

1 ***Subtitle B—Prescription Drug***
 2 ***Pricing Reform***

3 ***PART 1—LOWERING PRICES THROUGH DRUG***
 4 ***PRICE NEGOTIATION***

5 ***SEC. 11001. PROVIDING FOR LOWER PRICES FOR CERTAIN***
 6 ***HIGH-PRICED SINGLE SOURCE DRUGS.***

7 *(a) PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-*
 8 *PRICED SINGLE SOURCE DRUGS.—Title XI of the Social*
 9 *Security Act is amended by adding after section 1184 (42*
 10 *U.S.C. 1320e-3) the following new part:*

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

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

15 *“(a) IN GENERAL.—The Secretary shall establish a*
 16 *Drug 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;*

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

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

4 “(4) *carry out the publication and administra-*
5 *tive duties and compliance monitoring in accordance*
6 *with sections 1195 and 1196.*

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

9 “(1) *INITIAL PRICE APPLICABILITY YEAR.—The*
10 *term ‘initial price applicability year’ means a year*
11 *(beginning with 2026).*

12 “(2) *PRICE APPLICABILITY PERIOD.—The term*
13 *‘price applicability period’ means, with respect to a*
14 *qualifying single source drug, the period beginning*
15 *with the first initial price applicability year with re-*
16 *spect to which such drug is a selected drug and end-*
17 *ing with the last year during which the drug is a se-*
18 *lected drug.*

19 “(3) *SELECTED DRUG PUBLICATION DATE.—The*
20 *term ‘selected drug publication date’ means, with re-*
21 *spect to each initial price applicability year, Feb-*
22 *ruary 1 of the year that begins 2 years prior to such*
23 *year.*

24 “(4) *NEGOTIATION PERIOD.—The term ‘negotia-*
25 *tion period’ means, with respect to an initial price*

1 *applicability year with respect to a selected drug, the*
2 *period—*

3 “(A) *beginning on the sooner of—*

4 “(i) *the date on which the manufac-*
5 *turer of the drug and the Secretary enter*
6 *into an agreement under section 1193 with*
7 *respect to such drug; or*

8 “(ii) *February 28 following the selected*
9 *drug publication date with respect to such*
10 *selected drug; and*

11 “(B) *ending on November 1 of the year that*
12 *begins 2 years prior to the initial price applica-*
13 *bility year.*

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

15 “(1) *MANUFACTURER.—The term ‘manufacturer’*
16 *has the meaning given that term in section*
17 *1847A(c)(6)(A).*

18 “(2) *MAXIMUM FAIR PRICE ELIGIBLE INDI-*
19 *VIDUAL.—The term ‘maximum fair price eligible in-*
20 *dividual’ means, with respect to a selected drug—*

21 “(A) *in the case such drug is dispensed to*
22 *the individual at a pharmacy, by a mail order*
23 *service, or by another dispenser, an individual*
24 *who is enrolled in a prescription drug plan*
25 *under part D of title XVIII or an MA–PD plan*

1 *under part C of such title if coverage is provided*
2 *under such plan for such selected drug; and*

3 “(B) *in the case such drug is furnished or*
4 *administered to the individual by a hospital,*
5 *physician, or other provider of services or sup-*
6 *plier, an individual who is enrolled under part*
7 *B of title XVIII, including an individual who is*
8 *enrolled in an MA plan under part C of such*
9 *title, if payment may be made under part B for*
10 *such selected drug.*

11 “(3) *MAXIMUM FAIR PRICE.—The term ‘max-*
12 *imum fair price’ means, with respect to a year dur-*
13 *ing a price applicability period and with respect to*
14 *a selected drug (as defined in section 1192(c)) with*
15 *respect to such period, the price negotiated pursuant*
16 *to section 1194, and updated pursuant to section*
17 *1195(b), as applicable, for such drug and year.*

18 “(4) *REFERENCE PRODUCT.—The term ‘reference*
19 *product’ has the meaning given such term in section*
20 *351(i) of the Public Health Service Act.*

21 “(5) *TOTAL EXPENDITURES.—The term ‘total ex-*
22 *penditures’ includes, in the case of expenditures with*
23 *respect to part D of title XVIII, the total gross covered*
24 *prescription drug costs (as defined in section 1860D-*
25 *15(b)(3)). The term ‘total expenditures’ excludes, in*

1 *the case of expenditures with respect to part B of such*
2 *title, expenditures for a drug or biological product*
3 *that are bundled or packaged into the payment for*
4 *another service.*

5 *“(6) UNIT.—The term ‘unit’ means, with respect*
6 *to a drug or biological product, the lowest identifiable*
7 *amount (such as a capsule or tablet, milligram of*
8 *molecules, or grams) of the drug or biological product*
9 *that is dispensed or furnished.*

10 *“(d) TIMING FOR INITIAL PRICE APPLICABILITY YEAR*
11 *2026.—Notwithstanding the provisions of this part, in the*
12 *case of initial price applicability year 2026, the following*
13 *rules shall apply for purposes of implementing the program:*

14 *“(1) Subsection (b)(3) shall be applied by sub-*
15 *stituting ‘September 1, 2023’ for ‘, with respect to*
16 *each initial price applicability year, February 1 of*
17 *the year that begins 2 years prior to such year’.*

18 *“(2) Subsection (b)(4) shall be applied—*

19 *“(A) in subparagraph (A)(ii), by sub-*
20 *stituting ‘October 1, 2023’ for ‘February 28 fol-*
21 *lowing the selected drug publication date with*
22 *respect to such selected drug’; and*

23 *“(B) in subparagraph (B), by substituting*
24 *‘August 1, 2024’ for ‘November 1 of the year that*

1 *begins 2 years prior to the initial price applica-*
2 *bility year’.*

3 *“(3) Section 1192 shall be applied—*

4 *“(A) in subsection (b)(1)(A), by substituting*
5 *‘during the period beginning on June 1, 2022,*
6 *and ending on May 31, 2023’ for ‘during the*
7 *most recent period of 12 months prior to the se-*
8 *lected drug publication date (but ending not*
9 *later than October 31 of the year prior to the*
10 *year of such drug publication date), with respect*
11 *to such year, for which data are available’; and*

12 *“(B) in subsection (d)(1)(A), by sub-*
13 *stituting ‘during the period beginning on June*
14 *1, 2022, and ending on May 31, 2023’ for ‘dur-*
15 *ing the most recent period for which data are*
16 *available of at least 12 months prior to the se-*
17 *lected drug publication date (but ending no later*
18 *than October 31 of the year prior to the year of*
19 *such drug publication date), with respect to such*
20 *year’.*

21 *“(4) Section 1193(a) shall be applied by sub-*
22 *stituting ‘October 1, 2023’ for ‘February 28 following*
23 *the selected drug publication date with respect to such*
24 *selected drug’.*

25 *“(5) Section 1194(b)(2) shall be applied—*

1 “(A) in subparagraph (A), by substituting
2 ‘October 2, 2023’ for ‘March 1 of the year of the
3 selected drug publication date, with respect to the
4 selected drug’;

5 “(B) in subparagraph (B), by substituting
6 ‘February 1, 2024’ for ‘the June 1 following the
7 selected drug publication date’; and

8 “(C) in subparagraph (E), by substituting
9 ‘August 1, 2024’ for ‘the first day of November
10 following the selected drug publication date, with
11 respect to the initial price applicability year’.

12 “(6) Section 1195(a)(1) shall be applied by sub-
13 stituting ‘September 1, 2024’ for ‘November 30 of the
14 year that is 2 years prior to such initial price appli-
15 cability year’.

16 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
17 **AS SELECTED DRUGS.**

18 “(a) *IN GENERAL.*—Not later than the selected drug
19 publication date with respect to an initial price applica-
20 bility year, in accordance with subsection (b), the Secretary
21 shall select and publish a list of—

22 “(1) with respect to the initial price applica-
23 bility year 2026, 10 negotiation-eligible drugs de-
24 scribed in subparagraph (A) of subsection (d)(1), but
25 not subparagraph (B) of such subsection, with respect

1 to such year (or, all (if such number is less than 10)
2 such negotiation-eligible drugs with respect to such
3 year);

4 “(2) with respect to the initial price applica-
5 bility year 2027, 15 negotiation-eligible drugs de-
6 scribed in subparagraph (A) of subsection (d)(1), but
7 not subparagraph (B) of such subsection, with respect
8 to such year (or, all (if such number is less than 15)
9 such negotiation-eligible drugs with respect to such
10 year);

11 “(3) with respect to the initial price applica-
12 bility year 2028, 15 negotiation-eligible drugs de-
13 scribed in subparagraph (A) or (B) of subsection
14 (d)(1) with respect to such year (or, all (if such num-
15 ber is less than 15) such negotiation-eligible drugs
16 with respect to such year); and

17 “(4) with respect to the initial price applica-
18 bility year 2029 or a subsequent year, 20 negotiation-
19 eligible drugs described in subparagraph (A) or (B)
20 of subsection (d)(1), with respect to such year (or, all
21 (if such number is less than 20) such negotiation-eli-
22 gible drugs with respect to such year).

23 Subject to subsection (c)(2) and section 1194(f)(5), each
24 drug published on the list pursuant to the previous sentence
25 shall be subject to the negotiation process under section 1194

1 *for the negotiation period with respect to such initial price*
2 *applicability year (and the renegotiation process under*
3 *such section as applicable for any subsequent year during*
4 *the applicable price applicability period).*

5 “(b) *SELECTION OF DRUGS.—*

6 “(1) *IN GENERAL.—In carrying out subsection*
7 *(a), subject to paragraph (2), the Secretary shall,*
8 *with respect to an initial price applicability year, do*
9 *the following:*

10 “(A) *Rank negotiation-eligible drugs de-*
11 *scribed in subsection (d)(1) according to the total*
12 *expenditures for such drugs under parts B and*
13 *D of title XVIII, as determined by the Secretary,*
14 *during the most recent period of 12 months prior*
15 *to the selected drug publication date (but ending*
16 *not later than October 31 of the year prior to the*
17 *year of such drug publication date), with respect*
18 *to such year, for which data are available, with*
19 *the negotiation-eligible drugs with the highest*
20 *total expenditures being ranked the highest.*

21 “(B) *Select from such ranked drugs with re-*
22 *spect to such year the negotiation-eligible drugs*
23 *with the highest such rankings.*

24 “(2) *HIGH SPEND PART D DRUGS FOR 2026 AND*
25 *2027.—With respect to the initial price applicability*

1 *year 2026 and with respect to the initial price appli-*
2 *cability year 2027, the Secretary shall apply para-*
3 *graph (1) as if the reference to ‘negotiation-eligible*
4 *drugs described in subsection (d)(1)’ were a reference*
5 *to ‘negotiation-eligible drugs described in subsection*
6 *(d)(1)(A)’ and as if the reference to ‘total expendi-*
7 *tures for such drugs under parts B and D of title*
8 *XVIII’ were a reference to ‘total expenditures for such*
9 *drugs under part D of title XVIII’.*

10 *“(c) SELECTED DRUG.—*

11 *“(1) IN GENERAL.—For purposes of this part, in*
12 *accordance with subsection (e)(2) and subject to para-*
13 *graph (2), each negotiation-eligible drug included on*
14 *the list published under subsection (a) with respect to*
15 *an initial price applicability year shall be referred to*
16 *as a ‘selected drug’ with respect to such year and each*
17 *subsequent year beginning before the first year that*
18 *begins at least 9 months after the date on which the*
19 *Secretary determines at least one drug or biological*
20 *product—*

21 *“(A) is approved or licensed (as applica-*
22 *ble)—*

23 *“(i) under section 505(j) of the Federal*
24 *Food, Drug, and Cosmetic Act using such*
25 *drug as the listed drug; or*

1 “(ii) under section 351(k) of the Public
2 Health Service Act using such drug as the
3 reference product; and

4 “(B) is marketed pursuant to such approval
5 or licensure.

6 “(2) CLARIFICATION.—A negotiation-eligible
7 drug—

8 “(A) that is included on the list published
9 under subsection (a) with respect to an initial
10 price applicability year; and

11 “(B) for which the Secretary makes a deter-
12 mination described in paragraph (1) before or
13 during the negotiation period with respect to
14 such initial price applicability year;

15 shall not be subject to the negotiation process under
16 section 1194 with respect to such negotiation period
17 and shall continue to be considered a selected drug
18 under this part with respect to the number of negotia-
19 tion-eligible drugs published on the list under sub-
20 section (a) with respect to such initial price applica-
21 bility year.

22 “(d) NEGOTIATION-ELIGIBLE DRUG.—

23 “(1) IN GENERAL.—For purposes of this part,
24 subject to paragraph (2), the term ‘negotiation-eligible
25 drug’ means, with respect to the selected drug publica-

1 *tion date with respect to an initial price applicability*
2 *year, a qualifying single source drug, as defined in*
3 *subsection (e), that is described in either of the fol-*
4 *lowing subparagraphs (or, with respect to the initial*
5 *price applicability year 2026 or 2027, that is de-*
6 *scribed in subparagraph (A)):*

7 *“(A) PART D HIGH SPEND DRUGS.—The*
8 *qualifying single source drug is, determined in*
9 *accordance with subsection (e)(2), among the 50*
10 *qualifying single source drugs with the highest*
11 *total expenditures under part D of title XVIII,*
12 *as determined by the Secretary in accordance*
13 *with paragraph (3), during the most recent 12-*
14 *month period for which data are available prior*
15 *to such selected drug publication date (but end-*
16 *ing no later than October 31 of the year prior*
17 *to the year of such drug publication date).*

18 *“(B) PART B HIGH SPEND DRUGS.—The*
19 *qualifying single source drug is, determined in*
20 *accordance with subsection (e)(2), among the 50*
21 *qualifying single source drugs with the highest*
22 *total expenditures under part B of title XVIII,*
23 *as determined by the Secretary in accordance*
24 *with paragraph (3), during such most recent 12-*
25 *month period, as described in subparagraph (A).*

1 “(2) *EXCEPTION FOR SMALL BIOTECH DRUGS.*—

2 “(A) *IN GENERAL.*—Subject to subpara-
3 graph (C), the term ‘negotiation-eligible drug’
4 shall not include, with respect to the initial price
5 applicability years 2026, 2027, and 2028, a
6 qualifying single source drug that meets either of
7 the following:

8 “(i) *PART D DRUGS.*—The total ex-
9 penditures for the qualifying single source
10 drug under part D of title XVIII, as deter-
11 mined by the Secretary in accordance with
12 paragraph (3)(B), during 2021—

13 “(I) are equal to or less than 1
14 percent of the total expenditures under
15 such part D, as so determined, for all
16 covered part D drugs (as defined in
17 section 1860D–2(e)) during such year;
18 and

19 “(II) are equal to at least 80 per-
20 cent of the total expenditures under
21 such part D, as so determined, for all
22 covered part D drugs for which the
23 manufacturer of the drug has an agree-
24 ment in effect under section 1860D–
25 14A during such year.

1 “(ii) *PART B DRUGS.*—*The total ex-*
2 *penditures for the qualifying single source*
3 *drug under part B of title XVIII, as deter-*
4 *mined by the Secretary in accordance with*
5 *paragraph (3)(B), during 2021—*

6 “(I) *are equal to or less than 1*
7 *percent of the total expenditures under*
8 *such part B, as so determined, for all*
9 *qualifying single source drugs for*
10 *which payment may be made under*
11 *such part B during such year; and*

12 “(II) *are equal to at least 80 per-*
13 *cent of the total expenditures under*
14 *such part B, as so determined, for all*
15 *qualifying single source drugs of the*
16 *manufacturer for which payment may*
17 *be made under such part B during*
18 *such year.*

19 “(B) *CLARIFICATIONS RELATING TO MANU-*
20 *FACTURERS.*—

21 “(i) *AGGREGATION RULE.*—*All persons*
22 *treated as a single employer under sub-*
23 *section (a) or (b) of section 52 of the Inter-*
24 *nal Revenue Code of 1986 shall be treated*

1 *as one manufacturer for purposes of this*
2 *paragraph.*

3 “(ii) *LIMITATION.*—*A drug shall not be*
4 *considered to be a qualifying single source*
5 *drug described in clause (i) or (ii) of sub-*
6 *paragraph (A) if the manufacturer of such*
7 *drug is acquired after 2021 by another*
8 *manufacturer that does not meet the defini-*
9 *tion of a specified manufacturer under sec-*
10 *tion 1860D–14C(g)(4)(B)(ii), effective at the*
11 *beginning of the plan year immediately fol-*
12 *lowing such acquisition or, in the case of an*
13 *acquisition before 2025, effective January 1,*
14 *2025.*

15 “(C) *DRUGS NOT INCLUDED AS SMALL*
16 *BIOTECH DRUGS.*—*A new formulation, such as*
17 *an extended release formulation, of a qualifying*
18 *single source drug shall not be considered a*
19 *qualifying single source drug described in sub-*
20 *paragraph (A).*

21 “(3) *CLARIFICATIONS AND DETERMINATIONS.*—

22 “(A) *PREVIOUSLY SELECTED DRUGS AND*
23 *SMALL BIOTECH DRUGS EXCLUDED.*—*In apply-*
24 *ing subparagraphs (A) and (B) of paragraph*
25 *(1), the Secretary shall not consider or count—*

1 “(i) drugs that are already selected
2 drugs; and

3 “(ii) for initial price applicability
4 years 2026, 2027, and 2028, qualifying sin-
5 gle source drugs described in paragraph
6 (2)(A).

7 “(B) USE OF DATA.—In determining
8 whether a qualifying single source drug satisfies
9 any of the criteria described in paragraph (1) or
10 (2), the Secretary shall use data that is aggre-
11 gated across dosage forms and strengths of the
12 drug, including new formulations of the drug,
13 such as an extended release formulation, and not
14 based on the specific formulation or package size
15 or package type of the drug.

16 “(e) QUALIFYING SINGLE SOURCE DRUG.—

17 “(1) IN GENERAL.—For purposes of this part,
18 the term ‘qualifying single source drug’ means, with
19 respect to an initial price applicability year, subject
20 to paragraphs (2) and (3), a covered part D drug (as
21 defined in section 1860D–2(e)) that is described in
22 any of the following or a drug or biological product
23 for which payment may be made under part B of title
24 XVIII that is described in any of the following:

25 “(A) DRUG PRODUCTS.—A drug—

1 “(i) that is approved under section
2 505(c) of the Federal Food, Drug, and Cos-
3 metic Act and is marketed pursuant to such
4 approval;

5 “(ii) for which, as of the selected drug
6 publication date with respect to such initial
7 price applicability year, at least 7 years
8 will have elapsed since the date of such ap-
9 proval; and

10 “(iii) that is not the listed drug for
11 any drug that is approved and marketed
12 under section 505(j) of such Act.

13 “(B) *BIOLOGICAL PRODUCTS*.—A biological
14 product—

15 “(i) that is licensed under section
16 351(a) of the Public Health Service Act and
17 is marketed under section 351 of such Act;

18 “(ii) for which, as of the selected drug
19 publication date with respect to such initial
20 price applicability year, at least 11 years
21 will have elapsed since the date of such li-
22 censure; and

23 “(iii) that is not the reference product
24 for any biological product that is licensed

1 *and marketed under section 351(k) of such*
2 *Act.*

3 “(2) *TREATMENT OF AUTHORIZED GENERIC*
4 *DRUGS.—*

5 “(A) *IN GENERAL.—In the case of a quali-*
6 *fying single source drug described in subpara-*
7 *graph (A) or (B) of paragraph (1) that is the*
8 *listed drug (as such term is used in section*
9 *505(j) of the Federal Food, Drug, and Cosmetic*
10 *Act) or a product described in clause (ii) of sub-*
11 *paragraph (B), with respect to an authorized ge-*
12 *neric drug, in applying the provisions of this*
13 *part, such authorized generic drug and such list-*
14 *ed drug or such product shall be treated as the*
15 *same qualifying single source drug.*

16 “(B) *AUTHORIZED GENERIC DRUG DE-*
17 *FINED.—For purposes of this paragraph, the*
18 *term ‘authorized generic drug’ means—*

19 “(i) *in the case of a drug, an author-*
20 *ized generic drug (as such term is defined*
21 *in section 505(t)(3) of the Federal Food,*
22 *Drug, and Cosmetic Act); and*

23 “(ii) *in the case of a biological prod-*
24 *uct, a product that—*

1 “(I) has been licensed under sec-
2 tion 351(a) of such Act; and

3 “(II) is marketed, sold, or distrib-
4 uted directly or indirectly to retail
5 class of trade under a different label-
6 ing, packaging (other than repackaging
7 as the reference product in blister
8 packs, unit doses, or similar packaging
9 for use in institutions), product code,
10 labeler code, trade name, or trade mark
11 than the reference product.

12 “(3) *EXCLUSIONS.*—In this part, the term ‘quali-
13 fying single source drug’ does not include any of the
14 following:

15 “(A) *CERTAIN ORPHAN DRUGS.*—A drug
16 that is designated as a drug for only one rare
17 disease or condition under section 526 of the
18 Federal Food, Drug, and Cosmetic Act and for
19 which the only approved indication (or indica-
20 tions) is for such disease or condition.

21 “(B) *LOW SPEND MEDICARE DRUGS.*—A
22 drug or biological product with respect to which
23 the total expenditures under parts B and D of
24 title XVIII, as determined by the Secretary in
25 accordance with subsection (d)(3)(B)—

1 “(i) with respect to initial price appli-
2 cability year 2026, is less than, during the
3 period beginning on June 1, 2022, and end-
4 ing on May 31, 2023, \$200,000,000;

5 “(ii) with respect to initial price ap-
6 plicability year 2027, is less than, during
7 the most recent 12-month period applicable
8 under subparagraphs (A) and (B) of sub-
9 section (d)(1) for such year, the dollar
10 amount specified in clause (i) increased by
11 the annual percentage increase in the con-
12 sumer price index for all urban consumers
13 (all items; United States city average) for
14 the period beginning on June 1, 2023, and
15 ending on September 30, 2024; or

16 “(iii) with respect to a subsequent ini-
17 tial price applicability year, is less than,
18 during the most recent 12-month period ap-
19 plicable under subparagraphs (A) and (B)
20 of subsection (d)(1) for such year, the dollar
21 amount specified in this subparagraph for
22 the previous initial price applicability year
23 increased by the annual percentage increase
24 in such consumer price index for the 12-
25 month period ending on September 30 of the

1 *year prior to the year of the selected drug*
2 *publication date with respect to such subse-*
3 *quent initial price applicability year.*

4 “(C) *PLASMA-DERIVED PRODUCTS.—A bio-*
5 *logical product that is derived from human*
6 *whole blood or plasma.*

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 February 28 following*
12 *the selected drug publication date with respect to such se-*
13 *lected drug, under which—*

14 “(1) *during the negotiation period for the initial*
15 *price applicability year for the selected drug, the Sec-*
16 *retary and the manufacturer, in accordance with sec-*
17 *tion 1194, negotiate to determine (and, by not later*
18 *than the last date of such period, agree to) a max-*
19 *imum fair price for such selected drug of the manu-*
20 *facturer in order for the manufacturer to provide ac-*
21 *cess to such price—*

22 “(A) *to maximum fair price eligible indi-*
23 *viduals who with respect to such drug are de-*
24 *scribed in subparagraph (A) of section*
25 *1191(c)(2) and are dispensed such drug (and to*

1 *pharmacies, mail order services, and other dis-*
2 *pensers, with respect to such maximum fair*
3 *price eligible individuals who are dispensed such*
4 *drugs) during, subject to paragraph (2), the*
5 *price applicability period; and*

6 *“(B) to hospitals, physicians, and other*
7 *providers of services and suppliers with respect*
8 *to maximum fair price eligible individuals who*
9 *with respect to such drug are described in sub-*
10 *paragraph (B) of such section and are furnished*
11 *or administered such drug during, subject to*
12 *paragraph (2), the price applicability period;*

13 *“(2) the Secretary and the manufacturer shall,*
14 *in accordance with section 1194, renegotiate (and, by*
15 *not later than the last date of the period of renegoti-*
16 *ation, agree to) the maximum fair price for such*
17 *drug, in order for the manufacturer to provide access*
18 *to such maximum fair price (as so renegotiated)—*

19 *“(A) to maximum fair price eligible indi-*
20 *viduals who with respect to such drug are de-*
21 *scribed in subparagraph (A) of section*
22 *1191(c)(2) and are dispensed such drug (and to*
23 *pharmacies, mail order services, and other dis-*
24 *pensers, with respect to such maximum fair*
25 *price eligible individuals who are dispensed such*

1 *drugs) during any year during the price appli-*
2 *cability period (beginning after such renegoti-*
3 *ation) with respect to such selected drug; and*

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

11 *“(3) subject to subsection (d), access to the max-*
12 *imum fair price (including as renegotiated pursuant*
13 *to paragraph (2)), with respect to such a selected*
14 *drug, shall be provided by the manufacturer to—*

15 *“(A) maximum fair price eligible individ-*
16 *uals, who with respect to such drug are described*
17 *in subparagraph (A) of section 1191(c)(2), at the*
18 *pharmacy, mail order service, or other dispenser*
19 *at the point-of-sale of such drug (and shall be*
20 *provided by the manufacturer to the pharmacy,*
21 *mail order service, or other dispenser, with re-*
22 *spect to such maximum fair price eligible indi-*
23 *viduals who are dispensed such drugs), as de-*
24 *scribed in paragraph (1)(A) or (2)(A), as appli-*
25 *cable; and*

1 “(B) hospitals, physicians, and other pro-
2 viders of services and suppliers with respect to
3 maximum fair price eligible individuals who
4 with respect to such drug are described in sub-
5 paragraph (B) of such section and are furnished
6 or administered such drug, as described in para-
7 graph (1)(B) or (2)(B), as applicable;

8 “(4) the manufacturer submits to the Secretary,
9 in a form and manner specified by the Secretary, for
10 the negotiation period for the price applicability pe-
11 riod (and, if applicable, before any period of renegoti-
12 ation pursuant to section 1194(f)) with respect to
13 such drug—

14 “(A) information on the non-Federal aver-
15 age manufacturer price (as defined in section
16 8126(h)(5) of title 38, United States Code) for
17 the drug for the applicable year or period; and

18 “(B) information that the Secretary re-
19 quires to carry out the negotiation (or renegoti-
20 ation process) under this part; and

21 “(5) the manufacturer complies with require-
22 ments determined by the Secretary to be necessary for
23 purposes of administering the program and moni-
24 toring compliance with the program.

1 “(b) *AGREEMENT IN EFFECT UNTIL DRUG IS NO*
2 *LONGER A SELECTED DRUG.*—An agreement entered into
3 *under this section shall be effective, with respect to a selected*
4 *drug, until such drug is no longer considered a selected drug*
5 *under section 1192(c).*

6 “(c) *CONFIDENTIALITY OF INFORMATION.*—*Informa-*
7 *tion submitted to the Secretary under this part by a manu-*
8 *facturer of a selected drug that is proprietary information*
9 *of such manufacturer (as determined by the Secretary) shall*
10 *be used only by the Secretary or disclosed to and used by*
11 *the Comptroller General of the United States for purposes*
12 *of carrying out this part.*

13 “(d) *NONDUPLICATION WITH 340B CEILING PRICE.*—
14 *Under an agreement entered into under this section, the*
15 *manufacturer of a selected drug—*

16 “(1) *shall not be required to provide access to the*
17 *maximum fair price under subsection (a)(3), with re-*
18 *spect to such selected drug and maximum fair price*
19 *eligible individuals who are eligible to be furnished,*
20 *administered, or dispensed such selected drug at a*
21 *covered entity described in section 340B(a)(4) of the*
22 *Public Health Service Act, to such covered entity if*
23 *such selected drug is subject to an agreement described*
24 *in section 340B(a)(1) of such Act and the ceiling*
25 *price (defined in section 340B(a)(1) of such Act) is*

1 *lower than the maximum fair price for such selected*
2 *drug; and*

3 “(2) shall be required to provide access to the
4 *maximum fair price to such covered entity with re-*
5 *spect to maximum fair price eligible individuals who*
6 *are eligible to be furnished, administered, or dis-*
7 *persed such selected drug at such entity at such ceil-*
8 *ing price in a nonduplicated amount to the ceiling*
9 *price if such maximum fair price is below the ceiling*
10 *price for such selected drug.*

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

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

18 “(1) shall during the negotiation period with re-
19 *spect to such drug, in accordance with this section,*
20 *negotiate a maximum fair price for such drug for the*
21 *purpose described in section 1193(a)(1); and*

22 “(2) renegotiate, in accordance with the process
23 *specified pursuant to subsection (f), such maximum*
24 *fair price for such drug for the purpose described in*

1 *section 1193(a)(2) if such drug is a renegotiation-eli-*
2 *gible drug under such subsection.*

3 “(b) *NEGOTIATION PROCESS REQUIREMENTS.*—

4 “(1) *METHODOLOGY AND PROCESS.*—*The Sec-*
5 *retary shall develop and use a consistent methodology*
6 *and process, in accordance with paragraph (2), for*
7 *negotiations under subsection (a) that aims to achieve*
8 *the lowest maximum fair price for each selected drug.*

9 “(2) *SPECIFIC ELEMENTS OF NEGOTIATION*
10 *PROCESS.*—*As part of the negotiation process under*
11 *this section, with respect to a selected drug and the*
12 *negotiation period with respect to the initial price*
13 *applicability year with respect to such drug, the fol-*
14 *lowing shall apply:*

15 “(A) *SUBMISSION OF INFORMATION.*—*Not*
16 *later than March 1 of the year of the selected*
17 *drug publication date, with respect to the selected*
18 *drug, the manufacturer of the drug shall submit*
19 *to the Secretary, in accordance with section*
20 *1193(a)(4), the information described in such*
21 *section.*

22 “(B) *INITIAL OFFER BY SECRETARY.*—*Not*
23 *later than the June 1 following the selected drug*
24 *publication date, the Secretary shall provide the*
25 *manufacturer of the selected drug with a written*

1 *initial offer that contains the Secretary’s pro-*
2 *posal for the maximum fair price of the drug*
3 *and a concise justification based on the factors*
4 *described in section 1194(e) that were used in de-*
5 *veloping such offer.*

6 *“(C) RESPONSE TO INITIAL OFFER.—*

7 *“(i) IN GENERAL.—Not later than 30*
8 *days after the date of receipt of an initial*
9 *offer under subparagraph (B), the manufac-*
10 *turer shall either accept such offer or pro-*
11 *pose a counteroffer to such offer.*

12 *“(ii) COUNTEROFFER REQUIRE-*
13 *MENTS.—If a manufacturer proposes a*
14 *counteroffer, such counteroffer—*

15 *“(I) shall be in writing; and*

16 *“(II) shall be justified based on*
17 *the factors described in subsection (e).*

18 *“(D) RESPONSE TO COUNTEROFFER.—After*
19 *receiving a counteroffer under subparagraph (C),*
20 *the Secretary shall respond in writing to such*
21 *counteroffer.*

22 *“(E) DEADLINE.—All negotiations between*
23 *the Secretary and the manufacturer of the se-*
24 *lected drug shall end prior to the first day of No-*
25 *vember following the selected drug publication*

1 *date, with respect to the initial price applica-*
2 *bility year.*

3 “(F) *LIMITATIONS ON OFFER AMOUNT.—In*
4 *negotiating the maximum fair price of a selected*
5 *drug, with respect to the initial price applica-*
6 *bility year for the selected drug, and, as applica-*
7 *ble, in renegotiating the maximum fair price for*
8 *such drug, with respect to a subsequent year dur-*
9 *ing the price applicability period for such drug,*
10 *the Secretary shall not offer (or agree to a*
11 *counteroffer for) a maximum fair price for the*
12 *selected drug that—*

13 “(i) *exceeds the ceiling determined*
14 *under subsection (c) for the selected drug*
15 *and year; or*

16 “(ii) *as applicable, is less than the*
17 *floor determined under subsection (d) for the*
18 *selected drug and year.*

19 “(c) *CEILING FOR MAXIMUM FAIR PRICE.—*

20 “(1) *GENERAL CEILING.—*

21 “(A) *IN GENERAL.—The maximum fair*
22 *price negotiated under this section for a selected*
23 *drug, with respect to the first initial price appli-*
24 *cability year of the price applicability period*
25 *with respect to such drug, shall not exceed the*

1 *lower of the amount under subparagraph (B) or*
2 *the amount under subparagraph (C).*

3 “(B) *SUBPARAGRAPH (B) AMOUNT.—An*
4 *amount equal to the following:*

5 “(i) *COVERED PART D DRUG.—In the*
6 *case of a covered part D drug (as defined in*
7 *section 1860D–2(e)), the sum of the plan*
8 *specific enrollment weighted amounts for*
9 *each prescription drug plan or MA–PD*
10 *plan (as determined under paragraph (2)).*

11 “(ii) *PART B DRUG OR BIOLOGICAL.—*
12 *In the case of a drug or biological product*
13 *for which payment may be made under*
14 *part B of title XVIII, the payment amount*
15 *under section 1847A(b)(4) for the drug or*
16 *biological product for the year prior to the*
17 *year of the selected drug publication date*
18 *with respect to the initial price applica-*
19 *bility year for the drug or biological prod-*
20 *uct.*

21 “(C) *SUBPARAGRAPH (C) AMOUNT.—An*
22 *amount equal to the applicable percent described*
23 *in paragraph (3), with respect to such drug, of*
24 *the following:*

1 “(i) *INITIAL PRICE APPLICABILITY*
2 *YEAR 2026.*—*In the case of a selected drug*
3 *with respect to which such initial price ap-*
4 *plicability year is 2026, the average non-*
5 *Federal average manufacturer price for such*
6 *drug for 2021 (or, in the case that there is*
7 *not an average non-Federal average manu-*
8 *facturer price available for such drug for*
9 *2021, for the first full year following the*
10 *market entry for such drug), increased by*
11 *the percentage increase in the consumer*
12 *price index for all urban consumers (all*
13 *items; United States city average) from*
14 *September 2021 (or December of such first*
15 *full year following the market entry), as ap-*
16 *plicable, to September of the year prior to*
17 *the year of the selected drug publication*
18 *date with respect to such initial price ap-*
19 *plicability year.*

20 “(ii) *INITIAL PRICE APPLICABILITY*
21 *YEAR 2027 AND SUBSEQUENT YEARS.*—*In*
22 *the case of a selected drug with respect to*
23 *which such initial price applicability year*
24 *is 2027 or a subsequent year, the lower of—*

1 “(I) the average non-Federal aver-
2 age manufacturer price for such drug
3 for 2021 (or, in the case that there is
4 not an average non-Federal average
5 manufacturer price available for such
6 drug for 2021, for the first full year
7 following the market entry for such
8 drug), increased by the percentage in-
9 crease in the consumer price index for
10 all urban consumers (all items; United
11 States city average) from September
12 2021 (or December of such first full
13 year following the market entry), as
14 applicable, to September of the year
15 prior to the year of the selected drug
16 publication date with respect to such
17 initial price applicability year; or

18 “(II) the average non-Federal av-
19 erage manufacturer price for such drug
20 for the year prior to the selected drug
21 publication date with respect to such
22 initial price applicability year.

23 “(2) *PLAN SPECIFIC ENROLLMENT WEIGHTED*
24 *AMOUNT.*—For purposes of paragraph (1)(B)(i), the
25 *plan specific enrollment weighted amount for a pre-*

1 *scription drug plan or an MA–PD plan with respect*
2 *to a covered Part D drug is an amount equal to the*
3 *product of—*

4 *“(A) the negotiated price of the drug under*
5 *such plan under part D of title XVIII, net of all*
6 *price concessions received by such plan or phar-*
7 *macy benefit managers on behalf of such plan,*
8 *for the most recent year for which data is avail-*
9 *able; and*

10 *“(B) a fraction—*

11 *“(i) the numerator of which is the total*
12 *number of individuals enrolled in such plan*
13 *in such year; and*

14 *“(ii) the denominator of which is the*
15 *total number of individuals enrolled in a*
16 *prescription drug plan or an MA–PD plan*
17 *in such year.*

18 *“(3) APPLICABLE PERCENT DESCRIBED.—For*
19 *purposes of this subsection, the applicable percent de-*
20 *scribed in this paragraph is the following:*

21 *“(A) SHORT-MONOPOLY DRUGS AND VAC-*
22 *CINES.—With respect to a selected drug (other*
23 *than an extended-monopoly drug and a long-mo-*
24 *nopoly drug), 75 percent.*

1 “(B) *EXTENDED-MONOPOLY DRUGS.*—With
2 respect to an extended-monopoly drug, 65 per-
3 cent.

4 “(C) *LONG-MONOPOLY DRUGS.*—With re-
5 spect to a long-monopoly drug, 40 percent.

6 “(4) *EXTENDED-MONOPOLY DRUG DEFINED.*—

7 “(A) *IN GENERAL.*—In this part, subject to
8 subparagraph (B), the term ‘extended-monopoly
9 drug’ means, with respect to an initial price ap-
10 plicability year, a selected drug for which at
11 least 12 years, but fewer than 16 years, have
12 elapsed since the date of approval of such drug
13 under section 505(c) of the Federal Food, Drug,
14 and Cosmetic Act or since the date of licensure
15 of such drug under section 351(a) of the Public
16 Health Service Act, as applicable.

17 “(B) *EXCLUSIONS.*—The term ‘extended-mo-
18 nopoly drug’ shall not include any of the fol-
19 lowing:

20 “(i) A vaccine that is licensed under
21 section 351 of the Public Health Service Act
22 and marketed pursuant to such section.

23 “(ii) A selected drug for which a man-
24 ufacturer had an agreement under this part

1 *with the Secretary with respect to an initial*
2 *price applicability year that is before 2030.*

3 “(C) *CLARIFICATION.—Nothing in subpara-*
4 *graph (B)(ii) shall limit the transition of a se-*
5 *lected drug described in paragraph (3)(A) to a*
6 *long-monopoly drug if the selected drug meets the*
7 *definition of a long-monopoly drug.*

8 “(5) *LONG-MONOPOLY DRUG DEFINED.—*

9 “(A) *IN GENERAL.—In this part, subject to*
10 *subparagraph (B), the term ‘long-monopoly*
11 *drug’ means, with respect to an initial price ap-*
12 *plicability year, a selected drug for which at*
13 *least 16 years have elapsed since the date of ap-*
14 *proval of such drug under section 505(c) of the*
15 *Federal Food, Drug, and Cosmetic Act or since*
16 *the date of licensure of such drug under section*
17 *351(a) of the Public Health Service Act, as ap-*
18 *plicable.*

19 “(B) *EXCLUSION.—The term ‘long-monop-*
20 *oly drug’ shall not include a vaccine that is li-*
21 *censed under section 351 of the Public Health*
22 *Service Act and marketed pursuant to such sec-*
23 *tion.*

24 “(6) *AVERAGE NON-FEDERAL AVERAGE MANU-*
25 *FACTURER PRICE.—In this part, the term ‘average*

1 *non-Federal average manufacturer price’ means the*
2 *average of the non-Federal average manufacturer*
3 *price (as defined in section 8126(h)(5) of title 38,*
4 *United States Code) for the 4 calendar quarters of the*
5 *year involved.*

6 “(d) *TEMPORARY FLOOR FOR SMALL BIOTECH*
7 *DRUGS.—In the case of a selected drug that is a qualifying*
8 *single source drug described in section 1192(d)(2) and with*
9 *respect to which the first initial price applicability year*
10 *of the price applicability period with respect to such drug*
11 *is 2029 or 2030, the maximum fair price negotiated under*
12 *this section for such drug for such initial price applicability*
13 *year may not be less than 66 percent of the average non-*
14 *Federal average manufacturer price for such drug (as de-*
15 *finied in subsection (c)(6)) for 2021 (or, in the case that*
16 *there is not an average non-Federal average manufacturer*
17 *price available for such drug for 2021, for the first full year*
18 *following the market entry for such drug), increased by the*
19 *percentage increase in the consumer price index for all*
20 *urban consumers (all items; United States city average)*
21 *from September 2021 (or December of such first full year*
22 *following the market entry), as applicable, to September of*
23 *the year prior to the selected drug publication date with*
24 *respect to the initial price applicability year.*

1 “(e) *FACTORS.*—*For purposes of negotiating the max-*
2 *imum fair price of a selected drug under this part with*
3 *the manufacturer of the drug, the Secretary shall consider*
4 *the following factors, as applicable to the drug, as the basis*
5 *for determining the offers and counteroffers under sub-*
6 *section (b) for the drug:*

7 “(1) *MANUFACTURER-SPECIFIC DATA.*—*The fol-*
8 *lowing data, with respect to such selected drug, as*
9 *submitted by 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) *Current unit costs of production and*
15 *distribution of the drug.*

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

19 “(D) *Data on pending and approved patent*
20 *applications, exclusivities recognized by the Food*
21 *and Drug Administration, and applications and*
22 *approvals under section 505(c) of the Federal*
23 *Food, Drug, and Cosmetic Act or section 351(a)*
24 *of the Public Health Service Act for the drug.*

1 “(E) Market data and revenue and sales
2 volume data for the drug in the United States.

3 “(2) EVIDENCE ABOUT ALTERNATIVE TREAT-
4 MENTS.—The following evidence, as available, with
5 respect to such selected drug and therapeutic alter-
6 natives to such drug:

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

11 “(B) Prescribing information approved by
12 the Food and Drug Administration for such drug
13 and therapeutic alternatives to such drug.

14 “(C) Comparative effectiveness of such drug
15 and therapeutic alternatives to such drug, taking
16 into consideration the effects of such drug and
17 therapeutic alternatives to such drug on specific
18 populations, such as individuals with disabili-
19 ties, the elderly, the terminally ill, children, and
20 other patient populations.

21 “(D) The extent to which such drug and
22 therapeutic alternatives to such drug address
23 unmet medical needs for a condition for which
24 treatment or diagnosis is not addressed ade-
25 quately by available therapy.

1 *In using evidence described in subparagraph (C), the*
2 *Secretary shall not use evidence from comparative*
3 *clinical effectiveness research in a manner that treats*
4 *extending the life of an elderly, disabled, or termi-*
5 *nally ill individual as of lower value than extending*
6 *the life of an individual who is younger, nondisabled,*
7 *or not terminally ill.*

8 *“(f) RENEGOTIATION PROCESS.—*

9 *“(1) IN GENERAL.—In the case of a renegoti-*
10 *ation-eligible drug (as defined in paragraph (2)) that*
11 *is selected under paragraph (3), the Secretary shall*
12 *provide for a process of renegotiation (for years (be-*
13 *ginning with 2028) during the price applicability pe-*
14 *riod, with respect to such drug) of the maximum fair*
15 *price for such drug consistent with paragraph (4).*

16 *“(2) RENEGOTIATION-ELIGIBLE DRUG DE-*
17 *FINED.—In this section, the term ‘renegotiation-eli-*
18 *gible drug’ means a selected drug that is any of the fol-*
19 *lowing:*

20 *“(A) ADDITION OF NEW INDICATION.—A se-*
21 *lected drug for which a new indication is added*
22 *to the drug.*

23 *“(B) CHANGE OF STATUS TO AN EXTENDED-*
24 *MONOPOLY DRUG.—A selected drug that—*

1 “(i) is not an extended-monopoly or a
2 long-monopoly drug; and

3 “(ii) for which there is a change in
4 status to that of an extended-monopoly
5 drug.

6 “(C) CHANGE OF STATUS TO A LONG-MO-
7 NOPOLY DRUG.—A selected drug that—

8 “(i) is not a long-monopoly drug; and

9 “(ii) for which there is a change in
10 status to that of a long-monopoly drug.

11 “(D) MATERIAL CHANGES.—A selected drug
12 for which the Secretary determines there has been
13 a material change of any of the factors described
14 in paragraph (1) or (2) of subsection (e).

15 “(3) SELECTION OF DRUGS FOR RENEGOTI-
16 ATION.—For each year (beginning with 2028), the
17 Secretary shall select among renegotiation-eligible
18 drugs for renegotiation as follows:

19 “(A) ALL EXTENDED-MONOPOLY NEGOTIA-
20 TION-ELIGIBLE DRUGS.—The Secretary shall se-
21 lect all renegotiation-eligible drugs described in
22 paragraph (2)(B).

23 “(B) ALL LONG-MONOPOLY NEGOTIATION-
24 ELIGIBLE DRUGS.—The Secretary shall select all

1 *renegotiation-eligible drugs described in para-*
2 *graph (2)(C).*

3 “(C) *REMAINING DRUGS.*—*Among the re-*
4 *maining renegotiation-eligible drugs described in*
5 *subparagraphs (A) and (D) of paragraph (2),*
6 *the Secretary shall select renegotiation-eligible*
7 *drugs for which the Secretary expects renegoti-*
8 *ation is likely to result in a significant change*
9 *in the maximum fair price otherwise negotiated.*

10 “(4) *RENEGOTIATION PROCESS.*—

11 “(A) *IN GENERAL.*—*The Secretary shall*
12 *specify the process for renegotiation of maximum*
13 *fair prices with the manufacturer of a renegoti-*
14 *ation-eligible drug selected for renegotiation*
15 *under this subsection.*

16 “(B) *CONSISTENT WITH NEGOTIATION*
17 *PROCESS.*—*The process specified under subpara-*
18 *graph (A) shall, to the extent practicable, be con-*
19 *sistent with the methodology and process estab-*
20 *lished under subsection (b) and in accordance*
21 *with subsections (c), (d), and (e), and for pur-*
22 *poses of applying subsections (c)(1)(A) and (d),*
23 *the reference to the first initial price applica-*
24 *bility year of the price applicability period with*
25 *respect to such drug shall be treated as the first*

1 *initial price applicability year of such period for*
2 *which the maximum fair price established pursu-*
3 *ant to such renegotiation applies, including for*
4 *applying subsection (c)(3)(B) in the case of re-*
5 *negotiation-eligible drugs described in paragraph*
6 *(3)(A) of this subsection and subsection (c)(3)(C)*
7 *in the case of renegotiation-eligible drugs de-*
8 *scribed in paragraph (3)(B) of this subsection.*

9 “(5) *CLARIFICATION.—A renegotiation-eligible*
10 *drug for which the Secretary makes a determination*
11 *described in section 1192(c)(1) before or during the*
12 *period of renegotiation shall not be subject to the re-*
13 *negotiation process under this section.*

14 “(g) *CLARIFICATION.—The maximum fair price for a*
15 *selected drug described in subparagraph (A) or (B) of para-*
16 *graph (1) shall take effect no later than the first day of*
17 *the first calendar quarter that begins after the date de-*
18 *scribed in subparagraph (A) or (B), as applicable.*

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

20 “(a) *IN GENERAL.—With respect to an initial price*
21 *applicability year and a selected drug with respect to such*
22 *year—*

23 “(1) *not later than November 30 of the year that*
24 *is 2 years prior to such initial price applicability*
25 *year, the Secretary shall publish the maximum fair*

1 *price for such drug negotiated with the manufacturer*
2 *of such drug under this part; and*

3 “(2) *not later than March 1 of the year prior to*
4 *such initial price applicability year, the Secretary*
5 *shall publish, subject to section 1193(c), the expla-*
6 *nation for the maximum fair price with respect to the*
7 *factors as applied under section 1194(e) for such drug*
8 *described in paragraph (1).*

9 “(b) *UPDATES.—*

10 “(1) *SUBSEQUENT YEAR MAXIMUM FAIR*
11 *PRICES.—For a selected drug, for each year subse-*
12 *quent to the first initial price applicability year of*
13 *the price applicability period with respect to such*
14 *drug, with respect to which an agreement for such*
15 *drug is in effect under section 1193, not later than*
16 *November 30 of the year that is 2 years prior to such*
17 *subsequent year, the Secretary shall publish the max-*
18 *imum fair price applicable to such drug and year,*
19 *which shall be—*

20 “(A) *subject to subparagraph (B), the*
21 *amount equal to the maximum fair price pub-*
22 *lished for such drug for the previous year, in-*
23 *creased by the annual percentage increase in the*
24 *consumer price index for all urban consumers*
25 *(all items; United States city average) for the*

1 12-month period ending with the July imme-
2 diately preceding such November 30; or

3 “(B) in the case the maximum fair price for
4 such drug was renegotiated, for the first year for
5 which such price as so renegotiated applies, such
6 renegotiated maximum fair price.

7 “(2) *PRICES NEGOTIATED AFTER DEADLINE.*—In
8 the case of a selected drug with respect to an initial
9 price applicability year for which the maximum fair
10 price is determined under this part after the date of
11 publication under this section, the Secretary shall
12 publish such maximum fair price by not later than
13 30 days after the date such maximum price is so de-
14 termined.

15 **“SEC. 1196. ADMINISTRATIVE DUTIES AND COMPLIANCE**
16 **MONITORING.**

17 “(a) *ADMINISTRATIVE DUTIES.*—For purposes of sec-
18 tion 1191(a)(4), the administrative duties described in this
19 section are the following:

20 “(1) The establishment of procedures to ensure
21 that the maximum fair price for a selected drug is
22 applied before—

23 “(A) any coverage or financial assistance
24 under other health benefit plans or programs
25 that provide coverage or financial assistance for

1 *the purchase or provision of prescription drug*
2 *coverage on behalf of maximum fair price eligi-*
3 *ble individuals; and*

4 “(B) *any other discounts.*

5 “(2) *The establishment of procedures to compute*
6 *and apply the maximum fair price across different*
7 *strengths and dosage forms of a selected drug and not*
8 *based on the specific formulation or package size or*
9 *package type of such drug.*

10 “(3) *The establishment of procedures to carry out*
11 *the provisions of this part, as applicable, with respect*
12 *to—*

13 “(A) *maximum fair price eligible individ-*
14 *uals who are enrolled in a prescription drug*
15 *plan under part D of title XVIII or an MA–PD*
16 *plan under part C of such title; and*

17 “(B) *maximum fair price eligible individ-*
18 *uals who are enrolled under part B of such title,*
19 *including who are enrolled in an MA plan under*
20 *part C of such title.*

21 “(4) *The establishment of a negotiation process*
22 *and renegotiation process in accordance with section*
23 *1194.*

1 “(5) *The establishment of a process for manufac-*
2 *turers to submit information described in section*
3 *1194(b)(2)(A).*

4 “(6) *The sharing with the Secretary of the Treas-*
5 *ury of such information as is necessary to determine*
6 *the tax imposed by section 5000D of the Internal Rev-*
7 *enue Code of 1986, including the application of such*
8 *tax to a manufacturer, producer, or importer or the*
9 *determination of any date described in section*
10 *5000D(c)(1) of such Code. For purposes of the pre-*
11 *ceding sentence, such information shall include—*

12 “(A) *the date on which the Secretary re-*
13 *ceives notification of any termination of an*
14 *agreement under the Medicare coverage gap dis-*
15 *count program under section 1860D-14A and the*
16 *date on which any subsequent agreement under*
17 *such program is entered into;*

18 “(B) *the date on which the Secretary re-*
19 *ceives notification of any termination of an*
20 *agreement under the manufacturer discount pro-*
21 *gram under section 1860D-14C and the date on*
22 *which any subsequent agreement under such pro-*
23 *gram is entered into; and*

24 “(C) *the date on which the Secretary re-*
25 *ceives notification of any termination of a rebate*

1 *agreement described in section 1927(b) and the*
2 *date on which any subsequent rebate agreement*
3 *described in such section is entered into.*

4 “(7) *The establishment of procedures for purposes*
5 *of applying section 1192(d)(2)(B).*

6 “(b) *COMPLIANCE MONITORING.—The Secretary shall*
7 *monitor compliance by a manufacturer with the terms of*
8 *an agreement under section 1193 and establish a mecha-*
9 *nism through which violations of such terms shall be re-*
10 *ported.*

11 **“SEC. 1197. CIVIL MONETARY PENALTIES.**

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

19 “(1) *to a maximum fair price eligible individual*
20 *who with respect to such drug is described in sub-*
21 *paragraph (A) of section 1191(c)(2) and who is dis-*
22 *persed such drug during such year (and to phar-*
23 *macies, mail order services, and other dispensers,*
24 *with respect to such maximum fair price eligible in-*
25 *dividuals who are dispensed such drugs); or*

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

8 shall be subject to a civil monetary penalty equal to ten
9 times the amount equal to the product of the number of
10 units of such drug so furnished, dispensed, or administered
11 during such year and the difference between the price for
12 such drug made available for such year by such manufac-
13 turer with respect to such individual or hospital, physician,
14 provider of services, or supplier and the maximum fair
15 price for such drug for such year.

16 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
17 MENT.—Any manufacturer of a selected drug that has en-
18 tered into an agreement under section 1193, with respect
19 to a year during the price applicability period with respect
20 to such drug, that is in violation of a requirement imposed
21 pursuant to section 1193(a)(5), including the requirement
22 to submit information pursuant to section 1193(a)(4), shall
23 be subject to a civil monetary penalty equal to \$1,000,000
24 for each day of such violation.

1 “(c) *FALSE INFORMATION.*—Any manufacturer that
2 knowingly provides false information pursuant to section
3 1196(a)(7) shall be subject to a civil monetary penalty equal
4 to \$100,000,000 for each item of such false information.

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

10 **“SEC. 1198. LIMITATION ON ADMINISTRATIVE AND JUDI-**
11 **CIAL REVIEW.**

12 “*There shall be no administrative or judicial review*
13 *of any of the following:*

14 “(1) *The determination of a unit, with respect to*
15 *a drug or biological product, pursuant to section*
16 *1191(c)(6).*

17 “(2) *The selection of drugs under section 1192(b),*
18 *the determination of negotiation-eligible drugs under*
19 *section 1192(d), and the determination of qualifying*
20 *single source drugs under section 1192(e).*

21 “(3) *The determination of a maximum fair price*
22 *under subsection (b) or (f) of section 1194.*

23 “(4) *The determination of renegotiation-eligible*
24 *drugs under section 1194(f)(2) and the selection of re-*
25 *negotiation-eligible drugs under section 1194(f)(3).”.*

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

3 **(1) UNDER MEDICARE.—**

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

15 **(B) APPLICATION UNDER MA OF COST-**
16 **SHARING FOR PART B DRUGS BASED OFF OF NE-**
17 **GOTIATED PRICE.—***Section 1852(a)(1)(B)(iv) of*
18 *the Social Security Act (42 U.S.C. 1395w–*
19 *22(a)(1)(B)(iv)) is amended—*

20 *(i) by redesignating subclause (VII) as*
21 *subclause (VIII); and*

22 *(ii) by inserting after subclause (VI)*
23 *the following subclause:*

1 “(VII) *A drug or biological prod-*
2 *uct that is a selected drug (as referred*
3 *to in section 1192(c)).*”

4 (C) *EXCEPTION TO PART D NON-INTER-*
5 *ERENCE.—Section 1860D–11(i) of the Social*
6 *Security Act (42 U.S.C. 1395w–111(i)) is*
7 *amended—*

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

10 (ii) *in paragraph (2), by striking “or*
11 *institute a price structure for the reimburse-*
12 *ment of covered part D drugs.” and insert-*
13 *ing “, except as provided under section*
14 *1860D–4(b)(3)(l); and”;* and

15 (iii) *by adding at the end the following*
16 *new paragraph:*

17 “(3) *may not institute a price structure for the*
18 *reimbursement of covered part D drugs, except as pro-*
19 *vided under part E of title XI.*”

20 (D) *APPLICATION AS NEGOTIATED PRICE*
21 *UNDER PART D.—Section 1860D–2(d)(1) of the*
22 *Social Security Act (42 U.S.C. 1395w–*
23 *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 referred to in section*
10 *1192(c)), with respect to a price applicability*
11 *period (as defined in section 1191(b)(2)), the ne-*
12 *gotiated prices used for payment (as described in*
13 *this subsection) shall be no greater than the max-*
14 *imum fair price (as defined in section*
15 *1191(c)(3)) for such drug and for each year dur-*
16 *ing such period plus any dispensing fees for such*
17 *drug.”.*

18 (E) *COVERAGE OF SELECTED DRUGS.—Sec-*
19 *tion 1860D-4(b)(3) of the Social Security Act*
20 *(42 U.S.C. 1395w-104(b)(3)) is amended by*
21 *adding at the end the following new subpara-*
22 *graph:*

23 “(I) *REQUIRED INCLUSION OF SELECTED*
24 *DRUGS.—*

1 “(i) *IN GENERAL.*—For 2026 and each
 2 subsequent year, the PDP sponsor offering a
 3 prescription drug plan shall include each
 4 covered part D drug that is a selected drug
 5 under section 1192 for which a maximum
 6 fair price (as defined in section 1191(c)(3))
 7 is in effect with respect to the year.

8 “(ii) *CLARIFICATION.*—Nothing in
 9 clause (i) shall be construed as prohibiting
 10 a PDP sponsor from removing such a se-
 11 lected drug from a formulary if such re-
 12 moval would be permitted under section
 13 423.120(b)(5)(iv) of title 42, Code of Federal
 14 Regulations (or any successor regulation).”.

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

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

22 “(8) *PROVISION OF INFORMATION RELATED TO*
 23 *MAXIMUM FAIR PRICES.*—Each contract entered into
 24 with a PDP sponsor under this part with respect to
 25 a prescription drug plan offered by such sponsor shall

1 *require the sponsor to provide information to the Sec-*
 2 *retary as requested by the Secretary for purposes of*
 3 *carrying out section 1194.”*

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

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

12 (G) *CONDITIONS FOR COVERAGE.—*

13 (i) *MEDICARE PART D.—Section*
 14 *1860D-43(c) of the Social Security Act (42*
 15 *U.S.C. 1395w-153(c)) is amended—*

16 (I) *by redesignating paragraphs*
 17 *(1) and (2) as subparagraphs (A) and*
 18 *(B), respectively;*

19 (II) *by striking “AGREEMENTS.—*
 20 *Subsection” and inserting the fol-*
 21 *lowing: “AGREEMENTS.—*

22 *“(1) IN GENERAL.—Subject to paragraph (2),*
 23 *subsection”; and*

24 (III) *by adding at the end the fol-*
 25 *lowing new paragraph:*

1 “(2) *EXCEPTION.*—Paragraph (1)(A) shall not
 2 apply to a covered part D drug of a manufacturer for
 3 any period described in section 5000D(c)(1) of the In-
 4 ternal Revenue Code of 1986 with respect to the man-
 5 ufacturer.”.

6 (ii) *MEDICAID AND MEDICARE PART*
 7 *B.*—Section 1927(a)(3) of the Social Secu-
 8 rity Act (42 U.S.C. 1396r–8(a)(3)) is
 9 amended by adding at the end the following
 10 new sentence: “The preceding sentence shall
 11 not apply to a single source drug or inno-
 12 vator multiple source drug of a manufac-
 13 turer for any period described in section
 14 5000D(c)(1) of the Internal Revenue Code of
 15 1986 with respect to the manufacturer.”.

16 (H) *DISCLOSURE OF INFORMATION UNDER*
 17 *MEDICARE PART D.*—

18 (i) *CONTRACT REQUIREMENTS.*—Sec-
 19 tion 1860D–12(b)(3)(D)(i) of the Social Se-
 20 curity Act (42 U.S.C. 1395w–
 21 112(b)(3)(D)(i)) is amended by inserting “,
 22 or carrying out part E of title XI” after
 23 “appropriate”.

24 (ii) *SUBSIDIES.*—Section 1860D–
 25 15(f)(2)(A)(i) of the Social Security Act (42

1 U.S.C. 1395w-115(f)(2)(A)(i) is amended
2 by inserting “or part E of title XI” after
3 “this section”.

4 (2) DRUG PRICE NEGOTIATION PROGRAM PRICES
5 INCLUDED IN BEST PRICE.—Section 1927(c)(1)(C) of
6 the Social Security Act (42 U.S.C. 1396r-8(c)(1)(C))
7 is amended—

8 (A) in clause (i)(VI), by striking “any
9 prices charged” and inserting “subject to clause
10 (ii)(V), any prices charged”; and

11 (B) in clause (ii)—

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

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

17 (iii) by adding at the end the following
18 new subclause:

19 “(V) in the case of a rebate period
20 and a covered outpatient drug that is
21 a selected drug (as referred to in sec-
22 tion 1192(c)) during such rebate pe-
23 riod, shall be inclusive of the max-
24 imum fair price (as defined in section

1 *1191(c)(3)) for such drug with respect*
 2 *to such period.”.*

3 (3) *MAXIMUM FAIR PRICES EXCLUDED FROM AV-*
 4 *ERAGE MANUFACTURER PRICE.—Section*
 5 *1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C.*
 6 *1396r–8(k)(1)(B)(i)) is amended—*

7 (A) *in subclause (IV) by striking “; and” at*
 8 *the end;*

9 (B) *in subclause (V) by striking the period*
 10 *at the end and inserting “; and”; and*

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

13 *“(VI) any reduction in price paid*
 14 *during the rebate period to the manu-*
 15 *facturer for a drug by reason of appli-*
 16 *cation of part E of title XI.”.*

17 (c) *IMPLEMENTATION FOR 2026 THROUGH 2028.—The*
 18 *Secretary of Health and Human Services shall implement*
 19 *this section, including the amendments made by this sec-*
 20 *tion, for 2026, 2027, and 2028 by program instruction or*
 21 *other forms of program guidance.*

1 **SEC. 11002. SPECIAL RULE TO DELAY SELECTION AND NE-**
2 **GOTIATION OF BIOLOGICS FOR BIOSIMILAR**
3 **MARKET ENTRY.**

4 (a) *IN GENERAL.*—*Part E of title XI of the Social Se-*
5 *curity Act, as added by section 11001, is amended—*

6 (1) *in section 1192—*

7 (A) *in subsection (a), in the flush matter*
8 *following paragraph (4), by inserting “and sub-*
9 *section (b)(3)” after “the previous sentence”;*

10 (B) *in subsection (b)—*

11 (i) *in paragraph (1), by adding at the*
12 *end the following new subparagraph:*

13 “(C) *In the case of a biological product for*
14 *which the inclusion of the biological product as*
15 *a selected drug on a list published under sub-*
16 *section (a) has been delayed under subsection*
17 *(f)(2), remove such biological product from the*
18 *rankings under subparagraph (A) before making*
19 *the selections under subparagraph (B).”;* and

20 (ii) *by adding at the end the following*
21 *new paragraph:*

22 “(3) *INCLUSION OF DELAYED BIOLOGICAL PROD-*
23 *UCTS.*—*Pursuant to subparagraphs (B)(ii)(I) and*
24 *(C)(i) of subsection (f)(2), the Secretary shall select*
25 *and include on the list published under subsection (a)*
26 *the biological products described in such subpara-*

1 *graphs. Such biological products shall count towards*
2 *the required number of drugs to be selected under sub-*
3 *section (a)(1).”;* and

4 *(C) by adding at the end the following new*
5 *subsection:*

6 *“(f) SPECIAL RULE TO DELAY SELECTION AND NEGO-*
7 *TIATION OF BIOLOGICS FOR BIOSIMILAR MARKET*
8 *ENTRY.—*

9 *“(1) APPLICATION.—*

10 *“(A) IN GENERAL.—Subject to subpara-*
11 *graph (B), in the case of a biological product*
12 *that would (but for this subsection) be an ex-*
13 *tended-monopoly drug (as defined in section*
14 *1194(c)(4)) included as a selected drug on the*
15 *list published under subsection (a) with respect*
16 *to an initial price applicability year, the rules*
17 *described in paragraph (2) shall apply if the*
18 *Secretary determines that there is a high likeli-*
19 *hood (as described in paragraph (3)) that a bio-*
20 *similar biological product (for which such bio-*
21 *logical product will be the reference product) will*
22 *be licensed and marketed under section 351(k) of*
23 *the Public Health Service Act before the date*
24 *that is 2 years after the selected drug publication*

1 *date with respect to such initial price applica-*
2 *bility year.*

3 “(B) *REQUEST REQUIRED.*—

4 “(i) *IN GENERAL.*—*The Secretary shall*
5 *not provide for a delay under—*

6 “(I) *paragraph (2)(A) unless a re-*
7 *quest is made for such a delay by a*
8 *manufacturer of a biosimilar biological*
9 *product prior to the selected drug pub-*
10 *lication date for the list published*
11 *under subsection (a) with respect to the*
12 *initial price applicability year for*
13 *which the biological product may have*
14 *been included as a selected drug on*
15 *such list but for subparagraph (2)(A);*
16 *or*

17 “(II) *paragraph (2)(B)(iii) unless*
18 *a request is made for such a delay by*
19 *such a manufacturer prior to the se-*
20 *lected drug publication date for the list*
21 *published under subsection (a) with re-*
22 *spect to the initial price applicability*
23 *year that is 1 year after the initial*
24 *price applicability year for which the*
25 *biological product described in sub-*

1 *section (a) would have been included as*
2 *a selected drug on such list but for*
3 *paragraph (2)(A).*

4 “(ii) *INFORMATION AND DOCU-*
5 *MENTS.—*

6 “(I) *IN GENERAL.—A request*
7 *made under clause (i) shall be sub-*
8 *mitted to the Secretary by such manu-*
9 *facturer at a time and in a form and*
10 *manner specified by the Secretary, and*
11 *contain—*

12 “(aa) *information and docu-*
13 *ments necessary for the Secretary*
14 *to make determinations under this*
15 *subsection, as specified by the Sec-*
16 *retary and including, to the ex-*
17 *tent available, items described in*
18 *subclause (III); and*

19 “(bb) *all agreements related*
20 *to the biosimilar biological prod-*
21 *uct filed with the Federal Trade*
22 *Commission or the Assistant At-*
23 *torney General pursuant to sub-*
24 *sections (a) and (c) of section*
25 *1112 of the Medicare Prescription*

1 *Drug, Improvement, and Mod-*
2 *ernization Act of 2003.*

3 “(II) *ADDITIONAL INFORMATION*
4 *AND DOCUMENTS.*—*After the Secretary*
5 *has reviewed the request and materials*
6 *submitted under subclause (I), the*
7 *manufacturer shall submit any addi-*
8 *tional information and documents re-*
9 *quested by the Secretary necessary to*
10 *make determinations under this sub-*
11 *section.*

12 “(III) *ITEMS DESCRIBED.*—*The*
13 *items described in this clause are the*
14 *following:*

15 “(aa) *The manufacturing*
16 *schedule for such biosimilar bio-*
17 *logical product submitted to the*
18 *Food and Drug Administration*
19 *during its review of the applica-*
20 *tion under such section 351(k).*

21 “(bb) *Disclosures (in filings*
22 *by the manufacturer of such bio-*
23 *similar biological product with*
24 *the Securities and Exchange Com-*
25 *mission required under section*

1 12(b), 12(g), 13(a), or 15(d) of the
2 *Securities Exchange Act of 1934*
3 *about capital investment, revenue*
4 *expectations, and actions taken by*
5 *the manufacturer that are typical*
6 *of the normal course of business in*
7 *the year (or the 2 years, as appli-*
8 *cable) before marketing of a bio-*
9 *similar biological product) that*
10 *pertain to the marketing of such*
11 *biosimilar biological product, or*
12 *comparable documentation that is*
13 *distributed to the shareholders of*
14 *privately held companies.*

15 “(C) *AGGREGATION RULE.*—

16 “(i) *IN GENERAL.*—All persons treated
17 as a single employer under subsection (a) or
18 (b) of section 52 of the Internal Revenue
19 Code of 1986, or in a partnership, shall be
20 treated as one manufacturer for purposes of
21 paragraph (2)(D)(iv).

22 “(ii) *PARTNERSHIP DEFINED.*—In
23 clause (i), the term ‘partnership’ means a
24 syndicate, group, pool, joint venture, or
25 other organization through or by means of

1 *which any business, financial operation, or*
2 *venture is carried on by the manufacturer*
3 *of the biological product and the manufac-*
4 *turer of the biosimilar biological product.*

5 “(2) *RULES DESCRIBED.*—*The rules described in*
6 *this paragraph are the following:*

7 “(A) *DELAYED SELECTION AND NEGOTIA-*
8 *TION FOR 1 YEAR.*—*If a determination of high*
9 *likelihood is made under paragraph (3), the Sec-*
10 *retary shall delay the inclusion of the biological*
11 *product as a selected drug on the list published*
12 *under subsection (a) until such list is published*
13 *with respect to the initial price applicability*
14 *year that is 1 year after the initial price appli-*
15 *cability year for which the biological product*
16 *would have been included as a selected drug on*
17 *such list.*

18 “(B) *IF NOT LICENSED AND MARKETED*
19 *DURING THE INITIAL DELAY.*—

20 “(i) *IN GENERAL.*—*If, during the time*
21 *period between the selected drug publication*
22 *date on which the biological product would*
23 *have been included on the list as a selected*
24 *drug pursuant to subsection (a) but for sub-*
25 *paragraph (A) and the selected drug publi-*

1 *cation date with respect to the initial price*
2 *applicability year that is 1 year after the*
3 *initial price applicability year for which*
4 *such biological product would have been in-*
5 *cluded as a selected drug on such list, the*
6 *Secretary determines that the biosimilar bi-*
7 *ological product for which the manufacturer*
8 *submitted the request under paragraph*
9 *(1)(B)(i)(II) (and for which the Secretary*
10 *previously made a high likelihood deter-*
11 *mination under paragraph (3)) has not*
12 *been licensed and marketed under section*
13 *351(k) of the Public Health Service Act, the*
14 *Secretary shall, at the request of such man-*
15 *ufacturer—*

16 *“(I) reevaluate whether there is a*
17 *high likelihood (as described in para-*
18 *graph (3)) that such biosimilar biologi-*
19 *cal product will be licensed and mar-*
20 *keted under such section 351(k) before*
21 *the date that is 2 years after the se-*
22 *lected drug publication date for which*
23 *such biological product would have*
24 *been included as a selected drug on*

1 *such list published but for subpara-*
2 *graph (A); and*

3 “(II) evaluate whether, on the
4 basis of clear and convincing evidence,
5 the manufacturer of such biosimilar bi-
6 ological product has made a significant
7 amount of progress (as determined by
8 the Secretary) towards both such licen-
9 sure and the marketing of such bio-
10 similar biological product (based on
11 information from items described in
12 subclauses (I)(bb) and (II) of para-
13 graph (1)(B)(ii)) since the receipt by
14 the Secretary of the request made by
15 such manufacturer under paragraph
16 (1)(B)(i)(I).

17 “(i) SELECTION AND NEGOTIATION.—
18 If the Secretary determines that there is not
19 a high likelihood that such biosimilar bio-
20 logical product will be licensed and mar-
21 keted as described in clause (i)(I) or there
22 has not been a significant amount of
23 progress as described in clause (i)(II)—

24 “(I) the Secretary shall include
25 the biological product as a selected

1 *drug on the list published under sub-*
2 *section (a) with respect to the initial*
3 *price applicability year that is 1 year*
4 *after the initial price applicability*
5 *year for which such biological product*
6 *would have been included as a selected*
7 *drug on such list but for subparagraph*
8 *(A); and*

9 *“(II) the manufacturer of such bi-*
10 *ological product shall pay a rebate*
11 *under paragraph (4) with respect to*
12 *the year for which such manufacturer*
13 *would have provided access to a max-*
14 *imum fair price for such biological*
15 *product but for subparagraph (A).*

16 *“(iii) SECOND 1-YEAR DELAY.—If the*
17 *Secretary determines that there is a high*
18 *likelihood that such biosimilar biological*
19 *product will be licensed and marketed (as*
20 *described in clause (i)(I)) and a significant*
21 *amount of progress has been made by the*
22 *manufacturer of such biosimilar biological*
23 *product towards such licensure and mar-*
24 *keting (as described in clause (i)(II)), the*
25 *Secretary shall delay the inclusion of the bi-*

1 *ological product as a selected drug on the*
2 *list published under subsection (a) until the*
3 *selected drug publication date of such list*
4 *with respect to the initial price applica-*
5 *bility year that is 2 years after the initial*
6 *price applicability year for which such bio-*
7 *logical product would have been included as*
8 *a selected drug on such list but for this sub-*
9 *section.*

10 *“(C) IF NOT LICENSED AND MARKETED*
11 *DURING THE YEAR TWO DELAY.—If, during the*
12 *time period between the selected drug publication*
13 *date of the list for which the biological product*
14 *would have been included as a selected drug but*
15 *for subparagraph (B)(iii) and the selected drug*
16 *publication date with respect to the initial price*
17 *applicability year that is 2 years after the ini-*
18 *tial price applicability year for which such bio-*
19 *logical product would have been included as a se-*
20 *lected drug on such list but for this subsection,*
21 *the Secretary determines that such biosimilar bi-*
22 *ological product has not been licensed and mar-*
23 *keted—*

24 *“(i) the Secretary shall include such*
25 *biological product as a selected drug on such*

1 *list with respect to the initial price applica-*
2 *bility year that is 2 years after the initial*
3 *price applicability year for which such bio-*
4 *logical product would have been included as*
5 *a selected drug on such list; and*

6 *“(ii) the manufacturer of such biologi-*
7 *cal product shall pay a rebate under para-*
8 *graph (4) with respect to the years for*
9 *which such manufacturer would have pro-*
10 *vided access to a maximum fair price for*
11 *such biological product but for this sub-*
12 *section.*

13 *“(D) LIMITATIONS ON DELAYS.—*

14 *“(i) LIMITED TO 2 YEARS.—In no case*
15 *shall the Secretary delay the inclusion of a*
16 *biological product on the list published*
17 *under subsection (a) for more than 2 years.*

18 *“(ii) EXCLUSION OF BIOLOGICAL*
19 *PRODUCTS THAT TRANSITIONED TO A LONG-*
20 *MONOPOLY DRUG DURING THE DELAY.—In*
21 *the case of a biological product for which*
22 *the inclusion on the list published pursuant*
23 *to subsection (a) was delayed by 1 year*
24 *under subparagraph (A) and for which*
25 *there would have been a change in status to*

1 *a long-monopoly drug (as defined in section*
2 *1194(c)(5)) if such biological product had*
3 *been a selected drug, in no case may the*
4 *Secretary provide for a second 1-year delay*
5 *under subparagraph (B)(iii).*

6 “(iii) *EXCLUSION OF BIOLOGICAL*
7 *PRODUCTS IF MORE THAN 1 YEAR SINCE LI-*
8 *CENSURE.—In no case shall the Secretary*
9 *delay the inclusion of a biological product*
10 *on the list published under subsection (a) if*
11 *more than 1 year has elapsed since the bio-*
12 *similar biological product has been licensed*
13 *under section 351(k) of the Public Health*
14 *Service Act and marketing has not com-*
15 *menced for such biosimilar biological prod-*
16 *uct.*

17 “(iv) *CERTAIN MANUFACTURERS OF*
18 *BIOSIMILAR BIOLOGICAL PRODUCTS EX-*
19 *CLUDED.—In no case shall the Secretary*
20 *delay the inclusion of a biological product*
21 *as a selected drug on the list published*
22 *under subsection (a) if Secretary deter-*
23 *mined that the manufacturer of the bio-*
24 *similar biological product described in*
25 *paragraph (1)(A)—*

1 “(I) is the same as the manufac-
2 turer of the reference product described
3 in such paragraph or is treated as
4 being the same pursuant to paragraph
5 (1)(C); or

6 “(II) has, based on information
7 from items described in paragraph
8 (1)(B)(ii)(I)(bb), entered into any
9 agreement described in such paragraph
10 with the manufacturer of the reference
11 product described in paragraph (1)(A)
12 that—

13 “(aa) requires or incentivizes
14 the manufacturer of the biosimilar
15 biological product to submit a re-
16 quest described in paragraph
17 (1)(B); or

18 “(bb) restricts the quantity
19 (either directly or indirectly) of
20 the biosimilar biological product
21 that may be sold in the United
22 States over a specified period of
23 time.

24 “(3) *HIGH LIKELIHOOD.*—For purposes of this
25 subsection, there is a high likelihood described in

1 paragraph (1) or paragraph (2), as applicable, if the
2 Secretary finds that—

3 “(A) an application for licensure under sec-
4 tion 351(k) of the Public Health Service Act for
5 the biosimilar biological product has been accept-
6 ed for review or approved by the Food and Drug
7 Administration; and

8 “(B) information from items described in
9 sub clauses (I)(bb) and (III) of paragraph
10 (1)(B)(ii) submitted to the Secretary by the
11 manufacturer requesting a delay under such
12 paragraph provides clear and convincing evi-
13 dence that such biosimilar biological product
14 will, within the time period specified under
15 paragraph (1)(A) or (2)(B)(i)(I), be marketed.

16 “(4) REBATE.—

17 “(A) IN GENERAL.—For purposes of sub-
18 paragraphs (B)(ii)(II) and (C)(ii) of paragraph
19 (2), in the case of a biological product for which
20 the inclusion on the list under subsection (a) was
21 delayed under this subsection and for which the
22 Secretary has negotiated and entered into an
23 agreement under section 1193 with respect to
24 such biological product, the manufacturer shall
25 be required to pay a rebate to the Secretary at

1 *such time and in such manner as determined by*
2 *the Secretary.*

3 “(B) *AMOUNT.*—*Subject to subparagraph*
4 *(C), the amount of the rebate under subpara-*
5 *graph (A) with respect to a biological product*
6 *shall be equal to the estimated amount—*

7 “(i) *in the case of a biological product*
8 *that is a covered part D drug (as defined in*
9 *section 1860D–2(e)), that is the sum of the*
10 *products of—*

11 “(I) *75 percent of the amount by*
12 *which—*

13 “(aa) *the average manufac-*
14 *turer price, as reported by the*
15 *manufacturer of such covered part*
16 *D drug under section 1927 (or, if*
17 *not reported by such manufac-*
18 *turer under section 1927, as re-*
19 *ported by such manufacturer to*
20 *the Secretary pursuant to the*
21 *agreement under section 1193(a))*
22 *for such biological product, with*
23 *respect to each of the calendar*
24 *quarters of the price applicability*

1 *period that would have applied*
2 *but for this subsection; exceeds*

3 *“(bb) in the initial price ap-*
4 *plicability year that would have*
5 *applied but for a delay under—*

6 *“(AA) paragraph*
7 *(2)(A), the maximum fair*
8 *price negotiated under sec-*
9 *tion 1194 for such biological*
10 *product under such agree-*
11 *ment; or*

12 *“(BB) paragraph*
13 *(2)(B)(iii), such maximum*
14 *fair price, increased as de-*
15 *scribed in section*
16 *1195(b)(1)(A); and*

17 *“(II) the number of units dis-*
18 *persed under part D of title XVIII for*
19 *such covered part D drug during each*
20 *such calendar quarter of such price ap-*
21 *plicability period; and*

22 *“(ii) in the case of a biological product*
23 *for which payment may be made under*
24 *part B of title XVIII, that is the sum of the*
25 *products of—*

1 “(I) 80 percent of the amount by
2 which—

3 “(aa) the payment amount
4 for such biological product under
5 section 1847A(b), with respect to
6 each of the calendar quarters of
7 the price applicability period that
8 would have applied but for this
9 subsection; exceeds

10 “(bb) in the initial price ap-
11 plicability year that would have
12 applied but for a delay under—

13 “(AA) paragraph
14 (2)(A), the maximum fair
15 price negotiated under sec-
16 tion 1194 for such biological
17 product under such agree-
18 ment; or

19 “(BB) paragraph
20 (2)(B)(iii), such maximum
21 fair price, increased as de-
22 scribed in section
23 1195(b)(1)(A); and

24 “(II) the number of units (exclud-
25 ing units that are packaged into the

1 *payment amount for an item or service*
2 *and are not separately payable under*
3 *such part B) of the billing and pay-*
4 *ment code of such biological product*
5 *administered or furnished under such*
6 *part B during each such calendar*
7 *quarter of such price applicability pe-*
8 *riod.*

9 “(C) *SPECIAL RULE FOR DELAYED BIOLOGI-*
10 *CAL PRODUCTS THAT ARE LONG-MONOPOLY*
11 *DRUGS.—*

12 “(i) *IN GENERAL.—In the case of a bi-*
13 *ological product with respect to which a re-*
14 *bate is required to be paid under this para-*
15 *graph, if such biological product qualifies as*
16 *a long-monopoly drug (as defined in section*
17 *1194(c)(5)) at the time of its inclusion on*
18 *the list published under subsection (a), in*
19 *determining the amount of the rebate for*
20 *such biological product under subparagraph*
21 *(B), the amount described in clause (ii)*
22 *shall be substituted for the maximum fair*
23 *price described in clause (i)(I) or (ii)(I) of*
24 *such subparagraph (B), as applicable.*

1 “(ii) *AMOUNT DESCRIBED.*—*The*
2 *amount described in this clause is an*
3 *amount equal to 65 percent of the average*
4 *non-Federal average manufacturer price for*
5 *the biological product for 2021 (or, in the*
6 *case that there is not an average non-Fed-*
7 *eral average manufacturer price available*
8 *for such biological product for 2021, for the*
9 *first full year following the market entry for*
10 *such biological product), increased by the*
11 *percentage increase in the consumer price*
12 *index for all urban consumers (all items;*
13 *United States city average) from September*
14 *2021 (or December of such first full year*
15 *following the market entry), as applicable,*
16 *to September of the year prior to the se-*
17 *lected drug publication date with respect to*
18 *the initial price applicability year that*
19 *would have applied but for this subsection.*

20 “(D) *REBATE DEPOSITS.*—*Amounts paid as*
21 *rebates under this paragraph shall be deposited*
22 *into—*

23 “(i) *in the case payment is made for*
24 *such biological product under part B of title*
25 *XVIII, the Federal Supplementary Medical*

1 *Insurance Trust Fund established under*
 2 *section 1841; and*

3 “(ii) *in the case such biological prod-*
 4 *uct is a covered part D drug (as defined in*
 5 *section 1860D–2(e)), the Medicare Prescrip-*
 6 *tion Drug Account under section 1860D–16*
 7 *in such Trust Fund.*

8 “(5) *DEFINITIONS OF BIOSIMILAR BIOLOGICAL*
 9 *PRODUCT.—In this subsection, the term ‘biosimilar*
 10 *biological product’ has the meaning given such term*
 11 *in section 1847A(c)(6).”;*

12 (2) *in section 1193(a)(4)—*

13 (A) *in the matter preceding subparagraph*
 14 (A), *by inserting “, and for section 1192(f),”*
 15 *after “section 1194(f)”;*

16 (B) *in subparagraph (A), by striking “and”*
 17 *at the end;*

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

20 “(C) *information that the Secretary re-*
 21 *quires to carry out section 1192(f), including re-*
 22 *bates under paragraph (4) of such section; and”;*

23 (3) *in section 1196(a)(7), by striking “section*
 24 *1192(d)(2)(B)” and inserting “subsections (d)(2)(B)*
 25 *and (f)(1)(C) of section 1192”;*

1 (4) in section 1197—

2 (A) by redesignating subsections (b), (c),
3 and (d) as subsections (c), (d), and (e), respec-
4 tively; and

5 (B) by inserting after subsection (a) the fol-
6 lowing new subsection:

7 “(b) VIOLATIONS RELATING TO PROVIDING RE-
8 BATES.—Any manufacturer that fails to comply with the
9 rebate requirements under section 1192(f)(4) shall be subject
10 to a civil monetary penalty equal to 10 times the amount
11 of the rebate the manufacturer failed to pay under such sec-
12 tion.”; and

13 (5) in section 1198(b)(2), by inserting “the ap-
14 plication of section 1192(f),” after “section 1192(e)”.

15 (b) CONFORMING AMENDMENTS FOR DISCLOSURE OF
16 CERTAIN INFORMATION.—Section 1927(b)(3)(D)(i) of the
17 Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is
18 amended by striking “or to carry out section 1847B” and
19 inserting “or to carry out section 1847B or section 1192(f),
20 including rebates under paragraph (4) of such section”.

21 (c) IMPLEMENTATION FOR 2026 THROUGH 2028.—The
22 Secretary of Health and Human Services shall implement
23 this section, including the amendments made by this sec-
24 tion, for 2026, 2027, and 2028 by program instruction or
25 other forms of program guidance.

1 **SEC. 11003. EXCISE TAX IMPOSED ON DRUG MANUFACTUR-**
 2 **ERS DURING NONCOMPLIANCE PERIODS.**

3 (a) *IN GENERAL.*—*Subtitle D of the Internal Revenue*
 4 *Code of 1986 is amended by adding at the end the following*
 5 *new chapter:*

6 **“CHAPTER 50A—DESIGNATED DRUGS**

“Sec. 5000D. Designated drugs during noncompliance periods.

7 **“SEC. 5000D. DESIGNATED DRUGS DURING NONCOMPLI-**
 8 **ANCE PERIODS.**

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

14 “(1) *such tax, divided by*

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

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

20 “(1) *The period beginning on the March 1st (or,*
 21 *in the case of initial price applicability year 2026,*
 22 *the October 2nd) immediately following the date on*
 23 *which such drug is included on the list published*
 24 *under section 1192(a) of the Social Security Act and*
 25 *ending on the earlier of—*

1 “(A) the first date on which the manufac-
2 turer of such designated drug has in place an
3 agreement described in section 1193(a) of such
4 Act with respect to such drug, or

5 “(B) the date that the Secretary of Health
6 and Human Services has made a determination
7 described in section 1192(c)(1) of such Act with
8 respect to such designated drug.

9 “(2) The period beginning on the November 2nd
10 immediately following the March 1st described in
11 paragraph (1) (or, in the case of initial price appli-
12 cability year 2026, the August 2nd immediately fol-
13 lowing the October 2nd described in such paragraph)
14 and ending on the earlier of—

15 “(A) the first date on which the manufac-
16 turer of such designated drug and the Secretary
17 of Health and Human Services have agreed to a
18 maximum fair price under an agreement de-
19 scribed in section 1193(a) of the Social Security
20 Act, or

21 “(B) the date that the Secretary of Health
22 and Human Services has made a determination
23 described in section 1192(c)(1) of such Act with
24 respect to such designated drug.

1 “(3) *In the case of any designated drug which is*
2 *a selected drug (as defined in section 1192(c) of the*
3 *Social Security Act) that the Secretary of Health and*
4 *Human Services has selected for renegotiation under*
5 *section 1194(f) of such Act, the period beginning on*
6 *the November 2nd of the year that begins 2 years*
7 *prior to the first initial price applicability year of*
8 *the price applicability period for which the maximum*
9 *fair price established pursuant to such renegotiation*
10 *applies and ending on the earlier of—*

11 “(A) *the first date on which the manufac-*
12 *turer of such designated drug has agreed to a re-*
13 *negotiated maximum fair price under such*
14 *agreement, or*

15 “(B) *the date that the Secretary of Health*
16 *and Human Services has made a determination*
17 *described in section 1192(c)(1) of such Act with*
18 *respect to such designated drug.*

19 “(4) *With respect to information that is required*
20 *to be submitted to the Secretary of Health and*
21 *Human Services under an agreement described in sec-*
22 *tion 1193(a) of the Social Security Act, the period be-*
23 *ginning on the date on which such Secretary certifies*
24 *that such information is overdue and ending on the*
25 *date that such information is so submitted.*

1 “(c) *SUSPENSION OF TAX.*—

2 “(1) *IN GENERAL.*—A day shall not be taken
3 into account as a day during a period described in
4 subsection (b) if such day is also a day during the
5 period—

6 “(A) beginning on the first date on which—

7 “(i) the notice of terminations of all
8 applicable agreements of the manufacturer
9 have been received by the Secretary of
10 Health and Human Services, and

11 “(ii) none of the drugs of the manufac-
12 turer of the designated drug are covered by
13 an agreement under section 1860D-14A or
14 1860D-14C of the Social Security Act, and

15 “(B) ending on the last day of February fol-
16 lowing the earlier of—

17 “(i) the first day after the date de-
18 scribed in subparagraph (A) on which the
19 manufacturer enters into any subsequent
20 applicable agreement, or

21 “(ii) the first date any drug of the
22 manufacturer of the designated drug is cov-
23 ered by an agreement under section 1860D-
24 14A or 1860D-14C of the Social Security
25 Act.

1 “(2) *APPLICABLE AGREEMENT.*—For purposes of
2 this subsection, the term ‘applicable agreement’ means
3 the following:

4 “(A) An agreement under—

5 “(i) the Medicare coverage gap dis-
6 count program under section 1860D-14A of
7 the Social Security Act, or

8 “(ii) the manufacturer discount pro-
9 gram under section 1860D-14C of such Act.

10 “(B) A rebate agreement described in sec-
11 tion 1927(b) of such Act.

12 “(d) *APPLICABLE PERCENTAGE.*—For purposes of this
13 section, the term ‘applicable percentage’ means—

14 “(1) in the case of sales of a designated drug
15 during the first 90 days described in subsection (b)
16 with respect to such drug, 65 percent,

17 “(2) in the case of sales of such drug during the
18 91st day through the 180th day described in sub-
19 section (b) with respect to such drug, 75 percent,

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

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

25 “(e) *DEFINITIONS.*—For purposes of this section—

1 “(1) *DESIGNATED DRUG.*—*The term ‘designated*
2 *drug’ means any negotiation-eligible drug (as defined*
3 *in section 1192(d) of the Social Security Act) in-*
4 *cluded on the list published under section 1192(a) of*
5 *such Act which is manufactured or produced in the*
6 *United States or entered into the United States for*
7 *consumption, use, or warehousing.*

8 “(2) *UNITED STATES.*—*The term ‘United States’*
9 *has the meaning given such term by section*
10 *4612(a)(4).*

11 “(3) *OTHER TERMS.*—*The terms ‘initial price*
12 *applicability year’, ‘price applicability period’, and*
13 *‘maximum fair price’ have the meaning given such*
14 *terms in section 1191 of the Social Security Act.*

15 “(f) *SPECIAL RULES.*—

16 “(1) *COORDINATION WITH RULES FOR POSSES-*
17 *SIONS OF THE UNITED STATES.*—*Rules similar to the*
18 *rules of paragraphs (2) and (4) of section 4132(c)*
19 *shall apply for purposes of this section.*

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

1 “(g) *EXPORTS.*—*Rules similar to the rules of section*
2 *4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall*
3 *apply for purposes of this chapter.*

4 “(h) *REGULATIONS.*—*The Secretary shall prescribe*
5 *such regulations and other guidance as may be necessary*
6 *to carry out this section.”.*

7 “(b) *NO DEDUCTION FOR EXCISE TAX PAYMENTS.*—
8 *Section 275(a)(6) of the Internal Revenue Code of 1986 is*
9 *amended by inserting “50A,” after “46,”.*

10 “(c) *CLERICAL AMENDMENT.*—*The table of chapters for*
11 *subtitle D of the Internal Revenue Code of 1986 is amended*
12 *by adding at the end the following new item:*

“CHAPTER 50A—DESIGNATED DRUGS”.

13 “(d) *EFFECTIVE DATE.*—*The amendments made by this*
14 *section shall apply to sales after the date of the enactment*
15 *of this Act.*

16 **SEC. 11004. FUNDING.**

17 *In addition to amounts otherwise available, there is*
18 *appropriated to the Centers for Medicare & Medicaid Serv-*
19 *ices, out of any money in the Treasury not otherwise appro-*
20 *priated, \$3,000,000,000 for fiscal year 2022, to remain*
21 *available until expended, to carry out the provisions of, in-*
22 *cluding the amendments made by, this part.*

1 **PART 2—PRESCRIPTION DRUG INFLATION**
2 **REBATES**

3 **SEC. 11101. MEDICARE PART B REBATE BY MANUFACTUR-**
4 **ERS.**

5 (a) *IN GENERAL.*—Section 1847A of the Social Secu-
6 *rity Act (42 U.S.C. 1395w–3a) is amended by redesignating*
7 *subsection (i) as subsection (j) and by inserting after sub-*
8 *section (h) the following subsection:*

9 “(i) *REBATE BY MANUFACTURERS FOR SINGLE*
10 *SOURCE DRUGS AND BIOLOGICALS WITH PRICES INCREAS-*
11 *ING FASTER THAN INFLATION.*—

12 “(1) *REQUIREMENTS.*—

13 “(A) *SECRETARIAL PROVISION OF INFORMA-*
14 *TION.*—*Not later than 6 months after the end of*
15 *each calendar quarter beginning on or after Jan-*
16 *uary 1, 2023, the Secretary shall, for each part*
17 *B rebatable drug, report to each manufacturer of*
18 *such part B rebatable drug the following for such*
19 *calendar quarter:*

20 “(i) *Information on the total number*
21 *of units of the billing and payment code de-*
22 *scribed in subparagraph (A)(i) of para-*
23 *graph (3) with respect to such drug and cal-*
24 *endar quarter.*

25 “(ii) *Information on the amount (if*
26 *any) of the excess average sales price in-*

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

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

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

17 “(C) *TRANSITION RULE FOR REPORTING.*—
18 The Secretary may, for each part B rebtable
19 drug, delay the timeframe for reporting the in-
20 formation described in subparagraph (A) for cal-
21 endar quarters beginning in 2023 and 2024
22 until not later than September 30, 2025.

23 “(2) *PART B REBTABLE DRUG DEFINED.*—

24 “(A) *IN GENERAL.*—In this subsection, the
25 term ‘part B rebtable drug’ means a single

1 source drug or biological (as defined in subpara-
2 graph (D) of subsection (c)(6)), including a bio-
3 similar biological product (as defined in sub-
4 paragraph (H) of such subsection) but excluding
5 a qualifying biosimilar biological product (as de-
6 fined in subsection (b)(8)(B)(iii)), for which
7 payment is made under this part, except such
8 term shall not include such a drug or biologi-
9 cal—

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

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

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

20 “(i) for 2024, shall be the dollar
21 amount specified under such subparagraph
22 for 2023, increased by the percentage in-
23 crease in the consumer price index for all
24 urban consumers (United States city aver-

1 *age) for the 12-month period ending with*
2 *June of the previous year; and*

3 “(ii) *for a subsequent year, shall be the*
4 *dollar amount specified in this clause (or*
5 *clause (i)) for the previous year (without*
6 *application of subparagraph (C)), increased*
7 *by the percentage increase in the consumer*
8 *price index for all urban consumers (United*
9 *States city average) for the 12-month period*
10 *ending with June of the previous year.*

11 “(C) *ROUNDING.—Any dollar amount deter-*
12 *mined under subparagraph (B) that is not a*
13 *multiple of \$10 shall be rounded to the nearest*
14 *multiple of \$10.*

15 “(3) *REBATE AMOUNT.—*

16 “(A) *IN GENERAL.—For purposes of para-*
17 *graph (1), the amount specified in this para-*
18 *graph for a part B rebatable drug assigned to a*
19 *billing and payment code for a calendar quarter*
20 *is, subject to subparagraphs (B) and (G) and*
21 *paragraph (4), the estimated amount equal to*
22 *the product of—*

23 “(i) *the total number of units deter-*
24 *mined under subparagraph (B) for the bill-*
25 *ing and payment code of such drug; and*

1 “(ii) the amount (if any) by which—

2 “(I) the amount equal to—

3 “(aa) in the case of a part B

4 rebatable drug described in para-

5 graph (1)(B) of subsection (b),

6 106 percent of the amount deter-

7 mined under paragraph (4) of

8 such section for such drug during

9 the calendar quarter; or

10 “(bb) in the case of a part B

11 rebatable drug described in para-

12 graph (1)(C) of such subsection,

13 the payment amount under such

14 paragraph for such drug during

15 the calendar quarter; exceeds

16 “(II) the inflation-adjusted pay-

17 ment amount determined under sub-

18 paragraph (C) for such part B

19 rebatable drug during the calendar

20 quarter.

21 “(B) TOTAL NUMBER OF UNITS.—For pur-

22 poses of subparagraph (A)(i), the total number of

23 units for the billing and payment code with re-

24 spect to a part B rebatable drug furnished dur-

1 *ing a calendar quarter described in subpara-*
2 *graph (A) is equal to—*

3 *“(i) the number of units for the billing*
4 *and payment code of such drug furnished*
5 *during such calendar quarter, minus*

6 *“(ii) the number of units for such bill-*
7 *ing and payment code of such drug fur-*
8 *nished during such calendar quarter—*

9 *“(I) with respect to which the*
10 *manufacturer provides a discount*
11 *under the program under section 340B*
12 *of the Public Health Service Act or a*
13 *rebate under section 1927; or*

14 *“(II) that are packaged into the*
15 *payment amount for an item or service*
16 *and are not separately payable.*

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

22 *“(i) the payment amount for the bill-*
23 *ing and payment code for such drug in the*
24 *payment amount benchmark quarter (as de-*
25 *finied in subparagraph (D)); increased by*

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

6 “(D) PAYMENT AMOUNT BENCHMARK QUAR-
7 TER.—The term ‘payment amount benchmark
8 quarter’ means the calendar quarter beginning
9 July 1, 2021.

10 “(E) BENCHMARK PERIOD CPI-U.—The
11 term ‘benchmark period CPI-U’ means the con-
12 sumer price index for all urban consumers
13 (United States city average) for January 2021.

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

23 “(G) REDUCTION OR WAIVER FOR SHORT-
24 AGES AND SEVERE SUPPLY CHAIN DISRUP-
25 TIONS.—The Secretary shall reduce or waive the

1 *amount under subparagraph (A) with respect to*
2 *a part B rebatable drug and a calendar quar-*
3 *ter—*

4 “(i) *in the case of a part B rebatable*
5 *drug that is described as currently in short-*
6 *age on the shortage list in effect under sec-*
7 *tion 506E of the Federal Food, Drug, and*
8 *Cosmetic Act at any point during the cal-*
9 *endar quarter; or*

10 “(ii) *in the case of a biosimilar bio-*
11 *logical product, when the Secretary deter-*
12 *mines there is a severe supply chain disrup-*
13 *tion during the calendar quarter, such as*
14 *that caused by a natural disaster or other*
15 *unique or unexpected event.*

16 “(4) *SPECIAL TREATMENT OF CERTAIN DRUGS*
17 *AND EXEMPTION.—*

18 “(A) *SUBSEQUENTLY APPROVED DRUGS.—*
19 *In the case of a part B rebatable drug first ap-*
20 *proved or licensed by the Food and Drug Admin-*
21 *istration after December 1, 2020, clause (i) of*
22 *paragraph (3)(C) shall be applied as if the term*
23 *‘payment amount benchmark quarter’ were de-*
24 *finied under paragraph (3)(D) as the third full*
25 *calendar quarter after the day on which the drug*

1 *was first marketed and clause (ii) of paragraph*
2 *(3)(C) shall be applied as if the term ‘benchmark*
3 *period CPI–U’ were defined under paragraph*
4 *(3)(E) as if the reference to ‘January 2021’*
5 *under such paragraph were a reference to ‘the*
6 *first month of the first full calendar quarter after*
7 *the day on which the drug was first marketed’.*

8 “(B) *TIMELINE FOR PROVISION OF REBATES*
9 *FOR SUBSEQUENTLY APPROVED DRUGS.—In the*
10 *case of a part B rebatable drug first approved or*
11 *licensed by the Food and Drug Administration*
12 *after December 1, 2020, paragraph (1)(B) shall*
13 *be applied as if the reference to ‘January 1,*
14 *2023’ under such paragraph were a reference to*
15 *‘the later of the 6th full calendar quarter after*
16 *the day on which the drug was first marketed or*
17 *January 1, 2023’.*

18 “(C) *SELECTED DRUGS.—In the case of a*
19 *part B rebatable drug that is a selected drug (as*
20 *defined in section 1192(c)) with respect to a*
21 *price applicability period (as defined in section*
22 *1191(b)(2)), in the case such drug is no longer*
23 *considered to be a selected drug under section*
24 *1192(c), for each applicable period (as defined*
25 *under subsection (g)(7)) beginning after the price*

1 *applicability period with respect to such drug,*
2 *clause (i) of paragraph (3)(C) shall be applied as*
3 *if the term ‘payment amount benchmark quarter’*
4 *were defined under paragraph (3)(D) as the cal-*
5 *endar quarter beginning January 1 of the last*
6 *year during such price applicability period with*
7 *respect to such selected drug and clause (ii) of*
8 *paragraph (3)(C) shall be applied as if the term*
9 *‘benchmark period CPI-U’ were defined under*
10 *paragraph (3)(E) as if the reference to ‘January*
11 *2021’ under such paragraph were a reference to*
12 *‘the July of the year preceding such last year’.*

13 “(5) *APPLICATION TO BENEFICIARY COINSUR-*
14 *ANCE.—In the case of a part B rebatable drug fur-*
15 *nished on or after April 1, 2023, if the payment*
16 *amount described in paragraph (3)(A)(ii)(I) (or, in*
17 *the case of a part B rebatable drug that is a selected*
18 *drug (as defined in section 1192(c)), the payment*
19 *amount described in subsection (b)(1)(B) for such*
20 *drug) for a calendar quarter exceeds the inflation ad-*
21 *justed payment for such quarter—*

22 “(A) *in computing the amount of any coin-*
23 *surance applicable under this part to an indi-*
24 *vidual to whom such drug is furnished, the com-*
25 *putation of such coinsurance shall be equal to 20*

1 *percent of the inflation-adjusted payment*
2 *amount determined under paragraph (3)(C) for*
3 *such part B rebatable drug; and*

4 *“(B) the amount of such coinsurance for*
5 *such calendar quarter, as computed under sub-*
6 *paragraph (A), shall be applied as a percent, as*
7 *determined by the Secretary, to the payment*
8 *amount that would otherwise apply under sub-*
9 *paragraphs (B) or (C) of subsection (b)(1).*

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

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

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

4 “(8) *LIMITATION ON ADMINISTRATIVE OR JUDI-*
 5 *CIAL REVIEW.—There shall be no administrative or*
 6 *judicial review of any of the following:*

7 “(A) *The determination of units under this*
 8 *subsection.*

9 “(B) *The determination of whether a drug*
 10 *is a part B rebatable drug under this subsection.*

11 “(C) *The calculation of the rebate amount*
 12 *under this subsection.*

13 “(D) *The computation of coinsurance under*
 14 *paragraph (5) of this subsection.*

15 “(E) *The computation of amounts paid*
 16 *under section 1833(a)(1)(EE).”.*

17 (b) *AMOUNTS PAYABLE; COST-SHARING.—Section*
 18 *1833 of the Social Security Act (42 U.S.C. 1395l) is amend-*
 19 *ed—*

20 *(1) in subsection (a)(1)—*

21 *(A) in subparagraph (G), by inserting “,*
 22 *subject to subsection (i)(9),” after “the amounts*
 23 *paid”;*

1 (B) in subparagraph (S), by striking “with
2 respect to” and inserting “subject to subpara-
3 graph (EE), with respect to”;

4 (C) by striking “and (DD)” and inserting
5 “(DD)”; and

6 (D) by inserting before the semicolon at the
7 end the following: “, and (EE) with respect to a
8 part B rebatable drug (as defined in paragraph
9 (2) of section 1847A(i)) furnished on or after
10 April 1, 2023, for which the payment amount for
11 a calendar quarter under paragraph
12 (3)(A)(ii)(I) of such section (or, in the case of a
13 part B rebatable drug that is a selected drug (as
14 defined in section 1192(c) for which, the pay-
15 ment amount described in section
16 1847A(b)(1)(B)) for such drug for such quarter
17 exceeds the inflation-adjusted payment under
18 paragraph (3)(A)(ii)(II) of such section for such
19 quarter, the amounts paid shall be equal to the
20 percent of the payment amount under paragraph
21 (3)(A)(ii)(I) of such section or section
22 1847A(b)(1)(B), as applicable, that equals the
23 difference between (i) 100 percent, and (ii) the
24 percent applied under section 1847A(i)(5)(B)”;

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

3 “(9) In the case of a part B rebatable drug (as defined
4 in paragraph (2) of section 1847A(i)) for which payment
5 under this subsection is not packaged into a payment for
6 a service furnished on or after April 1, 2023, under the re-
7 vised payment system under this subsection, in lieu of cal-
8 culation of coinsurance and the amount of payment other-
9 wise applicable under this subsection, the provisions of sec-
10 tion 1847A(i)(5) and paragraph (1)(EE) of subsection (a),
11 shall, as determined appropriate by the Secretary, apply
12 under this subsection in the same manner as such provi-
13 sions of section 1847A(i)(5) and subsection (a) apply under
14 such section and subsection.”; and

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

17 “(F) PART B REBATABLE DRUGS.—In the
18 case of a part B rebatable drug (as defined in
19 paragraph (2) of section 1847A(i), except if such
20 drug does not have a copayment amount as a re-
21 sult of application of subparagraph (E)) for
22 which payment under this part is not packaged
23 into a payment for a covered OPD service (or
24 group of services) furnished on or after April 1,
25 2023, and the payment for such drug under this

1 *subsection is the same as the amount for a cal-*
 2 *endar quarter under paragraph (3)(A)(ii)(I) of*
 3 *section 1847A(i), under the system under this*
 4 *subsection, in lieu of calculation of the copay-*
 5 *ment amount and the amount of payment other-*
 6 *wise applicable under this subsection (other than*
 7 *the application of the limitation described in*
 8 *subparagraph (C)), the provisions of section*
 9 *1847A(i)(5) and paragraph (1)(EE) of sub-*
 10 *section (a), shall, as determined appropriate by*
 11 *the Secretary, apply under this subsection in the*
 12 *same manner as such provisions of section*
 13 *1847A(i)(5) and subsection (a) apply under such*
 14 *section and subsection.”.*

15 *(c) CONFORMING AMENDMENTS.—*

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

20 *(2) EXCLUDING PART B DRUG INFLATION RE-*
 21 *BATE FROM BEST PRICE.—Section*
 22 *1927(c)(1)(C)(ii)(I) of the Social Security Act (42*
 23 *U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by insert-*
 24 *ing “or section 1847A(i)” after “this section”.*

1 *including the amendments made by, this section in each*
2 *of fiscal years 2023 through 2031, to remain available until*
3 *expended.*

4 **SEC. 11102. MEDICARE PART D REBATE BY MANUFACTUR-**
5 **ERS.**

6 *(a) IN GENERAL.—Part D of title XVIII of the Social*
7 *Security Act is amended by inserting after section 1860D–*
8 *14A (42 U.S.C. 1395w–114a) the following new section:*

9 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
10 **DRUGS WITH PRICES INCREASING FASTER**
11 **THAN INFLATION.**

12 *“(a) REQUIREMENTS.—*

13 *“(1) SECRETARIAL PROVISION OF INFORMA-*
14 *TION.—Not later than 9 months after the end of each*
15 *applicable period (as defined in subsection (g)(7)),*
16 *subject to paragraph (3), the Secretary shall, for each*
17 *part D rebatable drug, report to each manufacturer of*
18 *such part D rebatable drug the following for such pe-*
19 *riod:*

20 *“(A) The amount (if any) of the excess an-*
21 *ual manufacturer price increase described in*
22 *subsection (b)(1)(A)(ii) for each dosage form and*
23 *strength with respect to such drug and period.*

1 “(B) *The rebate amount specified under*
2 *subsection (b) for each dosage form and strength*
3 *with respect to such drug and period.*

4 “(2) *MANUFACTURER REQUIREMENTS.—For each*
5 *applicable period, the manufacturer of a part D*
6 *rebtable drug, for each dosage form and strength*
7 *with respect to such drug, not later than 30 days after*
8 *the date of receipt from the Secretary of the informa-*
9 *tion described in paragraph (1) for such period, shall*
10 *provide to the Secretary a rebate that is equal to the*
11 *amount specified in subsection (b) for such dosage*
12 *form and strength with respect to such drug for such*
13 *period.*

14 “(3) *TRANSITION RULE FOR REPORTING.—The*
15 *Secretary may, for each rebtable covered part D*
16 *drug, delay the timeframe for reporting the informa-*
17 *tion and rebate amount described in subparagraphs*
18 *(A) and (B) of such paragraph for the applicable pe-*
19 *riods beginning October 1, 2022, and October 1, 2023,*
20 *until not later than December 31, 2025.*

21 “(b) *REBATE AMOUNT.—*

22 “(1) *IN GENERAL.—*

23 “(A) *CALCULATION.—For purposes of this*
24 *section, the amount specified in this subsection*
25 *for a dosage form and strength with respect to a*

1 *part D rebatable drug and applicable period is,*
2 *subject to subparagraph (C), paragraph (5)(B),*
3 *and paragraph (6), the estimated amount equal*
4 *to the product of—*

5 “(i) *subject to subparagraph (B) of this*
6 *paragraph, the total number of units of*
7 *such dosage form and strength for each*
8 *rebatable covered part D drug dispensed*
9 *under this part during the applicable pe-*
10 *riod; and*

11 “(ii) *the amount (if any) by which—*

12 “(I) *the annual manufacturer*
13 *price (as determined in paragraph (2))*
14 *paid for such dosage form and strength*
15 *with respect to such part D rebatable*
16 *drug for the period; exceeds*

17 “(II) *the inflation-adjusted pay-*
18 *ment amount determined under para-*
19 *graph (3) for such dosage form and*
20 *strength with respect to such part D*
21 *rebatable drug for the period.*

22 “(B) *EXCLUDED UNITS.—For purposes of*
23 *subparagraph (A)(i), beginning with plan year*
24 *2026, the Secretary shall exclude from the total*
25 *number of units for a dosage form and strength*

1 *with respect to a part D rebatable drug, with re-*
2 *spect to an applicable period, units of each dos-*
3 *age form and strength of such part D rebatable*
4 *drug for which the manufacturer provides a dis-*
5 *count under the program under section 340B of*
6 *the Public Health Service Act.*

7 “(C) *REDUCTION OR WAIVER FOR SHORT-*
8 *AGES AND SEVERE SUPPLY CHAIN DISRUP-*
9 *TIONS.—The Secretary shall reduce or waive the*
10 *amount under subparagraph (A) with respect to*
11 *a part D rebatable drug and an applicable pe-*
12 *riod—*

13 “(i) *in the case of a part D rebatable*
14 *drug that is described as currently in short-*
15 *age on the shortage list in effect under sec-*
16 *tion 506E of the Federal Food, Drug, and*
17 *Cosmetic Act at any point during the appli-*
18 *cable period;*

19 “(ii) *in the case of a generic part D*
20 *rebatable drug (described in subsection*
21 *(g)(1)(C)(ii)) or a biosimilar (defined as a*
22 *biological product licensed under section*
23 *351(k) of the Public Health Service Act),*
24 *when the Secretary determines there is a se-*
25 *vere supply chain disruption during the ap-*

1 *plicable period, such as that caused by a*
2 *natural disaster or other unique or unex-*
3 *pected event; and*

4 *“(iii) in the case of a generic Part D*
5 *rebtable drug (as so described), if the Sec-*
6 *retary determines that without such reduc-*
7 *tion or waiver, the drug is likely to be de-*
8 *scribed as in shortage on such shortage list*
9 *during a subsequent applicable period.*

10 *“(2) DETERMINATION OF ANNUAL MANUFAC-*
11 *TURER PRICE.—The annual manufacturer price de-*
12 *termined under this paragraph for a dosage form and*
13 *strength, with respect to a part D rebtable drug and*
14 *an applicable period, is the sum of the products of—*

15 *“(A) the average manufacturer price (as de-*
16 *finned in subsection (g)(6)) of such dosage form*
17 *and strength, as calculated for a unit of such*
18 *drug, with respect to each of the calendar quar-*
19 *ters of such period; and*

20 *“(B) the ratio of—*

21 *“(i) the total number of units of such*
22 *dosage form and strength reported under*
23 *section 1927 with respect to each such cal-*
24 *endar quarter of such period; to*

1 “(ii) the total number of units of such
2 dosage form and strength reported under
3 section 1927 with respect to such period, as
4 determined by the Secretary.

5 “(3) DETERMINATION OF INFLATION-ADJUSTED
6 PAYMENT AMOUNT.—The inflation-adjusted payment
7 amount determined under this paragraph for a dos-
8 age form and strength with respect to a part D
9 rebtable drug for an applicable period, subject to
10 paragraph (5), is—

11 “(A) the benchmark period manufacturer
12 price determined under paragraph (4) for such
13 dosage form and strength with respect to such
14 drug and period; increased by

15 “(B) the percentage by which the applicable
16 period CPI-U (as defined in subsection (g)(5))
17 for the period exceeds the benchmark period
18 CPI-U (as defined in subsection (g)(4)).

19 “(4) DETERMINATION OF BENCHMARK PERIOD
20 MANUFACTURER PRICE.—The benchmark period man-
21 ufacturer price determined under this paragraph for
22 a dosage form and strength, with respect to a part D
23 rebtable drug and an applicable period, is the sum
24 of the products of—

1 “(A) *the average manufacturer price (as de-*
 2 *defined in subsection (g)(6)) of such dosage form*
 3 *and strength, as calculated for a unit of such*
 4 *drug, with respect to each of the calendar quar-*
 5 *ters of the payment amount benchmark period*
 6 *(as defined in subsection (g)(3)); and*

7 “(B) *the ratio of—*

8 “(i) *the total number of units reported*
 9 *under section 1927 of such dosage form and*
 10 *strength with respect to each such calendar*
 11 *quarter of such payment amount benchmark*
 12 *period; to*

13 “(ii) *the total number of units reported*
 14 *under section 1927 of such dosage form and*
 15 *strength with respect to such payment*
 16 *amount benchmark period.*

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

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

20 *In the case of a part D rebatable drug first ap-*
 21 *proved or licensed by the Food and Drug Admin-*
 22 *istration after October 1, 2021, subparagraphs*
 23 *(A) and (B) of paragraph (4) shall be applied as*
 24 *if the term ‘payment amount benchmark period’*
 25 *were defined under subsection (g)(3) as the first*

1 *calendar year beginning after the day on which*
2 *the drug was first marketed and subparagraph*
3 *(B) of paragraph (3) shall be applied as if the*
4 *term ‘benchmark period CPI-U’ were defined*
5 *under subsection (g)(4) as if the reference to*
6 *‘January 2021’ under such subsection were a ref-*
7 *erence to ‘January of the first year beginning*
8 *after the date on which the drug was first mar-*
9 *keted’.*

10 “(B) *TREATMENT OF NEW FORMULA-*
11 *TIONS.—*

12 “(i) *IN GENERAL.—In the case of a*
13 *part D rebatable drug that is a line exten-*
14 *sion of a part D rebatable drug that is an*
15 *oral solid dosage form, the Secretary shall*
16 *establish a formula for determining the re-*
17 *bate amount under paragraph (1) and the*
18 *inflation adjusted payment amount under*
19 *paragraph (3) with respect to such part D*
20 *rebatable drug and an applicable period,*
21 *consistent with the formula applied under*
22 *subsection (c)(2)(C) of section 1927 for de-*
23 *termining a rebate obligation for a rebate*
24 *period under such section.*

1 “(ii) *LINE EXTENSION DEFINED.*—*In*
2 *this subparagraph, the term ‘line extension’*
3 *means, with respect to a part D rebatable*
4 *drug, a new formulation of the drug, such*
5 *as an extended release formulation, but does*
6 *not include an abuse-deterrent formulation*
7 *of the drug (as determined by the Sec-*
8 *retary), regardless of whether such abuse-de-*
9 *terrent formulation is an extended release*
10 *formulation.*

11 “(C) *SELECTED DRUGS.*—*In the case of a*
12 *part D rebatable drug that is a selected drug (as*
13 *defined in section 1192(c)) with respect to a*
14 *price applicability period (as defined in section*
15 *1191(b)(2)), in the case such drug is no longer*
16 *considered to be a selected drug under section*
17 *1192(c), for each applicable period (as defined*
18 *under subsection (g)(7)) beginning after the price*
19 *applicability period with respect to such drug,*
20 *subparagraphs (A) and (B) of paragraph (4)*
21 *shall be applied as if the term ‘payment amount*
22 *benchmark period’ were defined under subsection*
23 *(g)(3) as the last year beginning during such*
24 *price applicability period with respect to such*
25 *selected drug and subparagraph (B) of para-*

1 *graph (3) shall be applied as if the term ‘bench-*
2 *mark period CPI–U’ were defined under sub-*
3 *section (g)(4) as if the reference to ‘January*
4 *2021’ under such subsection were a reference to*
5 *‘January of the last year beginning during such*
6 *price applicability period with respect to such*
7 *drug’.*

8 “(6) *RECONCILIATION IN CASE OF REVISED IN-*
9 *FORMATION.—The Secretary shall provide for a meth-*
10 *od and process under which, in the case where a PDP*
11 *sponsor of a prescription drug plan or an MA organi-*
12 *zation offering an MA–PD plan submits revisions to*
13 *the number of units of a rebatable covered part D*
14 *drug dispensed, the Secretary determines, pursuant to*
15 *such revisions, adjustments, if any, to the calculation*
16 *of the amount specified in this subsection for a dosage*
17 *form and strength with respect to such part D*
18 *rebatable drug and an applicable period and rec-*
19 *onciles any overpayments or underpayments in*
20 *amounts paid as rebates under this subsection. Any*
21 *identified underpayment shall be rectified by the*
22 *manufacturer not later than 30 days after the date of*
23 *receipt from the Secretary of information on such un-*
24 *derpayment.*

1 “(c) *REBATE DEPOSITS.*—Amounts paid as rebates
2 under subsection (b) shall be deposited into the Medicare
3 Prescription Drug Account in the Federal Supplementary
4 Medical Insurance Trust Fund established under section
5 1841.

6 “(d) *INFORMATION.*—For purposes of carrying out this
7 section, the Secretary shall use information submitted by—

8 “(1) manufacturers under section 1927(b)(3);

9 “(2) States under section 1927(b)(2)(A); and

10 “(3) PDP sponsors of prescription drug plans
11 and MA organization offering MA–PD plans under
12 this part.

13 “(e) *CIVIL MONEY PENALTY.*—If a manufacturer of a
14 part D rebatable drug has failed to comply with the require-
15 ment under subsection (a)(2) with respect to such drug for
16 an applicable period, the manufacturer shall be subject to
17 a civil money penalty in an amount equal to 125 percent
18 of the amount specified in subsection (b) for such drug for
19 such period. The provisions of section 1128A (other than
20 subsections (a) (with respect to amounts of penalties or ad-
21 ditional assessments) and (b)) shall apply to a civil money
22 penalty under this subsection in the same manner as such
23 provisions apply to a penalty or proceeding under section
24 1128A(a).

1 “(f) *LIMITATION ON ADMINISTRATIVE OR JUDICIAL*
2 *REVIEW.*—*There shall be no administrative or judicial re-*
3 *view of any of the following:*

4 “(1) *The determination of units under this sec-*
5 *tion.*

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

8 “(3) *The calculation of the rebate amount under*
9 *this section.*

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

11 “(1) *PART D REBATABLE DRUG.*—

12 “(A) *IN GENERAL.*—*Except as provided in*
13 *subparagraph (B), the term ‘part D rebatable*
14 *drug’ means, with respect to an applicable pe-*
15 *riod, a drug or biological described in subpara-*
16 *graph (C) that is a covered part D drug (as such*
17 *term is defined under section 1860D–2(e)).*

18 “(B) *EXCLUSION.*—

19 “(i) *IN GENERAL.*—*Such term shall,*
20 *with respect to an applicable period, not in-*
21 *clude a drug or biological if the average an-*
22 *nuual total cost under this part for such pe-*
23 *riod per individual who uses such a drug or*
24 *biological, as determined by the Secretary,*
25 *is less than, subject to clause (ii), \$100, as*

1 *determined by the Secretary using the most*
2 *recent data available or, if data is not*
3 *available, as estimated by the Secretary.*

4 “(ii) *INCREASE.—The dollar amount*
5 *applied under clause (i)—*

6 “(I) *for the applicable period be-*
7 *ginning October 1, 2023, shall be the*
8 *dollar amount specified under such*
9 *clause for the applicable period begin-*
10 *ning October 1, 2022, increased by the*
11 *percentage increase in the consumer*
12 *price index for all urban consumers*
13 *(United States city average) for the 12-*
14 *month period beginning with October*
15 *of 2023; and*

16 “(II) *for a subsequent applicable*
17 *period, shall be the dollar amount spec-*
18 *ified in this clause for the previous ap-*
19 *plicable period, increased by the per-*
20 *centage increase in the consumer price*
21 *index for all urban consumers (United*
22 *States city average) for the 12-month*
23 *period beginning with October of the*
24 *previous period.*

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

4 “(C) *DRUG OR BIOLOGICAL DESCRIBED.*—A
5 *drug or biological described in this subparagraph*
6 *is a drug or biological that, as of the first day*
7 *of the applicable period involved, is—*

8 “(i) *a drug approved under a new*
9 *drug application under section 505(c) of the*
10 *Federal Food, Drug, and Cosmetic Act;*

11 “(ii) *a drug approved under an abbrevi-*
12 *ated new drug application under section*
13 *505(j) of the Federal Food, Drug, and Cos-*
14 *metic Act, in the case where—*

15 “(I) *the reference listed drug ap-*
16 *proved under section 505(c) of the Fed-*
17 *eral Food, Drug, and Cosmetic Act, in-*
18 *cluding any ‘authorized generic drug’*
19 *(as that term is defined in section*
20 *505(t)(3) of the Federal Food, Drug,*
21 *and Cosmetic Act), is not being mar-*
22 *keted, as identified in the Food and*
23 *Drug Administration’s National Drug*
24 *Code Directory;*

1 “(II) there is no other drug ap-
2 proved under section 505(j) of the Fed-
3 eral Food, Drug, and Cosmetic Act
4 that is rated as therapeutically equiva-
5 lent (under the Food and Drug Admin-
6 istration’s most recent publication of
7 ‘Approved Drug Products with Thera-
8 peutic Equivalence Evaluations’) and
9 that is being marketed, as identified in
10 the Food and Drug Administration’s
11 National Drug Code Directory;

12 “(III) the manufacturer is not a
13 ‘first applicant’ during the ‘180-day
14 exclusivity period’, as those terms are
15 defined in section 505(j)(5)(B)(iv) of
16 the Federal Food, Drug, and Cosmetic
17 Act; and

18 “(IV) the manufacturer is not a
19 ‘first approved applicant’ for a com-
20 petitive generic therapy, as that term
21 is defined in section 505(j)(5)(B)(v) of
22 the Federal Food, Drug, and Cosmetic
23 Act; or

24 “(iii) a biological licensed under sec-
25 tion 351 of the Public Health Service Act.

1 “(2) *UNIT*.—The term ‘unit’ means, with respect
2 to a part D rebatable drug, the lowest dispensable
3 amount (such as a capsule or tablet, milligram of
4 molecules, or grams) of the part D rebatable drug, as
5 reported under section 1927.

6 “(3) *PAYMENT AMOUNT BENCHMARK PERIOD*.—
7 The term ‘payment amount benchmark period’ means
8 the period beginning January 1, 2021, and ending in
9 the month immediately prior to October 1, 2021.

10 “(4) *BENCHMARK PERIOD CPI-U*.—The term
11 ‘benchmark period CPI-U’ means the consumer price
12 index for all urban consumers (United States city av-
13 erage) for January 2021.

14 “(5) *APPLICABLE PERIOD CPI-U*.—The term ‘ap-
15 plicable period CPI-U’ means, with respect to an ap-
16 plicable period, the consumer price index for all
17 urban consumers (United States city average) for the
18 first month of such applicable period.

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

1 “(7) *APPLICABLE PERIOD.*—*The term ‘applicable*
2 *period’ means a 12-month period beginning with Oc-*
3 *tober 1 of a year (beginning with October 1, 2022).*

4 “(h) *IMPLEMENTATION FOR 2022, 2023, AND 2024.*—
5 *The Secretary shall implement this section for 2022, 2023,*
6 *and 2024 by program instruction or other forms of program*
7 *guidance.”.*

8 (b) *CONFORMING AMENDMENTS.*—

9 (1) *TO PART B ASP CALCULATION.*—*Section*
10 *1847A(c)(3) of the Social Security Act (42 U.S.C.*
11 *1395w–3a(c)(3)), as amended by section 11101(c)(1),*
12 *is amended by striking “subsection (i) or section*
13 *1927” and inserting “subsection (i), section 1927, or*
14 *section 1860D–14B”.*

15 (2) *EXCLUDING PART D DRUG INFLATION RE-*
16 *BATE FROM BEST PRICE.*—*Section*
17 *1927(c)(1)(C)(ii)(I) of the Social Security Act (42*
18 *U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-*
19 *tion 11101(c)(2), is amended by striking “or section*
20 *1847A(i)” and inserting “, section 1847A(i), or sec-*
21 *tion 1860D–14B”.*

22 (3) *COORDINATION WITH MEDICAID REBATE IN-*
23 *FORMATION DISCLOSURE.*—*Section 1927(b)(3)(D)(i)*
24 *of the Social Security Act (42 U.S.C. 1396r–*
25 *8(b)(3)(D)(i)), as amended by sections 11002(b) and*

1 11101(c)(3), is amended by striking “or section
 2 1192(f), including rebates under paragraph (4) of
 3 such section” and inserting “, section 1192(f), includ-
 4 ing rebates under paragraph (4) of such section, or
 5 section 1860D–14B”.

6 (4) *EXCLUDING PART D DRUG INFLATION RE-*
 7 *BATES FROM AVERAGE MANUFACTURER PRICE.*—Sec-
 8 *tion 1927(k)(1)(B)(i) of the Social Security Act (42*
 9 *U.S.C. 1396r–8(k)(1)(B)(i)), as amended by section*
 10 *11001(b)(3) and section 11101(c)(4), is amended by*
 11 *adding at the end the following new subclause:*

12 (A) in subclause (VI), by striking “and” at
 13 the end;

14 (B) in subclause (VII), by striking the pe-
 15 riod at the end and inserting a semicolon; and

16 (C) by adding at the end the following new
 17 subclause:

18 “(VIII) rebates paid by manufac-
 19 turers under section 1860D–14B.”.

20 (c) *FUNDING.*—In addition to amounts otherwise
 21 available, there are appropriated to the Centers for Medi-
 22 care & Medicaid Services, out of any money in the Treasury
 23 not otherwise appropriated, \$80,000,000 for fiscal year
 24 2022, including \$12,500,000 to carry out the provisions of,
 25 including the amendments made by, this section in fiscal

1 year 2022, and \$7,500,000 to carry out the provisions of,
2 including the amendments made by, this section in each
3 of fiscal years 2023 through 2031, to remain available until
4 expended.

5 **PART 3—PART D IMPROVEMENTS AND MAXIMUM**
6 **OUT-OF-POCKET CAP FOR MEDICARE BENE-**
7 **FICIARIES**

8 **SEC. 11201. MEDICARE PART D BENEFIT REDESIGN.**

9 (a) *BENEFIT STRUCTURE REDESIGN.*—Section
10 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
11 102(b)) is amended—

12 (1) in paragraph (2)—

13 (A) in subparagraph (A), in the matter pre-
14 ceding clause (i), by inserting “for a year pre-
15 ceding 2025 and for costs above the annual de-
16 ductible specified in paragraph (1) and up to the
17 annual out-of-pocket threshold specified in para-
18 graph (4)(B) for 2025 and each subsequent year”
19 after “paragraph (3)”;

20 (B) in subparagraph (C)—

21 (i) in clause (i), in the matter pre-
22 ceding subclause (I), by inserting “for a
23 year preceding 2025,” after “paragraph
24 (4),”; and

- 1 (ii) in clause (ii)(III), by striking
2 “and each subsequent year” and inserting
3 “through 2024”; and
4 (C) in subparagraph (D)—
5 (i) in clause (i)—
6 (I) in the matter preceding sub-
7 clause (I), by inserting “for a year pre-
8 ceding 2025,” after “paragraph (4),”;
9 and
10 (II) in subclause (I)(bb), by strik-
11 ing “a year after 2018” and inserting
12 “each of years 2019 through 2024”;
13 and
14 (ii) in clause (ii)(V), by striking “2019
15 and each subsequent year” and inserting
16 “each of years 2019 through 2024”;
17 (2) in paragraph (3)(A)—
18 (A) in the matter preceding clause (i), by
19 inserting “for a year preceding 2025,” after
20 “and (4),”; and
21 (B) in clause (ii), by striking “for a subse-
22 quent year” and inserting “for each of years
23 2007 through 2024”; and
24 (3) in paragraph (4)—
25 (A) in subparagraph (A)—

1 *(i) in clause (i)—*

2 *(I) by redesignating subclauses (I)*
3 *and (II) as items (aa) and (bb), re-*
4 *spectively, and moving the margin of*
5 *each such redesignated item 2 ems to*
6 *the right;*

7 *(II) in the matter preceding item*
8 *(aa), as redesignated by subclause (I),*
9 *by striking “is equal to the greater*
10 *of—” and inserting “is equal to—*

11 *“(I) for a year preceding 2024,*
12 *the greater of—”;*

13 *(III) by striking the period at the*
14 *end of item (bb), as redesignated by*
15 *subclause (I), and inserting “; and”;*
16 *and*

17 *(IV) by adding at the end the fol-*
18 *lowing:*

19 *“(II) for 2024 and each suc-*
20 *ceeding year, \$0.”; and*

21 *(ii) in clause (ii)—*

22 *(I) by striking “clause (i)(I)” and*
23 *inserting “clause (i)(I)(aa)”;* and

24 *(II) by adding at the end the fol-*
25 *lowing new sentence: “The Secretary*