year beginning on**
10 **or after January 1, 2022, 150 per-**
11 **cent)” after “135 percent”;**

12 **(3) in paragraph (2)—**

13 **(A) by striking the paragraph**
14 **heading and inserting “OTHER LOW-IN-**
15 **COME INDIVIDUALS”;** and

16 **(B) in subparagraph (A)—**

17 **(i) by inserting “(or, with re-**
18 **spect to a plan year beginning on**
19 **or after January 1, 2022, 150 per-**
20 **cent)” after “135 percent”;** and

21 **(ii) by inserting “(or, with re-**
22 **spect to a plan year beginning on**
23 **or after January 1, 2022, 200 per-**
24 **cent)” after “150 percent”;** and

1 **(4) in paragraph (3)(A)(ii), by insert-**
 2 **ing “(or, with respect to a plan year be-**
 3 **ginning on or after January 1, 2022, 200**
 4 **percent)” after “150 percent”.**

5 **SEC. 405. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-IN-**
 6 **COME TERRITORIAL RESIDENTS FOR PRE-**
 7 **MIUM AND COST-SHARING SUBSIDIES UNDER**
 8 **THE MEDICARE PROGRAM; SUNSET OF EN-**
 9 **HANCED ALLOTMENT PROGRAM.**

10 **(a) AUTOMATIC ELIGIBILITY OF CERTAIN**
 11 **LOW-INCOME TERRITORIAL RESIDENTS FOR PRE-**
 12 **MIUM AND COST-SHARING SUBSIDIES UNDER THE**
 13 **MEDICARE PROGRAM.—**

14 **(1) IN GENERAL.—Section 1860D-**
 15 **14(a)(3) of the Social Security Act (42**
 16 **U.S.C. 1395w-114(a)(3)) is amended—**

17 **(A) in subparagraph (B)(v)—**

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

20 **(ii) in subclause (II), by strik-**
 21 **ing the period and inserting “;**
 22 **and”;** and

23 **(iii) by inserting after sub-**
 24 **clause (II) the following new sub-**
 25 **clause:**

1 **“(III) with respect to plan**
2 **years beginning on or after**
3 **January 1, 2021, shall provide**
4 **that any part D eligible indi-**
5 **vidual who is enrolled for**
6 **medical assistance under the**
7 **State Medicaid plan of a terri-**
8 **tory (as defined in section**
9 **1935(f)) under title XIX (or a**
10 **waiver of such a plan) shall**
11 **be treated as a subsidy eligi-**
12 **ble individual described in**
13 **paragraph (1).”;** and

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

21 **(2) CONFORMING AMENDMENT.—Section**
22 **1860D–31(j)(2)(D) of the Social Security**
23 **Act (42 U.S.C. 1395w–141(j)(2)(D)) is**
24 **amended by adding at the end the fol-**
25 **lowing new sentence: “The previous sen-**

1 **tence shall not apply with respect to**
2 **amounts made available to a State under**
3 **this paragraph on or after January 1,**
4 **2021.”.**

5 **(b) SUNSET OF ENHANCED ALLOTMENT PRO-**
6 **GRAM.—**

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

10 **(A) in paragraph (1)(A), by insert-**
11 **ing after “such State” the following:**
12 **“before January 1, 2021”; and**

13 **(B) in paragraph (3)—**

14 **(i) in subparagraph (A), in the**
15 **matter preceding clause (i), by in-**
16 **serting after “a year” the fol-**
17 **lowing: “(before 2021); and**

18 **(ii) in subparagraph (B)(iii),**
19 **by striking “a subsequent year”**
20 **and inserting “each of fiscal years**
21 **2008 through 2020”.**

22 **(2) TERRITORY DEFINED.—Section 1935**
23 **of the Social Security Act (42 U.S.C.**
24 **1396u-5) is amended by adding at the end**
25 **the following new subsection:**

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

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

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

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

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

17 **(3) by inserting after subclause (III)**
18 **the following new subclause:**

19 **“(IV) with respect to plan**
20 **years beginning on or after**
21 **January 1, 2022, shall, not-**
22 **withstanding the preceding**
23 **clauses of this subparagraph,**
24 **provide that any part D eligi-**
25 **ble individual not described**

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

19 **SEC. 407. ELIMINATING THE RESOURCE REQUIREMENT**
20 **WITH RESPECT TO SUBSIDY ELIGIBLE INDI-**
21 **VIDUALS UNDER PART D OF THE MEDICARE**
22 **PROGRAM.**

23 **Section 1860D-14(a)(3)(A)(iii) of the Social**
24 **Security Act (42 U.S.C. 1395w-114(a)(3)(A)(iii))**
25 **is amended by inserting “in the case of a plan**

1 year beginning before January 1, 2022,” be-
2 fore “meets”.

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

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

15 “(I) support and mainte-
16 nance furnished in kind shall
17 not be counted as income; and

18 “(II) for plan years begin-
19 ning on or after January 1,
20 2022, any distribution or with-
21 drawal from an eligible retire-
22 ment plan (as defined in sub-
23 paragraph (B) of section
24 402(c)(8) of the Internal Rev-
25 enue Code of 1986, but exclud-

1 **ing any defined benefit plan**
2 **described in clause (iv) or (v)**
3 **of such subparagraph and any**
4 **qualified trust (as defined in**
5 **subparagraph (A) of such sec-**
6 **tion) which is part of such a**
7 **defined benefit plan) shall be**
8 **counted as income; and”.**

9 **TITLE V—DRUG PRICE**
10 **TRANSPARENCY**

11 **SEC. 501. DRUG PRICE TRANSPARENCY.**

12 **Part A of title XI of the Social Security Act**
13 **is amended by adding at the end the following**
14 **new sections:**

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

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

17 **“(1) MANUFACTURER.—The term ‘manu-**
18 **facturer’ means the person—**

19 **“(A) that holds the application for**
20 **a drug approved under section 505 of**
21 **the Federal Food, Drug, and Cosmetic**
22 **Act or licensed under section 351 of**
23 **the Public Health Service Act; or**

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

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

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

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

21 **“(ii) not a preventative vac-**
22 **cine; and**

23 **“(B) for which, during the pre-**
24 **vious calendar year, at least 1 dollar**
25 **of the total amount of sales were for**

1 individuals enrolled under the Medi-
2 care program under title XVIII or
3 under a State Medicaid plan under
4 title XIX or under a waiver of such
5 plan.

6 **“(3) WHOLESALE ACQUISITION COST.—**
7 **The term ‘wholesale acquisition cost’ has**
8 **the meaning given that term in section**
9 **1847A(c)(6)(B).**

10 **“(b) REPORT.—**

11 **“(1) REPORT REQUIRED.—The manufac-**
12 **turer of a qualifying drug shall submit a**
13 **report to the Secretary if, with respect to**
14 **the qualifying drug—**

15 **“(A) there is an increase in the**
16 **price of the qualifying drug that re-**
17 **sults in an increase in the wholesale**
18 **acquisition cost of that drug that is**
19 **equal to—**

20 **“(i) 10 percent or more within**
21 **a 12-month period beginning on**
22 **or after January 1, 2019; or**

23 **“(ii) 25 percent or more with-**
24 **in a 36-month period beginning**
25 **on or after January 1, 2019;**

1 **“(B) the estimated price of the**
2 **qualifying drug or spending per indi-**
3 **vidual or per user of such drug (as es-**
4 **timated by the Secretary) for the ap-**
5 **plicable year (or per course of treat-**
6 **ment in such applicable year as de-**
7 **termined by the Secretary) is at least**
8 **\$26,000 beginning on or after January**
9 **1, 2021; or**

10 **“(C) there was an increase in the**
11 **price of the qualifying drug that re-**
12 **sulted in an increase in the wholesale**
13 **acquisition cost of that drug that is**
14 **equal to—**

15 **“(i) 10 percent or more within**
16 **a 12-month period that begins**
17 **and ends during the 5-year period**
18 **preceding January 1, 2021; or**

19 **“(ii) 25 percent or more with-**
20 **in a 36-month period that begins**
21 **and ends during the 5-year period**
22 **preceding January 1, 2021.**

23 **“(2) REPORT DEADLINE.—Each report**
24 **described in paragraph (1) shall be sub-**
25 **mitted to the Secretary—**

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

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

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

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

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

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

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

11 “(A) the percentage by which the
12 manufacturer will raise the wholesale
13 acquisition cost of the drug within
14 the 12-month period or 36-month pe-
15 riod as described in subsection
16 (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or
17 (b)(1)(C)(ii), as applicable, and the ef-
18 fective date of such price increase or
19 the cost associated with a qualifying
20 drug if such drug meets the criteria
21 under subsection (b)(1)(B) and the ef-
22 fective date at which such drug meets
23 such criteria;

24 “(B) an explanation for, and de-
25 scription of, each price increase for

1 **such drug that will occur during the**
2 **12-month period or the 36-month pe-**
3 **riod described in subsection**
4 **(b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or**
5 **(b)(1)(C)(ii), as applicable;**

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

11 **“(D) if known and different from**
12 **the manufacturer of the qualifying**
13 **drug, the identity of—**

14 **“(i) the sponsor or sponsors of**
15 **any investigational new drug ap-**
16 **plications under section 505(i) of**
17 **the Federal Food, Drug, and Cos-**
18 **metic Act for clinical investiga-**
19 **tions with respect to such drug,**
20 **for which the full reports are sub-**
21 **mitted as part of the applica-**
22 **tion—**

23 **“(I) for approval of the**
24 **drug under section 505 of**
25 **such Act; or**

1 **“(II) for licensure of the**
2 **drug under section 351 of the**
3 **Public Health Service Act; and**

4 **“(ii) the sponsor of an applica-**
5 **tion for the drug approved under**
6 **such section 505 of the Federal**
7 **Food, Drug, and Cosmetic Act or**
8 **licensed under section 351 of the**
9 **Public Health Service Act;**

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

21 **“(F) the current wholesale acqui-**
22 **sition cost of the drug;**

23 **“(G) the total expenditures of the**
24 **manufacturer on—**

1 “(i) materials and manufac-
2 turing for such drug;

3 “(ii) acquiring patents and li-
4 censing for such drug; and

5 “(iii) purchasing or acquiring
6 such drug from another manufac-
7 turer, if applicable;

8 “(H) the percentage of total ex-
9 penditures of the manufacturer on re-
10 search and development for such
11 drug that was derived from Federal
12 funds;

13 “(I) the total expenditures of the
14 manufacturer on research and devel-
15 opment for such drug that is nec-
16 essary to demonstrate that it meets
17 applicable statutory standards for ap-
18 proval under section 505 of the Fed-
19 eral Food, Drug, and Cosmetic Act or
20 licensure under section 351 of the
21 Public Health Service Act, as applica-
22 ble;

23 “(J) the total expenditures of the
24 manufacturer on pursuing new or ex-
25 panded indications or dosage changes

1 **for such drug under section 505 of the**
2 **Federal Food, Drug, and Cosmetic Act**
3 **or section 351 of the Public Health**
4 **Service Act;**

5 **“(K) the total expenditures of the**
6 **manufacturer on carrying out**
7 **postmarket requirements related to**
8 **such drug, including under section**
9 **505(o)(3) of the Federal Food, Drug,**
10 **and Cosmetic Act;**

11 **“(L) the total revenue and the net**
12 **profit generated from the qualifying**
13 **drug for each calendar year since the**
14 **approval of the application for the**
15 **drug under section 505 of the Federal**
16 **Food, Drug, and Cosmetic Act or the**
17 **issuance of the license for the drug**
18 **under section 351 of the Public**
19 **Health Service Act, or since the man-**
20 **ufacturer acquired such approved ap-**
21 **plication or license; and**

22 **“(M) the total costs associated**
23 **with marketing and advertising for**
24 **the qualifying drug;**

1 **“(2) with respect to the manufac-**
2 **turer—**

3 **“(A) the total revenue and the net**
4 **profit of the manufacturer for each of**
5 **the 12-month period described in sub-**
6 **section (b)(1)(A)(i) or (b)(1)(C)(i) or**
7 **the 36-month period described in sub-**
8 **section (b)(1)(A)(ii) or (b)(1)(C)(ii), as**
9 **applicable;**

10 **“(B) all stock-based performance**
11 **metrics used by the manufacturer to**
12 **determine executive compensation**
13 **for each of the 12-month periods de-**
14 **scribed in subsection (b)(1)(A)(i) or**
15 **(b)(1)(C)(i) or the 36-month periods**
16 **described in subsection (b)(1)(A)(ii) or**
17 **(b)(1)(C)(ii), as applicable; and**

18 **“(C) any additional information**
19 **the manufacturer chooses to provide**
20 **related to drug pricing decisions,**
21 **such as total expenditures on—**

22 **“(i) drug research and devel-**
23 **opment; or**

24 **“(ii) clinical trials, including**
25 **on drugs that failed to receive ap-**

1 proval by the Food and Drug Ad-
2 ministration; and

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

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

13 “(e) CIVIL MONETARY PENALTY.—Any manu-
14 facturer of a qualifying drug that fails to sub-
15 mit a report for the drug as required by this
16 section, following notification by the Sec-
17 retary to the manufacturer that the manufac-
18 turer is not in compliance with this section,
19 shall be subject to a civil monetary penalty of
20 \$75,000 for each day on which the violation
21 continues.

22 “(f) FALSE INFORMATION.—Any manufac-
23 turer that submits a report for a drug as re-
24 quired by this section that knowingly pro-
25 vides false information in such report is sub-

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

4 “(g) PUBLIC POSTING.—

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

12 “(2) FORMAT.—In developing the for-
13 mat in which reports will be publicly
14 posted under paragraph (1), the Sec-
15 retary shall consult with stakeholders, in-
16 cluding beneficiary groups, and shall
17 seek feedback from consumer advocates
18 and readability experts on the format
19 and presentation of the content of such
20 reports to ensure that such reports are—

21 “(A) user-friendly to the public;

22 and

23 “(B) written in plain language
24 that consumers can readily under-
25 stand.

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

12 **“(4) PROTECTED INFORMATION.—In car-**
13 **rying out this section, the Secretary shall**
14 **enforce applicable law concerning the**
15 **protection of confidential commercial in-**
16 **formation and trade secrets.**

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

18 **“(a) IN GENERAL.—Subject to subsection**
19 **(b), the Secretary shall submit to the Commit-**
20 **tees on Energy and Commerce and Ways and**
21 **Means of the House of Representatives and**
22 **the Committees on Health, Education, Labor,**
23 **and Pensions and Finance of the Senate, and**
24 **post on the public website of the Department**
25 **of Health and Human Services in a way that**

1 is user-friendly to the public and written in
2 plain language that consumers can readily
3 understand, an annual report—

4 “(1) summarizing the information re-
5 ported pursuant to section 1150C;

6 “(2) including copies of the reports
7 and supporting detailed economic anal-
8 yses submitted pursuant to such section;

9 “(3) detailing the costs and expendi-
10 tures incurred by the Department of
11 Health and Human Services in carrying
12 out section 1150C; and

13 “(4) explaining how the Department
14 of Health and Human Services is improv-
15 ing consumer and provider information
16 about drug value and drug price trans-
17 parency.

18 “(b) PROTECTED INFORMATION.—In car-
19 rying out this section, the Secretary shall en-
20 force applicable law concerning the protec-
21 tion of confidential commercial information
22 and trade secrets.”.

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

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

1 **(b) TABLE OF CONTENTS.—The table of con-**
 2 **tents is as follows:**

Sec. 1. Short title; table of contents.

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

Sec. 101. Providing for lower prices for certain high-priced sin-
gle 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.

3 **TITLE I—LOWERING PRICES**
 4 **THROUGH FAIR DRUG PRICE**
 5 **NEGOTIATION**

6 **SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN**
 7 **HIGH-PRICED SINGLE SOURCE DRUGS.**

8 **(a) PROGRAM TO LOWER PRICES FOR CER-**
 9 **TAIN HIGH-PRICED SINGLE SOURCE DRUGS.—**
 10 **Title XI of the Social Security Act (42 U.S.C.**
 11 **1301 et seq.) is amended by adding at the end**
 12 **the following new part:**

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

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

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

10 **“(1) publish a list of selected drugs in**
11 **accordance with section 1192;**

12 **“(2) enter into agreements with manu-**
13 **facturers of selected drugs with respect to**
14 **such period, in accordance with section**
15 **1193;**

16 **“(3) negotiate and, if applicable, re-**
17 **negotiate maximum fair prices for such**
18 **selected drugs, in accordance with section**
19 **1194; and**

20 **“(4) carry out the administrative du-**
21 **ties described in section 1196.**

22 **“(b) DEFINITIONS RELATING TO TIMING.—For**
23 **purposes of this part:**

24 **“(1) INITIAL PRICE APPLICABILITY**
25 **YEAR.—The term ‘initial price applica-**
26 **bility year’ means a plan year (beginning**

1 *with plan year 2023) or, if agreed to in an*
2 *agreement under section 1193 by the Sec-*
3 *retary and manufacturer involved, a pe-*
4 *riod of more than one plan year (begin-*
5 *ning on or after January 1, 2023).*

6 *“(2) PRICE APPLICABILITY PERIOD.—The*
7 *term ‘price applicability period’ means,*
8 *with respect to a drug, the period begin-*
9 *ning with the initial price applicability*
10 *year with respect to which such drug is a*
11 *selected drug and ending with the last*
12 *plan year during which the drug is a se-*
13 *lected drug.*

14 *“(3) SELECTED DRUG PUBLICATION*
15 *DATE.—The term ‘selected drug publica-*
16 *tion date’ means, with respect to each ini-*
17 *tial price applicability year, April 15 of*
18 *the plan year that begins 2 years prior to*
19 *such year.*

20 *“(4) VOLUNTARY NEGOTIATION PERIOD.—*
21 *The term ‘voluntary negotiation period’*
22 *means, with respect to an initial price ap-*
23 *plicability year with respect to a selected*
24 *drug, the period—*

25 *“(A) beginning on the sooner of—*

1 “(i) *the date on which the*
2 *manufacturer of the drug and the*
3 *Secretary enter into an agreement*
4 *under section 1193 with respect to*
5 *such drug; or*

6 “(ii) *June 15 following the se-*
7 *lected drug publication date with*
8 *respect to such selected drug; and*

9 “(B) *ending on March 31 of the*
10 *year that begins one year prior to the*
11 *initial price applicability year.*

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

14 “(1) *FAIR PRICE ELIGIBLE INDIVIDUAL.—*
15 *The term ‘fair price eligible individual’*
16 *means, with respect to a selected drug—*

17 “(A) *in the case such drug is fur-*
18 *nished or dispensed to the individual*
19 *at a pharmacy or by a mail order*
20 *service—*

21 “(i) *an individual who is en-*
22 *rolled under a prescription drug*
23 *plan under part D of title XVIII or*
24 *an MA–PD plan under part C of*

1 *such title under which coverage is*
2 *provided for such drug; and*

3 “(i) *an individual who is en-*
4 *rolled under a group health plan*
5 *or health insurance coverage of-*
6 *fered in the group or individual*
7 *market (as such terms are defined*
8 *in section 2791 of the Public*
9 *Health Service Act) with respect to*
10 *which there is in effect an agree-*
11 *ment with the Secretary under sec-*
12 *tion 1197 with respect to such se-*
13 *lected drug as so furnished or dis-*
14 *persed; and*

15 “(B) *in the case such drug is fur-*
16 *nished or administered to the indi-*
17 *vidual by a hospital, physician, or*
18 *other provider of services or sup-*
19 *plier—*

20 “(i) *an individual who is enti-*
21 *tled to benefits under part A of*
22 *title XVIII or enrolled under part*
23 *B of such title if such selected*
24 *drug is covered under the respec-*
25 *tive part; and*

1 “(ii) *an individual who is en-*
2 *rolled under a group health plan*
3 *or health insurance coverage of-*
4 *fered in the group or individual*
5 *market (as such terms are defined*
6 *in section 2791 of the Public*
7 *Health Service Act) with respect to*
8 *which there is in effect an agree-*
9 *ment with the Secretary under sec-*
10 *tion 1197 with respect to such se-*
11 *lected drug as so furnished or ad-*
12 *ministered.*

13 “(2) *MAXIMUM FAIR PRICE.—The term*
14 *‘maximum fair price’ means, with respect*
15 *to a plan year during a price applica-*
16 *bility period and with respect to a selected*
17 *drug (as defined in section 1192(c)) with*
18 *respect to such period, the price published*
19 *pursuant to section 1195 in the Federal*
20 *Register for such drug and year.*

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

23 “(A) *IN GENERAL.—The terms ‘aver-*
24 *age international market price’ and*
25 *‘AIM price’ mean, with respect to a*

1 *drug, the average price (which shall*
2 *be the net average price, if prac-*
3 *ticable, and volume-weighted, if prac-*
4 *ticable) for a unit (as defined in para-*
5 *graph (4)) of the drug for sales of such*
6 *drug (calculated across different dos-*
7 *age forms and strengths of the drug*
8 *and not based on the specific formula-*
9 *tion or package size or package type),*
10 *as computed (as of the date of publi-*
11 *cation of such drug as a selected drug*
12 *under section 1192(a)) in all countries*
13 *described in clause (ii) of subpara-*
14 *graph (B) that are applicable coun-*
15 *tries (as described in clause (i) of such*
16 *subparagraph) with respect to such*
17 *drug.*

18 “(B) *APPLICABLE COUNTRIES.—*

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

1 *sales of such drug in such coun-*
2 *try.*

3 “(i) *COUNTRIES DESCRIBED.—*
4 *For purposes of this paragraph,*
5 *the following are countries de-*
6 *scribed in this clause:*

7 “(I) *Australia.*

8 “(II) *Canada.*

9 “(III) *France.*

10 “(IV) *Germany.*

11 “(V) *Japan.*

12 “(VI) *The United Kingdom.*

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

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

19 *AS SELECTED DRUGS.*

20 “(a) *IN GENERAL.—Not later than the se-*
21 *lected drug publication date with respect to an*
22 *initial price applicability year, the Secretary*
23 *shall select and publish in the Federal Reg-*
24 *ister a list of—*

1 “(1)(A) *with respect to an initial price*
2 *applicability year during the period be-*
3 *ginning with 2023 and ending with 2027,*
4 *at least 25 negotiation-eligible drugs de-*
5 *scribed in subparagraphs (A) and (B), but*
6 *not subparagraph (C), of subsection (d)(1)*
7 *(or, with respect to an initial price appli-*
8 *cability year during such period begin-*
9 *ning after 2023, the maximum number (if*
10 *such number is less than 25) of such nego-*
11 *tiation-eligible drugs for the year) with*
12 *respect to such year;*

13 “(B) *with respect to an initial price*
14 *applicability year during the period be-*
15 *ginning with 2028 and ending with 2032,*
16 *at least 30 negotiation-eligible drugs de-*
17 *scribed in subparagraphs (A) and (B), but*
18 *not subparagraph (C), of subsection (d)(1)*
19 *(or, with respect to an initial price appli-*
20 *cability year during such period, the max-*
21 *imum number (if such number is less than*
22 *30) of such negotiation-eligible drugs for*
23 *the year) with respect to such year; and*

24 “(C) *with respect to an initial price*
25 *applicability year beginning after 2032, at*

1 *least 35 negotiation-eligible drugs de-*
2 *scribed in subparagraphs (A) and (B), but*
3 *not subparagraph (C), of subsection (d)(1)*
4 *(or, with respect to an initial price appli-*
5 *cability year during such period, the max-*
6 *imum number (if such number is less than*
7 *35) of such negotiation-eligible drugs for*
8 *the year) with respect to such year;*

9 *“(2) all negotiation-eligible drugs de-*
10 *scribed in subparagraph (C) of such sub-*
11 *section with respect to such year; and*

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

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

1 *count toward the required minimum amount*
2 *of drugs to be selected under paragraph (1) for*
3 *any subsequent year, including such a drug so*
4 *selected that is subject to renegotiation under*
5 *section 1194.*

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

1 “(c) **SELECTED DRUG.**—For purposes of this
2 part, each drug included on the list published
3 under subsection (a) with respect to an initial
4 price applicability year shall be referred to as
5 a ‘selected drug’ with respect to such year and
6 each subsequent plan year beginning before
7 the first plan year beginning after the date on
8 which the Secretary determines two or more
9 drug products—

10 “(1) are approved or licensed (as ap-
11 plicable)—

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

15 “(B) under section 351(k) of the
16 Public Health Service Act using such
17 drug as the reference product; and

18 “(2) continue to be marketed.

19 “(d) **NEGOTIATION-ELIGIBLE DRUG.**—

20 “(1) **IN GENERAL.**—For purposes of this
21 part, the term ‘negotiation-eligible drug’
22 means, with respect to the selected drug
23 publication date with respect to an initial
24 price applicability year, a qualifying sin-
25 gle source drug, as defined in subsection

1 *(e), that meets any of the following cri-*
2 *teria:*

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

13 *“(B) OTHER DRUGS.—The drug is*
14 *among the 125 drugs for which there*
15 *was an estimated greatest net spend-*
16 *ing in the United States (including*
17 *the 50 States, the District of Colum-*
18 *bia, and the territories of the United*
19 *States), as determined by the Sec-*
20 *retary, during the most recent plan*
21 *year prior to such drug publication*
22 *date for which data are available.*

23 *“(C) INSULIN.—The drug is a*
24 *qualifying single source drug de-*
25 *scribed in subsection (e)(3).*

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

10 “(3) **PUBLICATION.**—*Not later than the*
11 *selected drug publication date with re-*
12 *spect to an initial price applicability year,*
13 *the Secretary shall publish in the Federal*
14 *Register a list of negotiation-eligible*
15 *drugs with respect to such selected drug*
16 *publication date.*

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

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

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

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

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

7 “(A) *is licensed under section*
8 *351(a) of the Public Health Service*
9 *Act, including any product that has*
10 *been deemed to be licensed under sec-*
11 *tion 351 of such Act pursuant to sec-*
12 *tion 7002(e)(4) of the Biologics Price*
13 *Competition and Innovation Act of*
14 *2009, and continues to be marketed*
15 *under section 351 of such Act; and*

16 “(B) *is not the reference product*
17 *for any biological product that is li-*
18 *censed and continues to be marketed*
19 *under section 351(k) of such Act.*

20 “(3) *INSULIN PRODUCT.—Notwith-*
21 *standing paragraphs (1) and (2), any in-*
22 *sulin product that is approved under sub-*
23 *section (c) or (j) of section 505 of the Fed-*
24 *eral Food, Drug, and Cosmetic Act or li-*
25 *censed under subsection (a) or (k) of sec-*

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

11 *For purposes of applying paragraphs (1) and*
12 *(2), a drug or biological product that is mar-*
13 *keted by the same sponsor or manufacturer (or*
14 *an affiliate thereof or a cross-licensed pro-*
15 *ducer or distributor) as the listed drug or ref-*
16 *erence product described in such respective*
17 *paragraph shall not be taken into consider-*
18 *ation.*

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

1 *under section 1194, the Secretary shall use*
2 *data relating to the AIM price with respect to*
3 *such drug as available or provided to the Sec-*
4 *retary and shall on an ongoing basis request*
5 *from manufacturers of selected drugs informa-*
6 *tion on the AIM price of such a drug.*

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

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

15 **“(A) that is first approved or li-**
16 **censed, as described in paragraph (1),**
17 **(2), or (3) of subsection (e), as applica-**
18 **ble, during the year preceding such se-**
19 **lected drug publication date; and**

20 **“(B) that the Secretary determines**
21 **under paragraph (2) is likely to be a**
22 **negotiation-eligible drug with respect**
23 **to the subsequent selected drug publi-**
24 **cation date.**

1 “(2) **DETERMINATION.**—*In the case of a*
2 *qualifying single source drug that meets*
3 *the criteria described in subparagraphs*
4 *(A) and (B) of paragraph (1), with respect*
5 *to an initial price applicability year, if*
6 *the wholesale acquisition cost at which*
7 *such drug is first marketed in the United*
8 *States is equal to or greater than the me-*
9 *dian household income (as determined ac-*
10 *ording to the most recent data collected*
11 *by the United States Census Bureau), the*
12 *Secretary shall determine before the se-*
13 *lected drug publication date with respect*
14 *to the initial price applicability year, if*
15 *the drug is likely to be included as a nego-*
16 *tiation-eligible drug with respect to the*
17 *subsequent selected drug publication*
18 *date, based on the projected spending*
19 *under title XVIII or in the United States*
20 *on such drug. For purposes of this para-*
21 *graph the term ‘United States’ includes*
22 *the 50 States, the District of Columbia,*
23 *and the territories of the United States.*

1 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

2 **“(a) IN GENERAL.—For purposes of section**
3 **1191(a)(2), the Secretary shall enter into**
4 **agreements with manufacturers of selected**
5 **drugs with respect to a price applicability pe-**
6 **riod, by not later than June 15 following the**
7 **selected drug publication date with respect to**
8 **such selected drug, under which—**

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

19 **“(A) to fair price eligible individ-**
20 **uals who with respect to such drug**
21 **are described in subparagraph (A) of**
22 **section 1191(c)(1) and are furnished**
23 **or dispensed such drug during, sub-**
24 **ject to subparagraph (2), the price ap-**
25 **plicability period; and**

1 “(B) to hospitals, physicians, and
2 other providers of services and sup-
3 pliers with respect to fair price eligi-
4 ble individuals who with respect to
5 such drug are described in subpara-
6 graph (B) of such section and are fur-
7 nished or administered such drug
8 during, subject to subparagraph (2),
9 the price applicability period;

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

24 “(A) to fair price eligible individ-
25 uals who with respect to such drug

1 *are described in subparagraph (A) of*
2 *section 1191(c)(1) and are furnished*
3 *or dispensed such drug during any*
4 *year during the price applicability pe-*
5 *riod (beginning after such renegoti-*
6 *ation) with respect to such selected*
7 *drug; and*

8 *“(B) to hospitals, physicians, and*
9 *other providers of services and sup-*
10 *pliers with respect to fair price eligi-*
11 *ble individuals who with respect to*
12 *such drug are described in subpara-*
13 *graph (B) of such section and are fur-*
14 *nished or administered such drug*
15 *during any year described in subpara-*
16 *graph (A);*

17 *“(3) the maximum fair price (includ-*
18 *ing as renegotiated pursuant to para-*
19 *graph (2)), with respect to such a selected*
20 *drug, shall be provided to fair price eligi-*
21 *ble individuals, who with respect to such*
22 *drug are described in subparagraph (A)*
23 *of section 1191(c)(1), at the pharmacy or*
24 *by a mail order service at the point-of-sale*
25 *of such drug;*

1 “(4) *the manufacturer, subject to sub-*
2 *section (c), submits to the Secretary, in a*
3 *form and manner specified by the Sec-*
4 *retary—*

5 “(A) *for the voluntary negotiation*
6 *period for the price applicability pe-*
7 *riod (and, if applicable, before any pe-*
8 *riod of renegotiation specified pursu-*
9 *ant to paragraph (2)) with respect to*
10 *such drug all information that the*
11 *Secretary requires to carry out the ne-*
12 *gotiation (or renegotiation process)*
13 *under this part, including informa-*
14 *tion described in section 1192(f) and*
15 *section 1194(d)(1); and*

16 “(B) *on an ongoing basis, informa-*
17 *tion on changes in prices for such*
18 *drug that would affect the AIM price*
19 *for such drug or otherwise provide a*
20 *basis for renegotiation of the max-*
21 *imum fair price for such drug pursu-*
22 *ant to paragraph (2);*

23 “(5) *the manufacturer agrees that in*
24 *the case the selected drug of a manufac-*
25 *turer is a drug described in subsection (c),*

1 *the manufacturer will, in accordance*
2 *with such subsection, make any payment*
3 *required under such subsection with re-*
4 *spect to such drug; and*

5 *“(6) the manufacturer complies with*
6 *requirements imposed by the Secretary for*
7 *purposes of administering the program,*
8 *including with respect to the duties de-*
9 *scribed in section 1196.*

10 *“(b) AGREEMENT IN EFFECT UNTIL DRUG IS*
11 *NO LONGER A SELECTED DRUG.—An agreement*
12 *entered into under this section shall be effec-*
13 *tive, with respect to a drug, until such drug is*
14 *no longer considered a selected drug under*
15 *section 1192(c).*

16 *“(c) SPECIAL RULE FOR CERTAIN SELECTED*
17 *DRUGS WITHOUT AIM PRICE.—*

18 *“(1) IN GENERAL.—In the case of a se-*
19 *lected drug for which there is no AIM*
20 *price available with respect to the initial*
21 *price applicability year for such drug and*
22 *for which an AIM price becomes available*
23 *beginning with respect to a subsequent*
24 *plan year during the price applicability*
25 *period for such drug, if the Secretary de-*

1 *termines that the amount described in*
2 *paragraph (2)(A) for a unit of such drug*
3 *is greater than the amount described in*
4 *paragraph (2)(B) for a unit of such drug,*
5 *then by not later than one year after the*
6 *date of such determination, the manufac-*
7 *turer of such selected drug shall pay to*
8 *the Treasury an amount equal to the*
9 *product of—*

10 *“(A) the difference between such*
11 *amount described in paragraph (2)(A)*
12 *for a unit of such drug and such*
13 *amount described in paragraph (2)(B)*
14 *for a unit of such drug; and*

15 *“(B) the number of units of such*
16 *drug sold in the United States, includ-*
17 *ing the 50 States, the District of Co-*
18 *lumbia, and the territories of the*
19 *United States, during the period de-*
20 *scribed in paragraph (2)(B).*

21 *“(2) AMOUNTS DESCRIBED.—*

22 *“(A) WEIGHTED AVERAGE PRICE BE-*
23 *FORE AIM PRICE AVAILABLE.—For pur-*
24 *poses of paragraph (1), the amount*
25 *described in this subparagraph for a*

1 *selected drug described in such para-*
2 *graph, is the amount equal to the*
3 *weighted average manufacturer price*
4 *(as defined in section 1927(k)(1)) for*
5 *such dosage strength and form for the*
6 *drug during the period beginning*
7 *with the first plan year for which the*
8 *drug is included on the list of negotia-*
9 *tion-eligible drugs published under*
10 *section 1192(d) and ending with the*
11 *last plan year during the price appli-*
12 *cability period for such drug with re-*
13 *spect to which there is no AIM price*
14 *available for such drug.*

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

1 “(d) **CONFIDENTIALITY OF INFORMATION.**—In-
2 *formation submitted to the Secretary under*
3 *this part by a manufacturer of a selected drug*
4 *that is proprietary information of such manu-*
5 *facturer (as determined by the Secretary) may*
6 *be used only by the Secretary or disclosed to*
7 *and used by the Comptroller General of the*
8 *United States or the Medicare Payment Advi-*
9 *sory Commission for purposes of carrying out*
10 *this part.*

11 “(e) **REGULATIONS.**—

12 “(1) **IN GENERAL.**—*The Secretary shall,*
13 *pursuant to rulemaking, specify, in ac-*
14 *cordance with paragraph (2), the infor-*
15 *mation that must be submitted under sub-*
16 *section (a)(4).*

17 “(2) **INFORMATION SPECIFIED.**—*Informa-*
18 *tion described in paragraph (1), with re-*
19 *spect to a selected drug, shall include in-*
20 *formation on sales of the drug (by the*
21 *manufacturer of the drug or by another*
22 *entity under license or other agreement*
23 *with the manufacturer, with respect to the*
24 *sales of such drug, regardless of the name*
25 *under which the drug is sold) in any for-*

1 *foreign country that is part of the AIM price.*
2 *The Secretary shall verify, to the extent*
3 *practicable, such sales from appropriate*
4 *officials of the government of the foreign*
5 *country involved.*

6 *“(f) COMPLIANCE WITH REQUIREMENTS FOR*
7 *ADMINISTRATION OF PROGRAM.—Each manufac-*
8 *turer with an agreement in effect under this*
9 *section shall comply with requirements im-*
10 *posed by the Secretary or a third party with a*
11 *contract under section 1196(c)(1), as applica-*
12 *ble, for purposes of administering the pro-*
13 *gram.*

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

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

22 *“(1) shall during the voluntary nego-*
23 *tiation period with respect to the initial*
24 *price applicability year for such drug, in*
25 *accordance with this section, negotiate a*

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

4 *“(2) as applicable pursuant to section*
5 *1193(a)(2) and in accordance with the*
6 *process specified pursuant to such section,*
7 *renegotiate such maximum fair price for*
8 *such drug for the purpose described in*
9 *such section.*

10 *“(b) NEGOTIATING METHODOLOGY AND OB-*
11 *JECTIVE.—*

12 *“(1) IN GENERAL.—The Secretary shall*
13 *develop and use a consistent methodology*
14 *for negotiations under subsection (a) that,*
15 *in accordance with paragraph (2) and*
16 *subject to paragraph (3), achieves the low-*
17 *est maximum fair price for each selected*
18 *drug while appropriately rewarding inno-*
19 *vation.*

20 *“(2) PRIORITIZING FACTORS.—In consid-*
21 *ering the factors described in subsection*
22 *(d) in negotiating (and, as applicable, re-*
23 *negotiating) the maximum fair price for a*
24 *selected drug, the Secretary shall, to the*
25 *extent practicable, consider all of the*

1 *available factors listed but shall*
2 *prioritize the following factors:*

3 *“(A) RESEARCH AND DEVELOPMENT*
4 *COSTS.—The factor described in para-*
5 *graph (1)(A) of subsection (d).*

6 *“(B) MARKET DATA.—The factor de-*
7 *scribed in paragraph (1)(B) of such*
8 *subsection.*

9 *“(C) UNIT COSTS OF PRODUCTION*
10 *AND DISTRIBUTION.—The factor de-*
11 *scribed in paragraph (1)(C) of such*
12 *subsection.*

13 *“(D) COMPARISON TO EXISTING*
14 *THERAPEUTIC ALTERNATIVES.—The fac-*
15 *tor described in paragraph (2)(A) of*
16 *such subsection.*

17 *“(3) REQUIREMENT.—*

18 *“(A) IN GENERAL.—In negotiating*
19 *the maximum fair price of a selected*
20 *drug, with respect to an initial price*
21 *applicability year for the selected*
22 *drug, and, as applicable, in renegoti-*
23 *ating the maximum fair price for such*
24 *drug, with respect to a subsequent*
25 *year during the price applicability pe-*

1 *riod for such drug, in the case that*
2 *the manufacturer of the selected drug*
3 *offers under the negotiation or renegot-*
4 *tiation, as applicable, a price for such*
5 *drug that is not more than the target*
6 *price described in subparagraph (B)*
7 *for such drug for the respective year,*
8 *the Secretary shall agree under such*
9 *negotiation or renegotiation, respec-*
10 *tively, to such offered price as the*
11 *maximum fair price.*

12 **“(B) TARGET PRICE.—**

13 **“(i) IN GENERAL.—***Subject to*
14 *clause (ii), the target price de-*
15 *scribed in this subparagraph for a*
16 *selected drug with respect to a*
17 *year, is the average price (which*
18 *shall be the net average price, if*
19 *practicable, and volume-weighted,*
20 *if practicable) for a unit of such*
21 *drug for sales of such drug, as*
22 *computed (across different dosage*
23 *forms and strengths of the drug*
24 *and not based on the specific for-*
25 *mulation or package size or pack-*

1 *age type of the drug) in the appli-*
2 *cable country described in section*
3 *1191(c)(3)(B) with respect to such*
4 *drug that, with respect to such*
5 *year, has the lowest average price*
6 *for such drug as compared to the*
7 *average prices (as so computed) of*
8 *such drug with respect to such*
9 *year in the other applicable coun-*
10 *tries described in such section*
11 *with respect to such drug.*

12 *“(i) SELECTED DRUGS WITHOUT*
13 *AIM PRICE.—In applying this para-*
14 *graph in the case of negotiating*
15 *the maximum fair price of a se-*
16 *lected drug for which there is no*
17 *AIM price available with respect*
18 *to the initial price applicability*
19 *year for such drug, or, as applica-*
20 *ble, renegotiating the maximum*
21 *fair price for such drug with re-*
22 *spect to a subsequent year during*
23 *the price applicability period for*
24 *such drug before the first plan*
25 *year for which there is an AIM*

1 *price available for such drug, the*
2 *target price described in this sub-*
3 *paragraph for such drug and re-*
4 *spective year is the amount that is*
5 *80 percent of the average manu-*
6 *facturer price (as defined in sec-*
7 *tion 1927(k)(1)) for such drug and*
8 *year.*

9 “(4) *ANNUAL REPORT.*—*After the com-*
10 *pletion of each voluntary negotiation pe-*
11 *riod, the Secretary shall submit to Con-*
12 *gress a report on the maximum fair prices*
13 *negotiated (or, as applicable, renegoti-*
14 *ated) for such period. Such report shall*
15 *include information on how such prices so*
16 *negotiated (or renegotiated) meet the re-*
17 *quirements of this part, including the re-*
18 *quirements of this subsection.*

19 “(c) *LIMITATION.*—

20 “(1) *IN GENERAL.*—*Subject to para-*
21 *graph (2), the maximum fair price nego-*
22 *tiated (including as renegotiated) under*
23 *this section for a selected drug, with re-*
24 *spect to each plan year during a price ap-*
25 *plicability period for such drug, shall not*

1 *exceed 120 percent of the AIM price appli-*
2 *cable to such drug with respect to such*
3 *year.*

4 **“(2) SELECTED DRUGS WITHOUT AIM**
5 **PRICE.—***In the case of a selected drug for*
6 *which there is no AIM price available*
7 *with respect to the initial price applica-*
8 *bility year for such drug, for each plan*
9 *year during the price applicability period*
10 *before the first plan year for which there*
11 *is an AIM price available for such drug,*
12 *the maximum fair price negotiated (in-*
13 *cluding as renegotiated) under this sec-*
14 *tion for the selected drug shall not exceed*
15 *the amount equal to 85 percent of the av-*
16 *erage manufacturer price for the drug*
17 *with respect to such year.*

18 **“(d) CONSIDERATIONS.—***For purposes of ne-*
19 *gotiating and, as applicable, renegotiating*
20 *(including for purposes of determining wheth-*
21 *er to renegotiate) the maximum fair price of a*
22 *selected drug under this part with the manu-*
23 *facturer of the drug, the Secretary shall, con-*
24 *sistent with subsection (b)(2), take into consid-*
25 *eration the following factors:*

1 **“(1) MANUFACTURER-SPECIFIC INFORMA-**
2 **TION.—The following information, includ-**
3 **ing as submitted by the manufacturer:**

4 **“(A) Research and development**
5 **costs of the manufacturer for the drug**
6 **and the extent to which the manufac-**
7 **turer has recouped research and de-**
8 **velopment costs.**

9 **“(B) Market data for the drug, in-**
10 **cluding the distribution of sales**
11 **across different programs and pur-**
12 **chasers and projected future revenues**
13 **for the drug.**

14 **“(C) Unit costs of production and**
15 **distribution of the drug.**

16 **“(D) Prior Federal financial sup-**
17 **port for novel therapeutic discovery**
18 **and development with respect to the**
19 **drug.**

20 **“(E) Data on patents and on exist-**
21 **ing and pending exclusivity for the**
22 **drug.**

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

1 “(G) *Information on clinical trials*
2 *for the drug in the United States or in*
3 *applicable countries described in sec-*
4 *tion 1191(c)(3)(B).*

5 “(2) *INFORMATION ON ALTERNATIVE*
6 *PRODUCTS.—The following information:*

7 “(A) *The extent to which the drug*
8 *represents a therapeutic advance as*
9 *compared to existing therapeutic al-*
10 *ternatives and, to the extent such in-*
11 *formation is available, the costs of*
12 *such existing therapeutic alternatives.*

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

16 “(C) *Information on comparative*
17 *effectiveness analysis for such prod-*
18 *ucts, taking into consideration the ef-*
19 *fects of such products on specific pop-*
20 *ulations, such as individuals with dis-*
21 *abilities, the elderly, terminally ill,*
22 *children, and other patient popu-*
23 *lations.*

24 *In considering information described in*
25 *subparagraph (C), the Secretary shall not*

1 *use evidence or findings from comparative*
2 *clinical effectiveness research in a man-*
3 *ner that treats extending the life of an el-*
4 *derly, disabled, or terminally ill indi-*
5 *vidual as of lower value than extending*
6 *the life of an individual who is younger,*
7 *nondisabled, or not terminally ill. Noth-*
8 *ing in the previous sentence shall affect*
9 *the application or consideration of an*
10 *AIM price for a selected drug.*

11 *“(3) FOREIGN SALES INFORMATION.—To*
12 *the extent available on a timely basis, in-*
13 *cluding as provided by a manufacturer of*
14 *the selected drug or otherwise, informa-*
15 *tion on sales of the selected drug in each*
16 *of the countries described in section*
17 *1191(c)(3)(B).*

18 *“(4) ADDITIONAL INFORMATION.—Infor-*
19 *mation submitted to the Secretary, in ac-*
20 *cordance with a process specified by the*
21 *Secretary, by other parties that are af-*
22 *ected by the establishment of a maximum*
23 *fair price for the selected drug.*

24 *“(e) REQUEST FOR INFORMATION.—For pur-*
25 *poses of negotiating and, as applicable, re-*

1 *negotiating (including for purposes of deter-*
2 *mining whether to renegotiate) the maximum*
3 *fair price of a selected drug under this part*
4 *with the manufacturer of the drug, with re-*
5 *spect to a price applicability period, and other*
6 *relevant data for purposes of this section—*

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

14 “(2) *by not later than October 1 fol-*
15 *lowing the selected drug publication date,*
16 *the manufacturer of such selected drug*
17 *shall submit to the Secretary such re-*
18 *quested information in such form and*
19 *manner as the Secretary may require.*

20 *The Secretary shall request, from the manu-*
21 *facturer or others, such additional informa-*
22 *tion as may be needed to carry out the negotia-*
23 *tion and renegotiation process under this sec-*
24 *tion.*

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

2 *“(a) IN GENERAL.—With respect to an ini-*
3 *tial price applicability year and selected drug*
4 *with respect to such year, not later than April*
5 *1 of the plan year prior to such initial price*
6 *applicability year, the Secretary shall publish*
7 *in the Federal Register the maximum fair*
8 *price for such drug negotiated under this part*
9 *with the manufacturer of such drug.*

10 *“(b) UPDATES.—*

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

19 *“(A) subject to subparagraph (B),*
20 *the amount equal to the maximum*
21 *fair price published for such drug for*
22 *the previous year, increased by the an-*
23 *nuual percentage increase in the con-*
24 *sumer price index for all urban con-*
25 *sumers (all items; U.S. city average)*

1 *as of September of such previous year;*
2 *or*

3 *“(B) in the case the maximum fair*
4 *price for such drug was renegotiated,*
5 *for the first year for which such price*
6 *as so renegotiated applies, such re-*
7 *negotiated maximum fair price.*

8 **“(2) PRICES NEGOTIATED AFTER DEAD-**
9 **LINE.—***In the case of a selected drug with*
10 *respect to an initial price applicability*
11 *year for which the maximum fair price is*
12 *determined under this part after the date*
13 *of publication under this section, the Sec-*
14 *retary shall publish such maximum fair*
15 *price in the Federal Register by not later*
16 *than 30 days after the date such max-*
17 *imum price is so determined.*

18 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
19 **VISIONS.**

20 **“(a) ADMINISTRATIVE DUTIES.—**

21 **“(1) IN GENERAL.—***For purposes of sec-*
22 *tion 1191, the administrative duties de-*
23 *scribed in this section are the following:*

24 **“(A) The establishment of proce-**
25 **dures (including through agreements**

1 *with manufacturers under this part,*
2 *contracts with prescription drug*
3 *plans under part D of title XVIII and*
4 *MA-PD plans under part C of such*
5 *title, and agreements under section*
6 *1197 with group health plans and*
7 *health insurance issuers of health in-*
8 *surance coverage offered in the indi-*
9 *vidual or group market) under which*
10 *the maximum fair price for a selected*
11 *drug is provided to fair price eligible*
12 *individuals, who with respect to such*
13 *drug are described in subparagraph*
14 *(A) of section 1191(c)(1), at phar-*
15 *macies or by mail order service at the*
16 *point-of-sale of the drug for the appli-*
17 *cable price period for such drug and*
18 *providing that such maximum fair*
19 *price is used for determining cost-*
20 *sharing under such plans or coverage*
21 *for the selected drug.*

22 *“(B) The establishment of proce-*
23 *dures (including through agreements*
24 *with manufacturers under this part*
25 *and contracts with hospitals, physi-*

1 *cians, and other providers of services*
2 *and suppliers and agreements under*
3 *section 1197 with group health plans*
4 *and health insurance issuers of*
5 *health insurance coverage offered in*
6 *the individual or group market)*
7 *under which, in the case of a selected*
8 *drug furnished or administered by*
9 *such a hospital, physician, or other*
10 *provider of services or supplier to fair*
11 *price eligible individuals (who with*
12 *respect to such drug are described in*
13 *subparagraph (B) of section*
14 *1191(c)(1)), the maximum fair price*
15 *for the selected drug is provided to*
16 *such hospitals, physicians, and other*
17 *providers of services and suppliers (as*
18 *applicable) with respect to such indi-*
19 *viduals and providing that such max-*
20 *imum fair price is used for deter-*
21 *mining cost-sharing under the respec-*
22 *tive part, plan, or coverage for the se-*
23 *lected drug.*

24 *“(C) The establishment of proce-*
25 *dures (including through agreements*

1 *and contracts described in subpara-*
2 *graphs (A) and (B)) to ensure that, not*
3 *later than 90 days after the dis-*
4 *persing of a selected drug to a fair*
5 *price eligible individual by a phar-*
6 *macy or mail order service, the phar-*
7 *macy or mail order service is reim-*
8 *bursed for an amount equal to the dif-*
9 *ference between—*

10 *“(i) the lesser of—*

11 *“(I) the wholesale acquisi-*
12 *tion cost of the drug;*

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

16 *“(III) any other similar de-*
17 *termination of pharmacy ac-*
18 *quisition costs of the drug, as*
19 *determined by the Secretary;*
20 *and*

21 *“(ii) the maximum fair price*
22 *for the drug.*

23 *“(D) The establishment of proce-*
24 *dures to ensure that the maximum*

1 *fair price for a selected drug is ap-*
2 *plied before—*

3 “(i) *any coverage or financial*
4 *assistance under other health ben-*
5 *efit plans or programs that pro-*
6 *vide coverage or financial assist-*
7 *ance for the purchase or provision*
8 *of prescription drug coverage on*
9 *behalf of fair price eligible indi-*
10 *viduals as the Secretary may*
11 *specify; and*

12 “(ii) *any other discounts.*

13 “(E) *The establishment of proce-*
14 *dures to enter into appropriate agree-*
15 *ments and protocols for the ongoing*
16 *computation of AIM prices for selected*
17 *drugs, including, to the extent pos-*
18 *sible, to compute the AIM price for se-*
19 *lected drugs and including by pro-*
20 *viding that the manufacturer of such*
21 *a selected drug should provide infor-*
22 *mation for such computation not later*
23 *than 3 months after the first date of*
24 *the voluntary negotiation period for*
25 *such selected drug.*

1 “(F) *The establishment of proce-*
2 *dures to compute and apply the max-*
3 *imum fair price across different*
4 *strengths and dosage forms of a se-*
5 *lected drug and not based on the spe-*
6 *cific formulation or package size or*
7 *package type of the drug.*

8 “(G) *The establishment of proce-*
9 *dures to negotiate and apply the max-*
10 *imum fair price in a manner that*
11 *does not include any dispensing or*
12 *similar fee.*

13 “(H) *The establishment of proce-*
14 *dures to carry out the provisions of*
15 *this part, as applicable, with respect*
16 *to—*

17 “(i) *fair price eligible individ-*
18 *uals who are enrolled under a*
19 *prescription drug plan under part*
20 *D of title XVIII or an MA-PD plan*
21 *under part C of such title; and*

22 “(ii) *fair price eligible individ-*
23 *uals who are enrolled under a*
24 *group health plan or health insur-*
25 *ance coverage offered by a health*

1 *insurance issuer in the individual*
2 *or group market with respect to*
3 *which there is an agreement in ef-*
4 *fect under section 1197.*

5 “(I) *The establishment of a nego-*
6 *tiation process and renegotiation*
7 *process in accordance with section*
8 *1194, including a process for acquir-*
9 *ing information described in sub-*
10 *section (d) of such section and deter-*
11 *mining amounts described in sub-*
12 *section (b) of such section.*

13 “(J) *The provision of a reasonable*
14 *dispute resolution mechanism to re-*
15 *solve disagreements between manufac-*
16 *turers, fair price eligible individuals,*
17 *and the third party with a contract*
18 *under subsection (c)(1).*

19 “(2) *MONITORING COMPLIANCE.—*

20 “(A) *IN GENERAL.—The Secretary*
21 *shall monitor compliance by a manu-*
22 *facturer with the terms of an agree-*
23 *ment under section 1193, including by*
24 *establishing a mechanism through*

1 *which violations of such terms may be*
2 *reported.*

3 “(B) *NOTIFICATION.—If a third*
4 *party with a contract under sub-*
5 *section (c)(1) determines that the*
6 *manufacturer is not in compliance*
7 *with such agreement, the third party*
8 *shall notify the Secretary of such non-*
9 *compliance for appropriate enforce-*
10 *ment under section 4192 of the Inter-*
11 *nal Revenue Code of 1986 or section*
12 *1198, as applicable.*

13 “(b) *COLLECTION OF DATA.—*

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

22 “(2) *FROM HEALTH PLANS.—The Sec-*
23 *retary may collect appropriate data from*
24 *group health plans or health insurance*
25 *issuers offering group or individual*

1 *health insurance coverage in a timeframe*
2 *that allows for maximum fair prices to be*
3 *provided under this part for selected*
4 *drugs.*

5 “(3) *COORDINATION OF DATA COLLEC-*
6 *TION.—To the extent feasible, as deter-*
7 *mined by the Secretary, the Secretary*
8 *shall ensure that data collected pursuant*
9 *to this subsection is coordinated with, and*
10 *not duplicative of, other data collection*
11 *efforts.*

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

13 “(1) *IN GENERAL.—The Secretary may*
14 *enter into a contract with 1 or more third*
15 *parties to administer the requirements es-*
16 *tablished by the Secretary in order to*
17 *carry out this part. At a minimum, the*
18 *contract with a third party under the pre-*
19 *ceding sentence shall require that the*
20 *third party—*

21 “(A) *receive and transmit informa-*
22 *tion between the Secretary, manufac-*
23 *turers, and other individuals or enti-*
24 *ties the Secretary determines appro-*
25 *priate;*

1 “(B) *receive, distribute, or facili-*
2 *tate the distribution of funds of manu-*
3 *facturers to appropriate individuals*
4 *or entities in order to meet the obliga-*
5 *tions of manufacturers under agree-*
6 *ments under this part;*

7 “(C) *provide adequate and timely*
8 *information to manufacturers, con-*
9 *sistent with the agreement with the*
10 *manufacturer under this part, as nec-*
11 *essary for the manufacturer to fulfill*
12 *its obligations under this part; and*

13 “(D) *permit manufacturers to con-*
14 *duct periodic audits, directly or*
15 *through contracts, of the data and in-*
16 *formation used by the third party to*
17 *determine discounts for applicable*
18 *drugs of the manufacturer under the*
19 *program.*

20 “(2) *PERFORMANCE REQUIREMENTS.—*
21 *The Secretary shall establish performance*
22 *requirements for a third party with a con-*
23 *tract under paragraph (1) and safeguards*
24 *to protect the independence and integrity*

1 *of the activities carried out by the third*
2 *party under the program under this part.*

3 **“(d) COORDINATION WITH 340B PROGRAM.—**

4 *In the case of a manufacturer of a selected*
5 *drug, with respect to an initial price applica-*
6 *bility year, for each year with respect to which*
7 *a maximum fair price is applied under this*
8 *part for such drug, such drug shall not be con-*
9 *sidered a covered outpatient drug subject to*
10 *an agreement under section 340B of the Public*
11 *Health Service Act.*

12 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER HEALTH**
13 **PLANS.**

14 **“(a) AGREEMENT TO PARTICIPATE UNDER**
15 **PROGRAM.—**

16 **“(1) IN GENERAL.—***Subject to para-*
17 *graph (2), under the program under this*
18 *part the Secretary shall be treated as hav-*
19 *ing in effect an agreement with a group*
20 *health plan or health insurance issuer of-*
21 *fering health insurance coverage (as such*
22 *terms are defined in section 2791 of the*
23 *Public Health Service Act), with respect to*
24 *a price applicability period and a selected*
25 *drug with respect to such period—*

1 “(A) *with respect to such selected*
2 *drug furnished or dispensed at a*
3 *pharmacy or by mail order service if*
4 *coverage is provided under such plan*
5 *or coverage during such period for*
6 *such selected drug as so furnished or*
7 *dispensed; and*

8 “(B) *with respect to such selected*
9 *drug furnished or administered by a*
10 *hospital, physician, or other provider*
11 *of services or supplier if coverage is*
12 *provided under such plan or coverage*
13 *during such period for such selected*
14 *drug as so furnished or administered.*

15 “(2) *OPTING OUT OF AGREEMENT.—The*
16 *Secretary shall not be treated as having*
17 *in effect an agreement under the program*
18 *under this part with a group health plan*
19 *or health insurance issuer offering health*
20 *insurance coverage with respect to a price*
21 *applicability period and a selected drug*
22 *with respect to such period if such a plan*
23 *or issuer affirmatively elects, through a*
24 *process specified by the Secretary, not to*

1 *participate under the program with re-*
2 *spect to such period and drug.*

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

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

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

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

6 “(2) to a hospital, physician, or other
7 provider of services or supplier with re-
8 spect to fair price eligible individuals who
9 with respect to such drug is described in
10 subparagraph (B) of such section and is
11 furnished or administered such drug by
12 such hospital, physician, or provider or
13 supplier during such year;

14 shall be subject to a civil monetary penalty
15 equal to ten times the amount equal to the dif-
16 ference between the price for such drug made
17 available for such year by such manufacturer
18 with respect to such individual or hospital,
19 physician, provider, or supplier and the max-
20 imum fair price for such drug for such year.

21 “(b) VIOLATIONS OF CERTAIN TERMS OF
22 AGREEMENT.—Any manufacturer of a selected
23 drug that has entered into an agreement
24 under section 1193, with respect to a plan year
25 during the price applicability period for such

1 *drug, that is in violation of a requirement im-*
2 *posed pursuant to section 1193(a)(6) shall be*
3 *subject to a civil monetary penalty of not more*
4 *than \$1,000,000 for each such violation.*

5 “(c) *APPLICATION.—The provisions of sec-*
6 *tion 1128A (other than subsections (a) and (b))*
7 *shall apply to a civil monetary penalty under*
8 *this section in the same manner as such provi-*
9 *sions apply to a penalty or proceeding under*
10 *section 1128A(a).*

11 “SEC. 1199. MISCELLANEOUS PROVISIONS.

12 “(a) *PAPERWORK REDUCTION ACT.—Chapter*
13 *35 of title 44, United States Code, shall not*
14 *apply to data collected under this part.*

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

23 “(c) *MEDPAC STUDY.—Not later than De-*
24 *cember 31, 2025, the Medicare Payment Advi-*
25 *sory Commission shall conduct a study, and*

1 *submit to Congress a report, on the program*
2 *under this part with respect to the Medicare*
3 *program under title XVIII, including with re-*
4 *spect to the effect of the program on individ-*
5 *uals entitled to benefits or enrolled under such*
6 *title.*

7 *“(d) LIMITATION ON JUDICIAL REVIEW.—The*
8 *following shall not be subject to judicial re-*
9 *view:*

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

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

15 *“(3) The determination of the max-*
16 *imum fair price of a selected drug under*
17 *section 1194.*

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

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

1 *ices shall coordinate with such respective Sec-*
2 *retary.*

3 *“(f) DATA SHARING.—The Secretary shall*
4 *share with the Secretary of the Treasury such*
5 *information as is necessary to determine the*
6 *tax imposed by section 4192 of the Internal*
7 *Revenue Code of 1986.*

8 *“(g) GAO STUDY.—Not later than December*
9 *31, 2025, the Comptroller General of the United*
10 *States shall conduct a study of, and submit to*
11 *Congress a report on, the implementation of*
12 *the Fair Price Negotiation Program under this*
13 *part.*

14 *“(h) INFLATION REBATE FOR GROUP HEALTH*
15 *PLANS.—*

16 *“(1) IN GENERAL.—Not later than De-*
17 *cember 31, 2021, the Secretary of Labor*
18 *shall, in consultation with the Secretary*
19 *of Health and Human Services and the*
20 *Secretary of the Treasury, submit to Con-*
21 *gress a report on the feasibility of the Sec-*
22 *retary of Labor—*

23 *“(A) establishing an agreement*
24 *process with manufacturers of pre-*
25 *scription drugs under which manu-*

1 *facturers provide for inflation rebates*
2 *(in a manner similar to rebates under*
3 *section 1834(x) and 1860D–14B with*
4 *respect to part B and part D drugs, re-*
5 *spectively) with respect to drugs that*
6 *are furnished or dispensed to partici-*
7 *pants, enrollees, and beneficiaries of*
8 *health insurance coverage in connec-*
9 *tion with a group health plan; and*

10 *“(B) establishing an enforcement*
11 *mechanism with respect to such agree-*
12 *ment process that ensures that such*
13 *inflation rebates are, proportionally*
14 *distributed, with respect to costs, to—*

15 *“(i) participants, enrollees,*
16 *and beneficiaries of health insur-*
17 *ance coverage offered in the group*
18 *market; and*

19 *“(ii) a health insurance issuer*
20 *offering health insurance cov-*
21 *erage in the group market.*

22 *“(2) REGULATIONS.—Not later than De-*
23 *cember 31, 2022, the Secretary of Labor*
24 *shall, in consultation with the Secretary*
25 *of Health and Human Services and the*

1 *Secretary of the Treasury, promulgate reg-*
2 *ulations consistent with the information*
3 *contained in the report submitted pursu-*
4 *ant to paragraph (1) if—*

5 *“(A) the Secretary of Labor deter-*
6 *mines the prices of a sufficient num-*
7 *ber (as determined by the Secretary of*
8 *Labor) of drugs described in para-*
9 *graph (1)(A) have increased at a per-*
10 *centage that exceeds the percentage by*
11 *which the consumer price index for*
12 *all urban consumers (United States*
13 *city average) for a period of time (as*
14 *determined by the Secretary of Labor);*
15 *and*

16 *“(B) the Secretary of Labor finds*
17 *that the agreement process identified*
18 *pursuant to subparagraph (A) of*
19 *paragraph (1) and the enforcement*
20 *mechanism identified pursuant to*
21 *subparagraph (B) of such paragraph*
22 *are feasible.”.*

23 **(b) APPLICATION OF MAXIMUM FAIR PRICES**
24 **AND CONFORMING AMENDMENTS.—**

1 **(1) UNDER MEDICARE PRESCRIPTION**
2 **DRUG PROGRAM.—**

3 **(A) EXCEPTION TO NON-INTER-**
4 **ERENCE.—Section 1860D–11(i) of the**
5 **Social Security Act (42 U.S.C. 1395w–**
6 **111(i)) is amended by inserting “, ex-**
7 **cept as provided under part E of title**
8 **XI,” after “the Secretary”.**

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

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

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

19 **“(D) APPLICATION OF MAXIMUM FAIR**
20 **PRICE FOR SELECTED DRUGS.—In apply-**
21 **ing this section, in the case of a cov-**
22 **ered part D drug that is a selected**
23 **drug (as defined in section 1192(c)),**
24 **with respect to a price applicability**
25 **period (as defined in section**

1 ***1191(b)(2)), the negotiated price de-***
2 ***scribed in this subsection shall be the***
3 ***maximum fair price (as defined in***
4 ***section 1191(c)(2)) for such drug and***
5 ***for each plan year during such pe-***
6 ***riod.”.***

7 ***(C) INFORMATION FROM PRESCRIP-***
8 ***TION DRUG PLANS AND MA-PD PLANS RE-***
9 ***QUIRED.—***

10 ***(i) PRESCRIPTION DRUG***
11 ***PLANS.—Section 1860D-12(b) of the***
12 ***Social Security Act (42 U.S.C.***
13 ***1395w-112(b)) is amended by add-***
14 ***ing at the end the following new***
15 ***paragraph:***

16 ***“(8) PROVISION OF INFORMATION RE-***
17 ***LATED TO MAXIMUM FAIR PRICES.—Each con-***
18 ***tract entered into with a PDP sponsor***
19 ***under this part with respect to a prescrip-***
20 ***tion drug plan offered by such sponsor***
21 ***shall require the sponsor to provide infor-***
22 ***mation to the Secretary as requested by***
23 ***the Secretary in accordance with section***
24 ***1196(b).”.***

1 (ii) **MA-PD PLANS.**—Section
2 **1857(f)(3) of the Social Security**
3 **Act (42 U.S.C. 1395w-27(f)(3)) is**
4 **amended by adding at the end the**
5 **following new subparagraph:**

6 **“(E) PROVISION OF INFORMATION RE-**
7 **LATED TO MAXIMUM FAIR PRICES.—Sec-**
8 **tion 1860D-12(b)(8).”.**

9 **(2) UNDER GROUP HEALTH PLANS AND**
10 **HEALTH INSURANCE COVERAGE.—**

11 **(A) PHSA.**—Part A of title XXVII
12 **of the Public Health Service Act is**
13 **amended by inserting after section**
14 **2729 the following new section:**

15 **“SEC. 2729A. FAIR PRICE DRUG NEGOTIATION PROGRAM**
16 **AND APPLICATION OF MAXIMUM FAIR**
17 **PRICES.**

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

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

6 “(1) *the provisions of such part shall*
7 *apply to the plans or coverage offered by*
8 *such plan or issuer, and to the individ-*
9 *uals enrolled under such plans or cov-*
10 *erage, during such period, with respect to*
11 *such selected drug, in the same manner as*
12 *such provisions apply to prescription drug*
13 *plans and MA-PD plans, and to individ-*
14 *uals enrolled under such prescription*
15 *drug plans and MA-PD plans;*

16 “(2) *the plan or issuer shall apply any*
17 *cost-sharing responsibilities under such*
18 *plan or coverage, with respect to such se-*
19 *lected drug, by substituting the maximum*
20 *fair price negotiated under such part for*
21 *such drug in lieu of the contracted rate*
22 *under such plan or coverage for such se-*
23 *lected drug; and*

24 “(3) *the Secretary shall apply the pro-*
25 *visions of such part to such plan, issuer,*

1 *and coverage, and such individuals so en-*
2 *rolled in such plans.*

3 **“(b) NOTIFICATION REGARDING NONPARTICI-**
4 **PATION IN FAIR DRUG PRICE NEGOTIATION PRO-**
5 **GRAM.—A group health plan or a health insur-**
6 **ance issuer offering group or individual**
7 **health insurance coverage shall publicly dis-**
8 **close in a manner and in accordance with a**
9 **process specified by the Secretary any election**
10 **made under section 1197 of the Social Security**
11 **Act by the plan or issuer to not participate in**
12 **the Fair Drug Price Negotiation Program**
13 **under part E of title XI of such Act with re-**
14 **spect to a selected drug (as defined in section**
15 **1192(c) of such Act) for which coverage is pro-**
16 **vided under such plan or coverage before the**
17 **beginning of the plan year for which such elec-**
18 **tion was made.”.**

19 **(B) ERISA.—**

20 **(i) IN GENERAL.—Subpart B of**
21 **part 7 of subtitle B of title I of the**
22 **Employee Retirement Income Se-**
23 **curity Act of 1974 (29 U.S.C. 1181**
24 **et. seq.) is amended by adding at**
25 **the end the following new section:**

1 **“SEC. 716. FAIR PRICE DRUG NEGOTIATION PROGRAM AND**
2 **APPLICATION OF MAXIMUM FAIR PRICES.**

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

16 **“(1) the provisions of such part shall**
17 **apply, as applicable—**

18 **“(A) if coverage of such selected**
19 **drug is provided under such plan or**
20 **coverage if the drug is furnished or**
21 **dispensed at a pharmacy or by a mail**
22 **order service, to the plans or coverage**
23 **offered by such plan or issuer, and to**
24 **the individuals enrolled under such**
25 **plans or coverage, during such period,**
26 **with respect to such selected drug, in**

1 *the same manner as such provisions*
2 *apply to prescription drug plans and*
3 *MA–PD plans, and to individuals en-*
4 *rolled under such prescription drug*
5 *plans and MA–PD plans during such*
6 *period; and*

7 *“(B) if coverage of such selected*
8 *drug is provided under such plan or*
9 *coverage if the drug is furnished or*
10 *administered by a hospital, physician,*
11 *or other provider of services or sup-*
12 *plier, to the plans or coverage offered*
13 *by such plan or issuers, to the individ-*
14 *uals enrolled under such plans or cov-*
15 *erage, and to hospitals, physicians,*
16 *and other providers of services and*
17 *suppliers during such period, with re-*
18 *spect to such drug in the same man-*
19 *ner as such provisions apply to the*
20 *Secretary, to individuals entitled to*
21 *benefits under part A of title XVIII or*
22 *enrolled under part B of such title,*
23 *and to hospitals, physicians, and*
24 *other providers and suppliers partici-*

1 *pating under title XVIII during such*
2 *period;*

3 “(2) *the plan or issuer shall apply any*
4 *cost-sharing responsibilities under such*
5 *plan or coverage, with respect to such se-*
6 *lected drug, by substituting an amount*
7 *not more than the maximum fair price ne-*
8 *gotiated under such part E of title XI for*
9 *such drug in lieu of the drug price upon*
10 *which the cost-sharing would have other-*
11 *wise applied, and such cost-sharing re-*
12 *sponsibilities with respect to such selected*
13 *drug may not exceed such amount; and*

14 “(3) *the Secretary shall apply the pro-*
15 *visions of such part E to such plan, issuer,*
16 *and coverage, and such individuals so en-*
17 *rolled in such plans.*

18 “(b) **NOTIFICATION REGARDING NONPARTICI-**
19 **PATION IN FAIR DRUG PRICE NEGOTIATION PRO-**
20 **GRAM.**—*A group health plan or a health insur-*
21 *ance issuer offering group health insurance*
22 *coverage shall publicly disclose in a manner*
23 *and in accordance with a process specified by*
24 *the Secretary any election made under section*
25 *1197 of the Social Security Act by the plan or*

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

8 (ii) *APPLICATION TO RETIREE*
9 *AND CERTAIN SMALL GROUP HEALTH*
10 *PLANS.—Section 732(a) of the Em-*
11 *ployee Retirement Income Security*
12 *Act of 1974 (29 U.S.C. 1191a(a)) is*
13 *amended by striking “section 711”*
14 *and inserting “sections 711 and*
15 *716”.*

16 (iii) *CLERICAL AMENDMENT.—*
17 *The table of sections for subpart B*
18 *of part 7 of subtitle B of title I of*
19 *the Employee Retirement Income*
20 *Security Act of 1974 is amended by*
21 *adding at the end the following:*

“Sec. 716. Fair Price Drug Negotiation Program and applica-
 tion of maximum fair prices.”.

22 (C) *IRC.—*

23 (i) *IN GENERAL.—Subchapter B*
24 *of chapter 100 of the Internal Rev-*

1 *enue Code of 1986 is amended by*
2 *adding at the end the following*
3 *new section:*

4 *“SEC. 9816. FAIR PRICE DRUG NEGOTIATION PROGRAM AND*
5 *APPLICATION OF MAXIMUM FAIR PRICES.*

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

17 *“(1) the provisions of such part shall*
18 *apply to the plans offered by such plan,*
19 *and to the individuals enrolled under*
20 *such plans, during such period, with re-*
21 *spect to such selected drug, in the same*
22 *manner as such provisions apply to pre-*
23 *scription drug plans and MA–PD plans,*
24 *and to individuals enrolled under such*

1 *prescription drug plans and MA-PD*
2 *plans;*

3 *“(2) the plan shall apply any cost-*
4 *sharing responsibilities under such plan,*
5 *with respect to such selected drug, by sub-*
6 *stituting the maximum fair price nego-*
7 *tiated under such part for such drug in*
8 *lieu of the contracted rate under such*
9 *plan for such selected drug; and*

10 *“(3) the Secretary shall apply the pro-*
11 *visions of such part to such plan and such*
12 *individuals so enrolled in such plan.*

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

1 (ii) **CLERICAL AMENDMENT.—**
2 *The table of sections for sub-*
3 *chapter B of chapter 100 of such*
4 *Code is amended by adding at the*
5 *end the following new item:*

“Sec. 9816. Fair Price Drug Negotiation Program and applica-
 tion of maximum fair prices.”.

6 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX IM-**
7 **POSED DURING NONCOMPLIANCE PERIODS.**

8 **(a) IN GENERAL.—***Subchapter E of chapter*
9 **32 of the Internal Revenue Code of 1986 is**
10 *amended by adding at the end the following*
11 *new section:*

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

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

20 **“(1) such tax, divided by**

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

23 **“(b) NONCOMPLIANCE PERIODS.—***A day is*
24 *described in this subsection with respect to a*

1 *selected drug if it is a day during one of the*
2 *following periods:*

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

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

17 “(3) *In the case of a selected drug with*
18 *respect to which the Secretary of Health*
19 *and Human Services has specified a re-*
20 *negotiation period under such agreement,*
21 *the period beginning on the first date*
22 *after the last date of such renegotiation*
23 *period and ending on the first date dur-*
24 *ing which the manufacturer of the drug*

1 *has agreed to a renegotiated maximum*
2 *fair price under such agreement.*

3 “(4) *With respect to information that*
4 *is required to be submitted to the Sec-*
5 *retary of Health and Human Services*
6 *under such agreement, the period begin-*
7 *ning on the date on which such Secretary*
8 *certifies that such information is overdue*
9 *and ending on the date that such infor-*
10 *mation is so submitted.*

11 “(5) *In the case of a selected drug with*
12 *respect to which a payment is due under*
13 *subsection (c) of such section 1193, the pe-*
14 *riod beginning on the date on which the*
15 *Secretary of Health and Human Services*
16 *certifies that such payment is overdue and*
17 *ending on the date that such payment is*
18 *made in full.*

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

21 “(1) *in the case of sales of a selected*
22 *drug during the first 90 days described in*
23 *subsection (b) with respect to such drug,*
24 *65 percent,*

1 “(2) *in the case of sales of such drug*
2 *during the 91st day through the 180th day*
3 *described in subsection (b) with respect to*
4 *such drug, 75 percent,*

5 “(3) *in the case of sales of such drug*
6 *during the 181st day through the 270th*
7 *day described in subsection (b) with re-*
8 *spect to such drug, 85 percent, and*

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

11 “(d) *DEFINITIONS.—The terms ‘selected*
12 *drug publication date’ and ‘maximum fair*
13 *price’ have the meaning given such terms in*
14 *section 1191 of the Social Security Act and the*
15 *term ‘selected drug’ has the meaning given*
16 *such term in section 1192 of such Act.*

17 “(e) *ANTI-ABUSE RULE.—In the case of a*
18 *sale which was timed for the purpose of avoid-*
19 *ing the tax imposed by this section, the Sec-*
20 *retary may treat such sale as occurring during*
21 *a day described in subsection (b).”.*

22 “(b) *NO DEDUCTION FOR EXCISE TAX PAY-*
23 *MENTS.—Section 275 of the Internal Revenue*
24 *Code of 1986 is amended by adding “or by sec-*

1 *tion 4192” before the period at the end of sub-*
2 *section (a)(6).*

3 **(c) CONFORMING AMENDMENTS.—**

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

7 **(2) Section 6416(b)(2) of such Code is**
8 **amended by inserting “or 4192” after “sec-**
9 **tion 4191”.**

10 **(d) CLERICAL AMENDMENTS.—**

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

16 **(2) The table of subchapters for chap-**
17 **ter 32 of such Code is amended by striking**
18 **the item relating to subchapter E and in-**
19 **serting the following new item:**

“SUBCHAPTER E. OTHER MEDICAL PRODUCTS”.

20 **(3) The table of sections for sub-**
21 **chapter E of chapter 32 of such Code is**
22 **amended by adding at the end the fol-**
23 **lowing new item:**

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

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

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

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

8 (a) *IN GENERAL.*—*Section 1834 of the Social*
 9 *Security Act (42 U.S.C. 1395m) is amended by*
 10 *adding at the end the following new sub-*
 11 *section:*

12 “(x) *REBATE BY MANUFACTURERS FOR SINGLE*
 13 *SOURCE DRUGS WITH PRICES INCREASING FAST-*
 14 *ER THAN INFLATION.*—

15 “(1) *REQUIREMENTS.*—

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

1 “(i) *Information on the total*
2 *number of billing units described*
3 *in subparagraph (A)(i) of para-*
4 *graph (3) with respect to such*
5 *drug and calendar quarter.*

6 “(ii) *Information on the*
7 *amount (if any) of the excess aver-*
8 *age sales price increase described*
9 *in subparagraph (A)(ii) of such*
10 *paragraph for such drug and cal-*
11 *endar quarter.*

12 “(iii) *The rebate amount speci-*
13 *fied under such paragraph for*
14 *such part B rebatable drug and*
15 *calendar quarter.*

16 “(B) **MANUFACTURER REQUIRE-**
17 **MENT.—***For each calendar quarter be-*
18 *ginning on or after July 1, 2021, the*
19 *manufacturer of a part B rebatable*
20 *drug shall, for such drug, not later*
21 *than 30 days after the date of receipt*
22 *from the Secretary of the information*
23 *described in subparagraph (A) for*
24 *such calendar quarter, provide to the*
25 *Secretary a rebate that is equal to the*

1 *amount specified in paragraph (3) for*
2 *such drug for such calendar quarter.*

3 **“(2) PART B REBATABLE DRUG DE-**
4 **FINED.—**

5 **“(A) IN GENERAL.—***In this sub-*
6 *section, the term ‘part B rebatable*
7 *drug’ means a single source drug or*
8 *biological (as defined in subpara-*
9 *graph (D) of section 1847A(c)(6)), in-*
10 *cluding a biosimilar biological prod-*
11 *uct (as defined in subparagraph (H)*
12 *of such section), paid for under this*
13 *part, except such term shall not in-*
14 *clude such a drug or biological—*

15 **“(i) if the average total al-**
16 **lowed charges for a year per indi-**
17 **vidual that uses such a drug or bi-**
18 **ological, as determined by the Sec-**
19 **retary, are less than, subject to**
20 **subparagraph (B), \$100; or**

21 **“(ii) that is a vaccine de-**
22 **scribed in subparagraph (A) or**
23 **(B) of section 1861(s)(10).**

1 “(B) *INCREASE.—The dollar*
2 *amount applied under subparagraph*
3 *(A)(i)—*

4 “(i) *for 2022, shall be the dol-*
5 *lar amount specified under such*
6 *subparagraph for 2021, increased*
7 *by the percentage increase in the*
8 *consumer price index for all*
9 *urban consumers (United States*
10 *city average) as of the first quar-*
11 *ter of the previous year; and*

12 “(ii) *for a subsequent year,*
13 *shall be the dollar amount speci-*
14 *fied in this clause (or clause (i))*
15 *for the previous year, increased by*
16 *the percentage increase in the*
17 *consumer price index for all*
18 *urban consumers (United States*
19 *city average) as of the first quar-*
20 *ter of the previous year.*

21 *Any dollar amount specified under*
22 *this subparagraph that is not a mul-*
23 *tiple of \$10 shall be rounded to the*
24 *nearest multiple of \$10.*

25 “(3) *REBATE AMOUNT.—*

1 “(A) *IN GENERAL.*—*For purposes of*
2 *paragraph (1)(B), the amount speci-*
3 *fied in this paragraph for a part B*
4 *rebatable drug assigned to a billing*
5 *and payment code for a calendar*
6 *quarter is, subject to paragraph (4),*
7 *the amount equal to the product of—*

8 “(i) *subject to subparagraph*
9 *(B), the total number of billing*
10 *units, as described in section*
11 *1847A(b)(6)(B), for such part B*
12 *rebatable drug furnished under*
13 *this part during the calendar*
14 *quarter; and*

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

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

23 “(II) *the inflation-adjusted*
24 *payment amount determined*
25 *under subparagraph (C) for*

1 *such part B rebatable drug*
2 *during the calendar quarter.*

3 **“(B) EXCLUDED UNITS.—***For pur-*
4 *poses of subparagraph (A)(i), the total*
5 *number of billing units for part B*
6 *rebatable drugs furnished during a*
7 *calendar quarter shall not include—*

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

14 *“(ii) units included under the*
15 *single payment system for renal*
16 *dialysis services under section*
17 *1881(b)(14); or*

18 *“(iii) units of a part B*
19 *rebatable drug of a manufacturer*
20 *that is furnished to an individual,*
21 *if such manufacturer, with respect*
22 *to the furnishing of such units of*
23 *such drug, provides for discounts*
24 *under section 340B of the Public*

1 *Health Service Act or for rebates*
2 *under section 1927.*

3 **“(C) DETERMINATION OF INFLATION-**
4 **ADJUSTED PAYMENT AMOUNT.—***The in-*
5 *flation-adjusted payment amount de-*
6 *termined under this subparagraph for*
7 *a part B rebatable drug for a cal-*
8 *endar quarter is—*

9 *“(i) the payment amount for*
10 *the billing and payment code for*
11 *such drug in the payment amount*
12 *benchmark quarter (as defined in*
13 *subparagraph (D)); increased by*

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

20 **“(D) PAYMENT AMOUNT BENCHMARK**
21 **QUARTER.—***The term ‘payment amount*
22 *benchmark quarter’ means the cal-*
23 *endar quarter beginning January 1,*
24 *2016.*

1 “(E) **BENCHMARK PERIOD CPI-U.—**
2 *The term ‘benchmark period CPI-U’*
3 *means the consumer price index for*
4 *all urban consumers (United States*
5 *city average) for July 2015.*

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

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

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

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

14 **“(B) TIMELINE FOR PROVISION OF**
15 **REBATES FOR NEW DRUGS.—***In the case*
16 *of a part B rebatable drug first ap-*
17 *proved by the Food and Drug Admin-*
18 *istration after July 1, 2015, clause (i)*
19 *of paragraph (1)(B) shall be applied*
20 *as if the reference to ‘July 1, 2021’*
21 *under such paragraph were a ref-*
22 *erence to the later of the 6th full cal-*
23 *endar quarter after the day on which*
24 *the drug was first marketed or July 1,*
25 *2021.*

1 “(C) *EXEMPTION FOR SHORTAGES.*—

2 *The Secretary may reduce or waive*
3 *the rebate under paragraph (1)(B)*
4 *with respect to a part B rebatable*
5 *drug that appears on the drug short-*
6 *age list in effect under section 506(e)*
7 *of the Federal Food, Drug, and Cos-*
8 *metic Act or in the case of other exi-*
9 *gent circumstances, as determined by*
10 *the Secretary.*

11 “(D) *SELECTED DRUGS.*—*In the case*

12 *of a part B rebatable drug that is a*
13 *selected drug (as defined in section*
14 *1192(c)), for each applicable year be-*
15 *ginning after the price applicability*
16 *period (as defined in section*
17 *1191(b)(2) with respect to such drug,*
18 *clause (i) of paragraph (3)(C) shall be*
19 *applied as if the term ‘payment*
20 *amount benchmark quarter’ were de-*
21 *finied under paragraph (3)(D) as the*
22 *calendar quarter beginning January*
23 *1 of the last year beginning during*
24 *such price applicability period with*
25 *respect to such selected drug and*

1 *clause (ii) of paragraph (3)(C) shall*
2 *be applied as if the term ‘benchmark*
3 *period CPI-U’ were defined under*
4 *paragraph (3)(E) as if the reference to*
5 *‘July 2015’ under such paragraph*
6 *were a reference to the July of the*
7 *year preceding such last year.*

8 *“(5) APPLICATION TO BENEFICIARY COIN-*
9 *SURANCE.—In the case of a part B*
10 *rebtable drug for which a rebate is pay-*
11 *able under this subsection—*

12 *“(A) in computing the amount of*
13 *any coinsurance applicable under this*
14 *title to an individual with respect to*
15 *such drug, the computation of such*
16 *coinsurance shall be based on the in-*
17 *flation-adjusted payment amount de-*
18 *termined under paragraph (3)(C) for*
19 *such part B rebtable drug; and*

20 *“(B) the amount of such coinsur-*
21 *ance is equal to 20 percent of such in-*
22 *flation-adjusted payment amount so*
23 *determined.*

24 *“(6) REBATE DEPOSITS.—Amounts paid*
25 *as rebates under paragraph (1)(B) shall*

1 *be deposited into the Federal Supple-*
2 *mentary Medical Insurance Trust Fund*
3 *established under section 1841.*

4 *“(7) CIVIL MONEY PENALTY.—If a manu-*
5 *facturer of a part B rebatable drug has*
6 *failed to comply with the requirements*
7 *under paragraph (1)(B) for such drug for*
8 *a calendar quarter, the manufacturer*
9 *shall be subject to, in accordance with a*
10 *process established by the Secretary pur-*
11 *suant to regulations, a civil money pen-*
12 *alty in an amount equal to at least 125*
13 *percent of the amount specified in para-*
14 *graph (3) for such drug for such calendar*
15 *quarter. The provisions of section 1128A*
16 *(other than subsections (a) (with respect*
17 *to amounts of penalties or additional as-*
18 *sessments) and (b)) shall apply to a civil*
19 *money penalty under this paragraph in*
20 *the same manner as such provisions apply*
21 *to a penalty or proceeding under section*
22 *1128A(a).*

23 *“(8) STUDY AND REPORT.—*

24 *“(A) STUDY.—The Secretary shall*
25 *conduct a study of the feasibility of*

1 *and operational issues involved with*
2 *the following:*

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

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

11 “(iii) *Including drugs ex-*
12 *cluded under paragraph (2)(A)*
13 *and billing units of drugs ex-*
14 *cluded under paragraph (3)(B) in*
15 *the rebate system under this sub-*
16 *section.*

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

23 “(9) *APPLICATION TO MULTIPLE SOURCE*
24 *DRUGS.—The Secretary may, based on the*
25 *report submitted under paragraph (8)*

1 *and pursuant to rulemaking, apply the*
2 *provisions of this subsection to multiple*
3 *source drugs (as defined in section*
4 *1847A(c)(6)(C)), including, for purposes of*
5 *determining the rebate amount under*
6 *paragraph (3), by calculating manufac-*
7 *turer-specific average sales prices for the*
8 *benchmark period and the rebate pe-*
9 *riod.”.*

10 *(b) AMOUNTS PAYABLE; COST-SHARING.—Sec-*
11 *tion 1833(a) of the Social Security Act is*
12 *amended—*

13 *(1) in paragraph (1)—*

14 *(A) in subparagraph (S), by strik-*
15 *ing “with respect to” and inserting*
16 *“subject to subparagraph (DD), with*
17 *respect to”;*

18 *(B) by striking “and (CC)” and in-*
19 *serting “(CC)”;* and

20 *(C) by inserting before the semi-*
21 *colon at the end the following: “, and*
22 *(DD) with respect to a part B*
23 *rebatable drug (as defined in para-*
24 *graph (2) of section 1834(x)) for which*
25 *a rebate is payable under such sec-*

1 *tion, the amounts paid shall be the*
2 *difference between (i) the payment*
3 *amount under paragraph (3)(A)(i)(I)*
4 *of such section for such drug, and (ii)*
5 *20 percent of the inflation-adjusted*
6 *payment amount under paragraph*
7 *(3)(A)(i)(II) of such section for such*
8 *drug”; and*

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

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

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

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

22 *Part D of title XVIII of the Social Security*
23 *Act is amended by inserting after section*
24 *1860D–14A (42 U.S.C. 1395w–114a) the fol-*
25 *lowing new section:*

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

4 **“(a) IN GENERAL.—Subject to the provisions**
5 **of this section, in order for coverage to be**
6 **available under this part for a part D**
7 **rebtable drug of a manufacturer dispensed**
8 **during an applicable year, the manufacturer**
9 **must have entered into and have in effect an**
10 **agreement described in subsection (b). For**
11 **purposes of this section the term ‘applicable**
12 **year’ means a year beginning with 2022.**

13 **“(b) AGREEMENTS.—**

14 **“(1) TERMS OF AGREEMENT.—An agree-**
15 **ment described in this subsection, with re-**
16 **spect to a manufacturer of a part D**
17 **rebtable drug, is an agreement under**
18 **which the following applies:**

19 **“(A) SECRETARIAL PROVISION OF IN-**
20 **FORMATION.—Not later than 9 months**
21 **after the end of each applicable year**
22 **with respect to which the agreement is**
23 **in effect, the Secretary, for the part D**
24 **rebtable drug of the manufacturer,**
25 **reports to the manufacturer the fol-**
26 **lowing for such year:**

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

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

14 “(iii) *The rebate amount speci-*
15 *fied under subsection (c) for each*
16 *dosage form and strength with re-*
17 *spect to such drug and year.*

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

1 *the information described in subpara-*
2 *graph (A) for such year, provides to*
3 *the Secretary a rebate that is equal to*
4 *the amount specified in subsection (c)*
5 *for such dosage form and strength*
6 *with respect to such drug for such*
7 *year.*

8 **“(2) LENGTH OF AGREEMENT.—**

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

17 **“(B) TERMINATION.—**

18 **“(i) BY SECRETARY.—***The Sec-*
19 *retary may provide for termi-*
20 *nation of an agreement under this*
21 *section for violation of the re-*
22 *quirements of the agreement or*
23 *other good cause shown. Such ter-*
24 *mination shall not be effective*
25 *earlier than 60 days after the date*

1 *of notice of such termination. The*
2 *Secretary shall provide, upon re-*
3 *quest, a manufacturer with a*
4 *hearing concerning such a termi-*
5 *nation, but such hearing shall not*
6 *delay the effective date of the ter-*
7 *mination.*

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

16 “(C) *EFFECTIVENESS OF TERMI-*
17 *NATION.—Any termination under this*
18 *paragraph shall not affect rebates*
19 *due under the agreement under this*
20 *section before the effective date of its*
21 *termination.*

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

1 *such agreement with the manufac-*
2 *turer (or a successor manufacturer)*
3 *may not be entered into before the sub-*
4 *sequent plan year, unless the Sec-*
5 *retary finds good cause for an earlier*
6 *reinstatement of such an agreement.*

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

11 **“(c) REBATE AMOUNT.—**

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

19 **“(A) the total average number of**
20 *units weighted by, and dispensed for,*
21 *such dosage form and strength with*
22 *respect to such part D rebatable drug*
23 *and year; and*

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

1 “(i) *the average manufacturer*
2 *price (as defined in subsection (g))*
3 *paid for such dosage form and*
4 *strength with respect to such part*
5 *D rebatable drug during the year;*
6 *exceeds*

7 “(ii) *the inflation-adjusted*
8 *payment amount determined*
9 *under paragraph (2) for such dos-*
10 *age form and strength with re-*
11 *spect to such part D rebatable*
12 *drug during the year.*

13 “(2) *DETERMINATION OF INFLATION-AD-*
14 *JUSTED PAYMENT AMOUNT.—The inflation-*
15 *adjusted payment amount determined*
16 *under this paragraph for a dosage form*
17 *and strength with respect to a part D*
18 *rebatable drug for an applicable year,*
19 *subject to subparagraphs (A) and (D) of*
20 *paragraph (3), is—*

21 “(A) *the average manufacturer*
22 *price paid for such dosage form and*
23 *strength with respect to such drug in*
24 *the payment amount benchmark year*

1 *(as defined in subsection (g)(3)); in-*
2 *creased by*

3 *“(B) the percentage by which the*
4 *rebate period CPI-U (as defined in*
5 *subsection (g)(5)) for the applicable*
6 *year exceeds the benchmark period*
7 *CPI-U (as defined in subsection*
8 *(g)(4)).*

9 **“(3) SPECIAL TREATMENT OF CERTAIN**
10 **DRUGS AND EXEMPTION.—**

11 **“(A) SUBSEQUENTLY APPROVED**
12 **DRUGS.—***In the case of a part D*
13 *rebatable drug first approved by the*
14 *Food and Drug Administration after*
15 *January 1, 2016, subparagraph (A) of*
16 *paragraph (2) shall be applied as if*
17 *the term ‘payment amount benchmark*
18 *year’ were defined under subsection*
19 *(g)(3) as the first year beginning after*
20 *the day on which the drug was first*
21 *marketed and subparagraph (B) of*
22 *paragraph (2) shall be applied as if*
23 *the term ‘benchmark period CPI-U’*
24 *were defined under subsection (g)(4)*
25 *as if the reference to ‘January 2016’*

1 *under such subsection were a ref-*
2 *erence to ‘January of the first year be-*
3 *ginning after the date on which the*
4 *drug was first marketed by any manu-*
5 *facturer’.*

6 “(B) *EXEMPTION FOR SHORTAGES.—*
7 *The Secretary may reduce or waive*
8 *the rebate under paragraph (1) with*
9 *respect to a part D rebatable drug in*
10 *the case of a shortage of such drug or*
11 *other exigent circumstances, as deter-*
12 *mined by the Secretary.*

13 “(C) *TREATMENT OF NEW FORMULA-*
14 *TIONS.—*

15 “(i) *IN GENERAL.—In the case of*
16 *a part D rebatable drug that is a*
17 *line extension of a single source*
18 *drug or an innovator multiple*
19 *source drug that is an oral solid*
20 *dosage form, the Secretary shall*
21 *establish a formula for deter-*
22 *mining the amount specified in*
23 *this subsection with respect to*
24 *such part D rebatable drug and*
25 *an applicable year with consider-*

1 *ation of the single source drug or*
2 *an innovator multiple source*
3 *drug.*

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

18 *“(D) SELECTED DRUGS.—In the case*
19 *of a part D rebatable drug that is a*
20 *selected drug (as defined in section*
21 *1192(c)), for each applicable year be-*
22 *ginning after the price applicability*
23 *period (as defined in section*
24 *1191(b)(2) with respect to such drug,*
25 *subparagraph (A) of paragraph (2)*

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

16 “(d) **REBATE DEPOSITS.**—*Amounts paid as*
17 *rebates under subsection (c) shall be deposited*
18 *into the Medicare Prescription Drug Account*
19 *in the Federal Supplementary Medical Insur-*
20 *ance Trust Fund established under section*
21 *1841.*

22 “(e) **CIVIL MONEY PENALTY.**—*In the case of*
23 *a manufacturer of a part D rebatable drug*
24 *with an agreement in effect under this section*
25 *who has failed to comply with the terms of the*

1 *agreement under subsection (b)(1)(B) with re-*
2 *spect to such drug for an applicable year, the*
3 *Secretary may impose a civil money penalty on*
4 *such manufacturer in an amount equal to 125*
5 *percent of the amount specified in subsection*
6 *(c) for such drug for such year. The provisions*
7 *of section 1128A (other than subsections (a)*
8 *(with respect to amounts of penalties or addi-*
9 *tional assessments) and (b)) shall apply to a*
10 *civil money penalty under this subsection in*
11 *the same manner as such provisions apply to*
12 *a penalty or proceeding under section*
13 *1128A(a).*

14 *“(f) JUDICIAL REVIEW.—There shall be no*
15 *judicial review of the following:*

16 *“(1) The determination of units under*
17 *this section.*

18 *“(2) The determination of whether a*
19 *drug is a part D rebatable drug under*
20 *this section.*

21 *“(3) The calculation of the rebate*
22 *amount under this section.*

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

24 *“(1) PART D REBATABLE DRUG DE-*
25 *FINED.—*

1 “(A) *IN GENERAL.*—*The term ‘part*
2 *D rebatable drug’ means a drug or bi-*
3 *ological that would (without applica-*
4 *tion of this section) be a covered part*
5 *D drug, except such term shall, with*
6 *respect to an applicable year, not in-*
7 *clude such a drug or biological if the*
8 *average total cost under a prescrip-*
9 *tion drug plan under this part or MA-*
10 *PD plan under part C for such year*
11 *per individual who uses such a drug*
12 *or biological, as determined by the*
13 *Secretary, are less than, subject to*
14 *subparagraph (B), \$100, as deter-*
15 *mined by the Secretary using the most*
16 *recent data available or, if data is not*
17 *available, as estimated by the Sec-*
18 *retary.*

19 “(B) *INCREASE.*—*The dollar*
20 *amount applied under subparagraph*
21 *(A)—*

22 “(i) *for 2023, shall be the dol-*
23 *lar amount specified under such*
24 *subparagraph for 2022, increased*
25 *by the percentage increase in the*

1 *consumer price index for all*
2 *urban consumers (United States*
3 *city average) as of January of*
4 *2022; and*

5 “(ii) *for a subsequent year,*
6 *shall be the dollar amount speci-*
7 *fied in this subparagraph (or sub-*
8 *paragraph (A)) for the previous*
9 *year, increased by the percentage*
10 *increase in the consumer price*
11 *index for all urban consumers*
12 *(United States city average) as of*
13 *January of the previous year.*

14 *Any dollar amount specified under*
15 *this subparagraph that is not a mul-*
16 *tiple of \$10 shall be rounded to the*
17 *nearest multiple of \$10.*

18 “(2) *UNIT DEFINED.—The term ‘unit’*
19 *means, with respect to a part D rebatable*
20 *drug, the lowest identifiable quantity*
21 *(such as a capsule or tablet, milligram of*
22 *molecules, or grams) of the part D*
23 *rebatable drug that is dispensed to indi-*
24 *viduals enrolled under a prescription*

1 *drug plan under this part or an MA-PD*
2 *plan under part C.*

3 “(3) *PAYMENT AMOUNT BENCHMARK*
4 *YEAR.—The term ‘payment amount bench-*
5 *mark year’ means the year beginning Jan-*
6 *uary 1, 2016.*

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

12 “(5) *REBATE PERIOD CPI-U.—The term*
13 *‘rebate period CPI-U’ means, with respect*
14 *to an applicable year, the consumer price*
15 *index for all urban consumers (United*
16 *States city average) for January of such*
17 *year.*

18 “(6) *AVERAGE MANUFACTURER PRICE.—*
19 *The term ‘average manufacturer price’*
20 *has the meaning, with respect to a part D*
21 *rebatable drug of a manufacturer for an*
22 *applicable year, given such term in sec-*
23 *tion 1927(k)(1), with respect to a covered*
24 *outpatient drug of a manufacturer for a*
25 *rebate period under section 1927. For pur-*

1 *poses of applying the previous sentence,*
2 *with respect to a part D rebatable drug of*
3 *a manufacturer and an applicable year,*
4 *the Secretary shall use the information*
5 *with respect to the average manufacturer*
6 *price for such drug reported by the manu-*
7 *facturer under section 1927(b)(3) with re-*
8 *spect to each of the quarters in the appli-*
9 *cable year and calculate an annual aver-*
10 *age manufacturer price for such applica-*
11 *ble year as the average of such average*
12 *manufacturer prices for each such quar-*
13 *ter, weighted by units of such drug sold or*
14 *dispensed with respect to such applicable*
15 *year.”.*

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

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

21 **(a) BENEFIT STRUCTURE REDESIGN.—Sec-**
22 **tion 1860D–2(b) of the Social Security Act (42**
23 **U.S.C. 1395w–102(b)) is amended—**
24 **(1) in paragraph (2)—**

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

10 (B) *in subparagraph (C)—*

11 (i) *in clause (i), in the matter*
12 *preceding subclause (I), by insert-*
13 *ing “for a year preceding 2022,”*
14 *after “paragraph (4),”; and*

15 (ii) *in clause (ii)(III), by strik-*
16 *ing “and each subsequent year”*
17 *and inserting “and 2021”; and*

18 (C) *in subparagraph (D)—*

19 (i) *in clause (i)—*

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

24 (II) *in subclause (I)(bb), by*
25 *striking “a year after 2018”*

1 *and inserting “each of years*
2 *2018 through 2021”;* and

3 *(ii) in clause (ii)(V), by strik-*
4 *ing “2019 and each subsequent*
5 *year” and inserting “each of years*
6 *2019 through 2021”;*

7 *(2) in paragraph (3)(A)—*

8 *(A) in the matter preceding clause*
9 *(i), by inserting “for a year preceding*
10 *2022,” after “and (4),”;* and

11 *(B) in clause (ii), by striking “for*
12 *a subsequent year” and inserting “for*
13 *each of years 2007 through 2021”;* and

14 *(3) in paragraph (4)—*

15 *(A) in subparagraph (A)—*

16 *(i) in clause (i)—*

17 *(I) by redesignating sub-*
18 *clauses (I) and (II) as items*
19 *(aa) and (bb), respectively,*
20 *and moving the margin of*
21 *each such redesignated item 2*
22 *ems to the right;*

23 *(II) in the matter pre-*
24 *ceding item (aa), as redesign-*
25 *ated by subclause (I), by*

1 *striking “is equal to the great-*
2 *er of—” and inserting “is*
3 *equal to—*

4 *“(I) for a year preceding*
5 *2022, the greater of—”;*

6 *(III) by striking the period*
7 *at the end of item (bb), as re-*
8 *designated by subclause (I),*
9 *and inserting “; and”; and*

10 *(IV) by adding at the end*
11 *the following:*

12 *“(II) for 2022 and each*
13 *succeeding year, \$0.”; and*

14 *(ii) in clause (ii)—*

15 *(I) by striking “clause*
16 *(i)(I)” and inserting “clause*
17 *(i)(I)(aa)”;* and

18 *(II) by adding at the end*
19 *the following new sentence:*

20 *“The Secretary shall continue*
21 *to calculate the dollar*
22 *amounts specified in clause*
23 *(i)(I)(aa), including with the*
24 *adjustment under this clause,*

1 *after 2021 for purposes of sec-*
2 *tion 1860D–14(a)(1)(D)(iii).”;*

3 **(B) in subparagraph (B)—**

4 **(i) in clause (i)—**

5 **(I) in subclause (V), by**
6 **striking “or” at the end;**

7 **(II) in subclause (VI)—**

8 **(aa) by striking “for a**
9 **subsequent year” and in-**
10 **serting “for 2021”; and**

11 **(bb) by striking the pe-**
12 **riod at the end and insert-**
13 **ing a semicolon; and**

14 **(III) by adding at the end**
15 **the following new subclauses:**

16 **“(VII) for 2022, is equal to**
17 **\$2,000; or**

18 **“(VIII) for a subsequent**
19 **year, is equal to the amount**
20 **specified in this subparagraph**
21 **for the previous year, in-**
22 **creased by the annual percent-**
23 **age increase described in**
24 **paragraph (6) for the year in-**
25 **volved.”; and**

1 (ii) in clause (ii), by striking
2 “clause (i)(II)” and inserting
3 “clause (i)”;

4 (C) in subparagraph (C)(i), by
5 striking “and for amounts” and in-
6 serting “and, for a year preceding
7 2022, for amounts”; and

8 (D) in subparagraph (E), by strik-
9 ing “In applying” and inserting “For
10 each of years 2011 through 2021, in
11 applying”.

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

18 (c) **MANUFACTURER DISCOUNT PROGRAM.**—

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

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

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

14 **“(b) TERMS OF AGREEMENT.—**

15 **“(1) IN GENERAL.—**

16 **“(A) AGREEMENT.—An agreement**
17 **under this section shall require the**
18 **manufacturer to provide applicable**
19 **beneficiaries access to discounted**
20 **prices for applicable drugs of the**
21 **manufacturer that are dispensed on**
22 **or after January 1, 2022.**

23 **“(B) PROVISION OF DISCOUNTED**
24 **PRICES AT THE POINT-OF-SALE.—The dis-**
25 **counted prices described in subpara-**
26 **graph (A) shall be provided to the ap-**

1 *plicable beneficiary at the pharmacy*
2 *or by the mail order service at the*
3 *point-of-sale of an applicable drug.*

4 **“(C) TIMING OF AGREEMENT.—**

5 **“(i) SPECIAL RULE FOR 2022.—In**
6 ***order for an agreement with a***
7 ***manufacturer to be in effect under***
8 ***this section with respect to the pe-***
9 ***riod beginning on January 1,***
10 ***2022, and ending on December 31,***
11 ***2022, the manufacturer shall enter***
12 ***into such agreement not later***
13 ***than 30 days after the date of the***
14 ***establishment of a model agree-***
15 ***ment under subsection (a).***

16 **“(ii) 2023 AND SUBSEQUENT**
17 ***YEARS.—In order for an agreement***
18 ***with a manufacturer to be in ef-***
19 ***fect under this section with re-***
20 ***spect to plan year 2023 or a subse-***
21 ***quent plan year, the manufacturer***
22 ***shall enter into such agreement***
23 ***(or such agreement shall be re-***
24 ***newed under paragraph (4)(A))***

1 *not later than January 30 of the*
2 *preceding year.*

3 “(2) *PROVISION OF APPROPRIATE DATA.—*
4 *Each manufacturer with an agreement in*
5 *effect under this section shall collect and*
6 *have available appropriate data, as deter-*
7 *mined by the Secretary, to ensure that it*
8 *can demonstrate to the Secretary compli-*
9 *ance with the requirements under the pro-*
10 *gram.*

11 “(3) *COMPLIANCE WITH REQUIREMENTS*
12 *FOR ADMINISTRATION OF PROGRAM.—Each*
13 *manufacturer with an agreement in effect*
14 *under this section shall comply with re-*
15 *quirements imposed by the Secretary or a*
16 *third party with a contract under sub-*
17 *section (d)(3), as applicable, for purposes*
18 *of administering the program, including*
19 *any determination under subparagraph*
20 *(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*
24 *under this section shall be effective*
25 *for an initial period of not less than*

1 *12 months and shall be automatically*
2 *renewed for a period of not less than*
3 *1 year unless terminated under sub-*
4 *paragraph (B).*

5 “(B) *TERMINATION.—*

6 “(i) *BY THE SECRETARY.—The*
7 *Secretary may provide for termi-*
8 *nation of an agreement under this*
9 *section for a knowing and willful*
10 *violation of the requirements of*
11 *the agreement or other good cause*
12 *shown. Such termination shall not*
13 *be effective earlier than 30 days*
14 *after the date of notice to the man-*
15 *ufacturer of such termination. The*
16 *Secretary shall provide, upon re-*
17 *quest, a manufacturer with a*
18 *hearing concerning such a termi-*
19 *nation, and such hearing shall*
20 *take place prior to the effective*
21 *date of the termination with suffi-*
22 *cient time for such effective date*
23 *to be repealed if the Secretary de-*
24 *termines appropriate.*

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

7 “(I) *if the termination oc-*
8 *curs before January 30 of a*
9 *plan year, as of the day after*
10 *the end of the plan year; and*

11 “(II) *if the termination oc-*
12 *curs on or after January 30 of*
13 *a plan year, as of the day after*
14 *the end of the succeeding plan*
15 *year.*

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

23 “(iv) **NOTICE TO THIRD PARTY.**—
24 *The Secretary shall provide notice*
25 *of such termination to a third*

1 *party with a contract under sub-*
2 *section (d)(3) within not less than*
3 *30 days before the effective date of*
4 *such termination.*

5 **“(c) DUTIES DESCRIBED.—The duties de-**
6 **scribed in this subsection are the following:**

7 **“(1) ADMINISTRATION OF PROGRAM.—Ad-**
8 **ministering the program, including—**

9 **“(A) the determination of the**
10 **amount of the discounted price of an**
11 **applicable drug of a manufacturer;**

12 **“(B) the establishment of proce-**
13 **dures under which discounted prices**
14 **are provided to applicable bene-**
15 **ficiaries at pharmacies or by mail**
16 **order service at the point-of-sale of an**
17 **applicable drug;**

18 **“(C) the establishment of proce-**
19 **dures to ensure that, not later than**
20 **the applicable number of calendar**
21 **days after the dispensing of an appli-**
22 **cable drug by a pharmacy or mail**
23 **order service, the pharmacy or mail**
24 **order service is reimbursed for an**

1 *amount equal to the difference be-*
2 *tween—*

3 *“(i) the negotiated price of the*
4 *applicable drug; and*

5 *“(ii) the discounted price of*
6 *the applicable drug;*

7 *“(D) the establishment of proce-*
8 *dures to ensure that the discounted*
9 *price for an applicable drug under*
10 *this section is applied before any cov-*
11 *erage or financial assistance under*
12 *other health benefit plans or pro-*
13 *grams that provide coverage or finan-*
14 *cial assistance for the purchase or*
15 *provision of prescription drug cov-*
16 *erage on behalf of applicable bene-*
17 *ficiaries as the Secretary may specify;*
18 *and*

19 *“(E) providing a reasonable dis-*
20 *pute resolution mechanism to resolve*
21 *disagreements between manufactur-*
22 *ers, applicable beneficiaries, and the*
23 *third party with a contract under sub-*
24 *section (d)(3).*

25 *“(2) MONITORING COMPLIANCE.—*

1 “(A) *IN GENERAL.*—*The Secretary*
2 *shall monitor compliance by a manu-*
3 *facturer with the terms of an agree-*
4 *ment under this section.*

5 “(B) *NOTIFICATION.*—*If a third*
6 *party with a contract under sub-*
7 *section (d)(3) determines that the*
8 *manufacturer is not in compliance*
9 *with such agreement, the third party*
10 *shall notify the Secretary of such non-*
11 *compliance for appropriate enforce-*
12 *ment under subsection (e).*

13 “(3) *COLLECTION OF DATA FROM PRE-*
14 *SCRIPTION DRUG PLANS AND MA-PD PLANS.*—
15 *The Secretary may collect appropriate*
16 *data from prescription drug plans and*
17 *MA-PD plans in a timeframe that allows*
18 *for discounted prices to be provided for*
19 *applicable drugs under this section.*

20 “(d) *ADMINISTRATION.*—

21 “(1) *IN GENERAL.*—*Subject to para-*
22 *graph (2), the Secretary shall provide for*
23 *the implementation of this section, includ-*
24 *ing the performance of the duties de-*
25 *scribed in subsection (c).*

1 “(2) *LIMITATION.*—*In providing for the*
2 *implementation of this section, the Sec-*
3 *retary shall not receive or distribute any*
4 *funds of a manufacturer under the pro-*
5 *gram.*

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

14 “(A) *receive and transmit informa-*
15 *tion between the Secretary, manufac-*
16 *turers, and other individuals or enti-*
17 *ties the Secretary determines appro-*
18 *priate;*

19 “(B) *receive, distribute, or facili-*
20 *tate the distribution of funds of manu-*
21 *facturers to appropriate individuals*
22 *or entities in order to meet the obliga-*
23 *tions of manufacturers under agree-*
24 *ments under this section;*

1 “(C) *provide adequate and timely*
2 *information to manufacturers, con-*
3 *sistent with the agreement with the*
4 *manufacturer under this section, as*
5 *necessary for the manufacturer to ful-*
6 *fill its obligations under this section;*
7 *and*

8 “(D) *permit manufacturers to con-*
9 *duct periodic audits, directly or*
10 *through contracts, of the data and in-*
11 *formation used by the third party to*
12 *determine discounts for applicable*
13 *drugs of the manufacturer under the*
14 *program.*

15 “(4) *PERFORMANCE REQUIREMENTS.—*
16 *The Secretary shall establish performance*
17 *requirements for a third party with a con-*
18 *tract under paragraph (3) and safeguards*
19 *to protect the independence and integrity*
20 *of the activities carried out by the third*
21 *party under the program under this sec-*
22 *tion.*

23 “(5) *IMPLEMENTATION.—The Secretary*
24 *may implement the program under this*

1 *section by program instruction or other-*
2 *wise.*

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

6 “(e) *ENFORCEMENT.—*

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

11 “(2) *CIVIL MONEY PENALTY.—*

12 “(A) *IN GENERAL.—The Secretary*
13 *may impose a civil money penalty on a*
14 *manufacturer that fails to provide ap-*
15 *licable beneficiaries discounts for*
16 *applicable drugs of the manufacturer*
17 *in accordance with such agreement*
18 *for each such failure in an amount*
19 *the Secretary determines is commen-*
20 *surate with the sum of—*

21 “(i) *the amount that the man-*
22 *ufacturer would have paid with*
23 *respect to such discounts under*
24 *the agreement, which will then be*
25 *used to pay the discounts which*

1 *the manufacturer had failed to*
2 *provide; and*

3 “(i) 25 percent of such
4 *amount.*

5 “(B) APPLICATION.—*The provisions*
6 *of section 1128A (other than sub-*
7 *sections (a) and (b)) shall apply to a*
8 *civil money penalty under this para-*
9 *graph in the same manner as such*
10 *provisions apply to a penalty or pro-*
11 *ceeding under section 1128A(a).*

12 “(f) CLARIFICATION REGARDING AVAILABILITY
13 *OF OTHER COVERED PART D DRUGS.—Nothing in*
14 *this section shall prevent an applicable bene-*
15 *ficiary from purchasing a covered part D drug*
16 *that is not an applicable drug (including a ge-*
17 *neric drug or a drug that is not on the for-*
18 *mulary of the prescription drug plan or MA-*
19 *PD plan that the applicable beneficiary is en-*
20 *rolled in).*

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

22 “(1) APPLICABLE BENEFICIARY.—*The*
23 *term ‘applicable beneficiary’ means an in-*
24 *dividual who, on the date of dispensing a*
25 *covered part D drug—*

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

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

5 “(C) *has incurred costs for covered*
6 *part D drugs in the year that are*
7 *equal to or exceed the annual deduct-*
8 *ible specified in section 1860D–2(b)(1)*
9 *for such year.*

10 “(2) *APPLICABLE DRUG.—The term ‘ap-*
11 *plicable drug’, with respect to an applica-*
12 *ble beneficiary—*

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

15 “(i) *approved under a new*
16 *drug application under section*
17 *505(b) of the Federal Food, Drug,*
18 *and Cosmetic Act or, in the case of*
19 *a biologic product, licensed under*
20 *section 351 of the Public Health*
21 *Service Act; and*

22 “(ii)(I) *if the PDP sponsor of*
23 *the prescription drug plan or the*
24 *MA organization offering the MA–*
25 *PD plan uses a formulary, which*

1 *is on the formulary of the pre-*
2 *scription drug plan or MA-PD*
3 *plan that the applicable bene-*
4 *ficiary is enrolled in;*

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

13 *“(III) is provided through an*
14 *exception or appeal; and*

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

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

23 *“(A) with respect to claims for re-*
24 *imbursement submitted electronically,*
25 *14 days; and*

1 “(B) *with respect to claims for re-*
2 *imbursement submitted otherwise, 30*
3 *days.*

4 “(4) *DISCOUNTED PRICE.—*

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

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

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

23 “(B) *CLARIFICATION.—Nothing in*
24 *this section shall be construed as af-*
25 *fecting the responsibility of an appli-*

1 *cable beneficiary for payment of a dis-*
2 *persing fee for an applicable drug.*

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

5 “(i) *CLAIMS SPANNING DEDUCT-*
6 *IBLE.—In the case where the entire*
7 *amount of the negotiated price of*
8 *an individual claim for an appli-*
9 *cable drug with respect to an ap-*
10 *licable beneficiary does not fall*
11 *at or above the annual deductible*
12 *specified in section 1860D–2(b)(1)*
13 *for the year, the manufacturer of*
14 *the applicable drug shall provide*
15 *the discounted price under this*
16 *section on only the portion of the*
17 *negotiated price of the applicable*
18 *drug that falls at or above such*
19 *annual deductible.*

20 “(ii) *CLAIMS SPANNING OUT-OF-*
21 *POCKET THRESHOLD.—In the case*
22 *where the entire amount of the ne-*
23 *gotiated price of an individual*
24 *claim for an applicable drug with*
25 *respect to an applicable bene-*

1 *ficiary does not fall entirely below*
2 *or entirely above the annual out-*
3 *of-pocket threshold specified in*
4 *section 1860D-2(b)(4)(B)(i) for the*
5 *year, the manufacturer of the ap-*
6 *plicable drug shall provide the*
7 *discounted price—*

8 *“(I) in accordance with*
9 *subparagraph (A)(i) on the*
10 *portion of the negotiated price*
11 *of the applicable drug that*
12 *falls below such threshold;*
13 *and*

14 *“(II) in accordance with*
15 *subparagraph (A)(ii) on the*
16 *portion of such price of such*
17 *drug that falls at or above*
18 *such threshold.*

19 *“(5) MANUFACTURER.—The term ‘manu-*
20 *facturer’ means any entity which is en-*
21 *gaged in the production, preparation,*
22 *propagation, compounding, conversion, or*
23 *processing of prescription drug products,*
24 *either directly or indirectly by extraction*
25 *from substances of natural origin, or*

1 *independently by means of chemical syn-*
2 *thesis, or by a combination of extraction*
3 *and chemical synthesis. Such term does*
4 *not include a wholesale distributor of*
5 *drugs or a retail pharmacy licensed*
6 *under State law.*

7 “(6) *NEGOTIATED PRICE.—The term ‘ne-*
8 *gotiated price’ has the meaning given*
9 *such term in section 423.100 of title 42,*
10 *Code of Federal Regulations (as in effect*
11 *on the date of enactment of section 1860D-*
12 *14A), except that such negotiated price*
13 *shall not include any dispensing fee for*
14 *the applicable drug.*

15 “(7) *QUALIFIED RETIREE PRESCRIPTION*
16 *DRUG PLAN.—The term ‘qualified retiree*
17 *prescription drug plan’ has the meaning*
18 *given such term in section 1860D-*
19 *22(a)(2).”.*

20 (2) *SUNSET OF MEDICARE COVERAGE GAP*
21 *DISCOUNT PROGRAM.—Section 1860D-14A of*
22 *the Social Security Act (42 U.S.C. 1395-*
23 *114a) is amended—*

24 (A) *in subsection (a), in the first*
25 *sentence, by striking “The Secretary”*

1 *and inserting “Subject to subsection*
2 *(h), the Secretary”; and*

3 *(B) by adding at the end the fol-*
4 *lowing new subsection:*

5 *“(h) SUNSET OF PROGRAM.—*

6 *“(1) IN GENERAL.—The program shall*
7 *not apply with respect to applicable drugs*
8 *dispensed on or after January 1, 2022,*
9 *and, subject to paragraph (2), agreements*
10 *under this section shall be terminated as*
11 *of such date.*

12 *“(2) CONTINUED APPLICATION FOR APPLI-*
13 *CABLE DRUGS DISPENSED PRIOR TO SUN-*
14 *SET.—The provisions of this section (in-*
15 *cluding all responsibilities and duties)*
16 *shall continue to apply after January 1,*
17 *2022, with respect to applicable drugs dis-*
18 *persed prior to such date.”.*

19 *(3) INCLUSION OF ACTUARIAL VALUE OF*
20 *MANUFACTURER DISCOUNTS IN BIDS.—Sec-*
21 *tion 1860D–11 of the Social Security Act*
22 *(42 U.S.C. 1395w–111) is amended—*

23 *(A) in subsection (b)(2)(C)(iii)—*

1 *(i) by striking “assumptions*
2 *regarding the reinsurance” an in-*
3 *serting “assumptions regarding—*

4 *“(I) the reinsurance”; and*

5 *(ii) by adding at the end the*
6 *following:*

7 *“(II) for 2022 and each*
8 *subsequent year, the manufac-*
9 *turer discounts provided*
10 *under section 1860D-14C sub-*
11 *tracted from the actuarial*
12 *value to produce such bid;*
13 *and”; and*

14 *(B) in subsection (c)(1)(C)—*

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

19 *“(i) the reinsurance”;*

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

23 *(iii) by adding at the end the*
24 *following:*

1 “(ii) for 2022 and each subse-
2 quent year, the manufacturer dis-
3 counts provided under section
4 1860D-14C;”.

5 **(d) CONFORMING AMENDMENTS.—**

6 **(1) Section 1860D-2 of the Social Secu-**
7 **urity Act (42 U.S.C. 1395w-102) is amend-**
8 **ed—**

9 **(A) in subsection (a)(2)(A)(i)(I), by**
10 **striking “, or an increase in the ini-**
11 **tial” and inserting “or, for a year pre-**
12 **ceding 2022, an increase in the ini-**
13 **tial”;**

14 **(B) in subsection (c)(1)(C)—**

15 **(i) in the subparagraph head-**
16 **ing, by striking “AT INITIAL COV-**
17 **ERAGE LIMIT”; and**

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

1 (C) *in subsection (d)(1)(A), by*
2 *striking “or an initial” and inserting*
3 *“or, for a year preceding 2022, an ini-*
4 *tial”.*

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

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

13 (A) *in paragraph (1)—*

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

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

22 (iii) *in subparagraph (E), by*
23 *striking “The elimination” and in-*
24 *serting “For a year preceding*
25 *2022, the elimination”;* and

1 ***(B) in paragraph (2)—***

2 ***(i) in subparagraph (C), by***
3 ***striking “The continuation” and***
4 ***inserting “For a year preceding***
5 ***2022, the continuation”;*** and

6 ***(ii) in subparagraph (E)—***

7 ***(I) by inserting “for a year***
8 ***preceding 2022,” after “sub-***
9 ***section (c)”;*** and

10 ***(II) by striking “1860D-***
11 ***2(b)(4)(A)(i)(I)” and inserting***
12 ***“1860D-2(b)(4)(A)(i)(I)(aa)”.***

13 ***(4) Section 1860D-21(d)(7) of the So-***
14 ***cial Security Act (42 U.S.C. 1395w-***
15 ***131(d)(7)) is amended by striking “section***
16 ***1860D-2(b)(4)(B)(i)” and inserting “sec-***
17 ***tion 1860D-2(b)(4)(C)(i)”.***

18 ***(5) Section 1860D-22(a)(2)(A) of the***
19 ***Social Security Act (42 U.S.C. 1395w-***
20 ***132(a)(2)(A)) is amended—***

21 ***(A) by striking “the value of any***
22 ***discount” and inserting the following:***
23 ***“the value of—***

24 ***“(i) for years prior to 2022, any***
25 ***discount”.***

1 ***(B) in clause (i), as inserted by***
2 ***subparagraph (A) of this paragraph,***
3 ***by striking the period at the end and***
4 ***inserting “; and”; and***

5 ***(C) by adding at the end the fol-***
6 ***lowing new clause:***

7 ***“(ii) for 2022 and each subse-***
8 ***quent year, any discount provided***
9 ***pursuant to section 1860D–14C.”.***

10 ***(6) Section 1860D–41(a)(6) of the So-***
11 ***cial Security Act (42 U.S.C. 1395w–***
12 ***151(a)(6)) is amended—***

13 ***(A) by inserting “for a year before***
14 ***2022” after “1860D–2(b)(3)”;*** and

15 ***(B) by inserting “for such year” be-***
16 ***fore the period.***

17 ***(7) Paragraph (1) of section 1860D–***
18 ***43(a) of the Social Security Act (42 U.S.C.***
19 ***1395w–153(a)) is amended to read as fol-***
20 ***lows:***

21 ***“(1) participate in—***

22 ***“(A) for 2011 through 2021, the***
23 ***Medicare coverage gap discount pro-***
24 ***gram under section 1860D–14A; and***

1 **“(B) for 2022 and each subsequent**
2 **year, the manufacturer discount pro-**
3 **gram under section 1860D-14C;”.**

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

Union Calendar No. 264

116TH CONGRESS
1ST Session

H. R. 3

[Report No. 116-324, Parts I, II and III]

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.

DECEMBER 9, 2019

Reported from the Committee on Education and Labor with an amendment; committed to the Committee of the Whole House on the State of the Union and ordered to be printed