

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

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

5 **SEC. 129001. PROVIDING FOR LOWER PRICES FOR CERTAIN**
6 **HIGH-PRICED SINGLE SOURCE DRUGS.**

7 (a) PROGRAM TO LOWER PRICES FOR CERTAIN
8 HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
9 Social Security Act is amended by adding after section
10 1184 (42 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
18 each 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
22 of selected drugs with respect to such period, in ac-
23 cordance 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.—
20 The term ‘selected drug publication date’ means,
21 with respect to each initial price applicability year,
22 February 1 of the year that begins 2 years prior to
23 such year.

24 “(4) NEGOTIATION PERIOD.—The term ‘nego-
25 tiation 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 se-
9 lected drug publication date with respect to
10 such selected drug; and

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

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

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

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

1 vided under such plan for such selected drug;
2 and

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

11 “(2) 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 “(3) REFERENCE PRODUCT.—The term ‘ref-
19 erence product’ has the meaning given such term in
20 section 351(i) of the Public Health Service Act.

21 “(4) UNIT.—The term ‘unit’ means, with re-
22 spect to a drug or biological product, the lowest
23 identifiable amount (such as a capsule or tablet, mil-
24 ligram of molecules, or grams) of the drug or bio-
25 logical product that is dispensed or furnished. The

1 determination of a unit, with respect to a drug or
2 biological product, pursuant to this paragraph shall
3 not be subject to administrative or judicial review.

4 “(5) TOTAL EXPENDITURES.—The term ‘total
5 expenditures’ includes, in the case of expenditures
6 with respect to part D of title XVIII, the total gross
7 covered prescription drug costs (as defined in section
8 1860D–15(b)(3)). The term ‘total expenditures’ ex-
9 cludes, in the case of expenditures with respect to
10 part B of such title, expenditures for a drug or bio-
11 logical product that are bundled or packaged into
12 the payment for another service.

13 “(d) TIMING FOR INITIAL PRICE APPLICABILITY
14 YEAR 2026.—Notwithstanding the provisions of this part,
15 in the case of initial price applicability year 2026, the fol-
16 lowing rules shall apply for purposes of implementing the
17 program:

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

22 “(2) Subsection (b)(4) shall be applied—

23 “(A) in subparagraph (A)(ii), by sub-
24 stituting ‘October 1, 2023’ for ‘February 28

1 following the selected drug publication date
2 with respect to such selected drug'; and

3 “(B) in subparagraph (B), by substituting
4 ‘August 1, 2024’ for ‘November 1 of the year
5 that begins 2 years prior to the initial price ap-
6 plicability year’.

7 “(3) Section 1192 shall be applied—

8 “(A) in subsection (b)(1)(A), by sub-
9 stituting ‘during the period beginning on June
10 1, 2022, and ending on May 31, 2023’ for ‘dur-
11 ing the most recent period of 12 months prior
12 to the selected drug publication date (but end-
13 ing not later than October 31 of the year prior
14 to the year of such drug publication date), with
15 respect to such year’;

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

1 “(C) in subsection (e)(3)(B), by sub-
2 stituting ‘during the period beginning on June
3 1, 2022, and ending on May 31, 2023’ for ‘dur-
4 ing the most recent period for which data are
5 available of at least 12 months prior to the se-
6 lected drug publication date (but ending no
7 later than October 31 of the year prior to the
8 year of such drug publication date), with re-
9 spect to such year’.

10 “(4) Section 1193(a) shall be applied by sub-
11 stituting ‘October 1, 2023’ for ‘February 28 fol-
12 lowing the selected drug publication date with re-
13 spect to such selected drug’.

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

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

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

22 “(C) in subparagraph (E), by substituting
23 ‘August 1, 2024’ for ‘the first day of November
24 following the selected drug publication date,

1 with respect to the initial price applicability
2 year ’.

3 “(6) Section 1195(a) shall be applied—

4 “(A) in paragraph (1), by substituting
5 ‘September 1, 2024’ for ‘November 30 of the
6 year that is 2 years prior to such initial price
7 applicability year’; and

8 “(B) in paragraph (2), by substituting
9 ‘March 1, 2025’ for ‘March 1 of the year prior
10 to such initial price applicability year’.

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

13 “(a) IN GENERAL.—Not later than the selected drug
14 publication date with respect to an initial price applica-
15 bility year, in accordance with subsection (b), the Sec-
16 retary shall select and publish a list of—

17 “(1) with respect to the initial price applica-
18 bility year 2026, 10 negotiation-eligible drugs de-
19 scribed in subparagraph (A) of subsection (d)(1),
20 but not subparagraph (B) of such subsection, with
21 respect to such year (or, all (if such number is less
22 than 10) such negotiation-eligible drugs with respect
23 to such year);

24 “(2) with respect to the initial price applica-
25 bility year 2027, 15 negotiation-eligible drugs de-

1 scribed in subparagraph (A) of subsection (d)(1),
2 but not subparagraph (B) of such subsection, with
3 respect to such year (or, all (if such number is less
4 than 15) such negotiation-eligible drugs with respect
5 to such year);

6 “(3) with respect to the initial price applica-
7 bility year 2028, 15 negotiation-eligible drugs de-
8 scribed in subparagraph (A) or (B) of subsection
9 (d)(1) with respect to such year (or, all (if such
10 number is less than 15) such negotiation-eligible
11 drugs with respect to such year); and

12 “(4) with respect to the initial price applica-
13 bility year 2029 or a subsequent year, 20 negotia-
14 tion-eligible drugs described in subparagraph (A) or
15 (B) of subsection (d)(1), with respect to such year
16 (or, all (if such number is less than 20) such nego-
17 tiation-eligible drugs with respect to such year); and

18 Subject to subsection (c)(2) and section 1194(f)(5), each
19 drug published on the list pursuant to the previous sen-
20 tence shall be subject to the negotiation process under sec-
21 tion 1194 for the negotiation period with respect to such
22 initial price applicability year (and the renegotiation proc-
23 ess under such section as applicable for any subsequent
24 year during the applicable price applicability period).

25 “(b) SELECTION OF DRUGS.—

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

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

17 “(B) Select from such ranked drugs with
18 respect to such year the negotiation-eligible
19 drugs with the highest such rankings.

20 “(2) HIGH SPEND PART D DRUGS FOR 2026 AND
21 2027.—With respect to the initial price applicability
22 year 2026 and with respect to the initial price appli-
23 cability year 2027, the Secretary shall apply para-
24 graph (1) as if the reference to ‘negotiation-eligible
25 drugs described in subsection (d)(1)’ were a ref-

1 erence to ‘negotiation-eligible drugs described in sub-
2 section (d)(1)(A)’ and as if the reference to ‘total ex-
3 penditures for such drugs under parts B and D of
4 title XVIII’ were a reference to ‘total expenditures
5 for such drugs under part D of title XVIII’.

6 “(c) SELECTED DRUG.—

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

17 “(A) is approved or licensed (as applica-
18 ble)—

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

22 “(ii) under section 351(k) of the Pub-
23 lic Health Service Act using such drug as
24 the reference product; and

1 “(B) is marketed pursuant to such ap-
2 proval or licensure.

3 “(2) CLARIFICATION.—A negotiation-eligible
4 drug—

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

8 “(B) for which the Secretary makes a de-
9 termination described in paragraph (1) before
10 or during the negotiation period with respect to
11 such initial price applicability year;

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

19 “(d) NEGOTIATION-ELIGIBLE DRUG.—

20 “(1) IN GENERAL.—For purposes of this part,
21 subject to paragraph (2), the term ‘negotiation-eli-
22 gible drug’ means, with respect to the selected drug
23 publication date with respect to an initial price ap-
24 plicability year, a qualifying single source drug, as
25 defined in subsection (e), that is described in either

1 of the following subparagraphs (or, with respect to
2 the initial price applicability year 2026 or 2027, that
3 is described in subparagraph (A)):

4 “(A) PART D HIGH SPEND DRUGS.—The
5 qualifying single source drug is, determined in
6 accordance with subsection (e)(2), among the
7 50 qualifying single source drugs with the high-
8 est total expenditures under part D of title
9 XVIII, as determined by the Secretary in ac-
10 cordance with paragraph (3), during the most
11 recent period for which data are available of at
12 least 12 months prior to the selected drug pub-
13 lication date (but ending no later than October
14 31 of the year prior to the year of such drug
15 publication date), with respect to such year.

16 “(B) PART B HIGH SPEND DRUGS.—The
17 qualifying single source drug is, determined in
18 accordance with subsection (e)(2), among the
19 50 qualifying single source drugs with the high-
20 est total expenditures under part B of title
21 XVIII, as determined by the Secretary in ac-
22 cordance with paragraph (3), during such most
23 recent period, as described in clause (i).

24 “(2) EXCEPTION FOR SMALL BIOTECH
25 DRUGS.—

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

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

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

18 “(II) are equal to at least 80 per-
19 cent of the total expenditures under
20 such part D, as so determined, for all
21 covered part D drugs for which the
22 manufacturer of the drug has an
23 agreement in effect under section
24 1860D–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
8 under such part B, as so determined,
9 for all qualifying single source drugs
10 covered under such part B during
11 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 that are covered under
17 such part B during such year.

18 “(B) CLARIFICATIONS RELATING TO MAN-
19 UFACTURERS.—

20 “(i) AGGREGATION RULE.—All per-
21 sons treated as a single employer under
22 subsection (a) or (b) of section 52 of the
23 Internal Revenue Code of 1986 shall be
24 treated as one manufacturer for purposes
25 of this paragraph.

1 “(ii) LIMITATION.—A drug shall not
2 be considered to be a qualifying single
3 source drug described in clause (i) or (ii)
4 of subparagraph (A) if the manufacturer
5 of such drug is acquired after 2021 by an-
6 other manufacturer that does not meet the
7 definition of a specified manufacturer
8 under section 1860D–14C(g)(4)(B)(ii), ef-
9 fective at the beginning of the plan year
10 immediately following such acquisition or,
11 in the case of an acquisition before 2025,
12 effective January 1, 2025.

13 “(C) DRUGS NOT INCLUDED AS SMALL
14 BIOTECH DRUGS.—The following shall not be
15 considered a qualifying single source drug de-
16 scribed in subparagraph (A):

17 “(i) A vaccine that is licensed under
18 section 351 of the Public Health Service
19 Act and is marketed pursuant to such sec-
20 tion.

21 “(ii) A new formulation, such as an
22 extended release formulation, of a quali-
23 fying single source drug.

24 “(3) CLARIFICATIONS AND DETERMINATIONS.—

1 “(A) PREVIOUSLY SELECTED DRUGS AND
2 SMALL BIOTECH DRUGS EXCLUDED.—In apply-
3 ing subparagraphs (A) and (B) of paragraph
4 (1), the Secretary shall not consider or count—

5 “(i) drugs that are already selected
6 drugs; and

7 “(ii) for initial price applicability
8 years 2026, 2027, and 2028, qualifying
9 single source drugs described in paragraph
10 (2)(A).

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

20 “(e) QUALIFYING SINGLE SOURCE DRUG.—

21 “(1) IN GENERAL.—For purposes of this part,
22 the term ‘qualifying single source drug’ means, with
23 respect to an initial price applicability year, subject
24 to paragraphs (2) and (3), a covered part D drug
25 (as defined in section 1860D–2(e)) that is described

1 in any of the following or a drug or biological prod-
2 uct covered under part B of title XVIII that is de-
3 scribed in any of the following:

4 “(A) DRUG PRODUCTS.—A drug—

5 “(i) that is approved under section
6 505(e) of the Federal Food, Drug, and
7 Cosmetic Act and is marketed pursuant to
8 such approval;

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

14 “(iii) that is not the listed drug for
15 any drug that is approved and marketed
16 under section 505(j) of such Act.

17 “(B) BIOLOGICAL PRODUCTS.—A biologi-
18 cal product—

19 “(i) that is licensed under section
20 351(a) of the Public Health Service Act
21 and is marketed under section 351 of such
22 Act;

23 “(ii) for which, as of the selected drug
24 publication date with respect to such initial
25 price applicability year, at least 11 years

1 will have elapsed since the date of such li-
2 censure; and

3 “(iii) that is not the reference product
4 for any biological product that is licensed
5 and marketed under section 351(k) of such
6 Act.

7 “(2) TREATMENT OF AUTHORIZED GENERIC
8 DRUGS.—

9 “(A) IN GENERAL.—In the case of a quali-
10 fying single source drug described in subpara-
11 graph (A) or (B) of paragraph (1) that is the
12 listed drug (as such term is used in section
13 505(j) of the Federal Food, Drug, and Cos-
14 metic Act) or a product described in clause (ii)
15 of subparagraph (B), with respect to an author-
16 ized generic drug, in applying the provisions of
17 this part, such authorized generic drug and
18 such listed drug or such product shall be treat-
19 ed as the same qualifying single source drug.

20 “(B) AUTHORIZED GENERIC DRUG DE-
21 FINED.—For purposes of this paragraph, the
22 term ‘authorized generic drug’ means—

23 “(i) in the case of a drug, an author-
24 ized generic drug (as such term is defined

1 in section 505(t)(3) of the Federal Food,
2 Drug, and Cosmetic Act); and

3 “(ii) in the case of a biological prod-
4 uct, a product that—

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

7 “(II) is marketed, sold, or dis-
8 tributed directly or indirectly to retail
9 class of trade under a different label-
10 ing, packaging (other than repack-
11 aging as the reference product in blis-
12 ter packs, unit doses, or similar pack-
13 aging for use in institutions), product
14 code, labeler code, trade name, or
15 trade mark than the reference prod-
16 uct.

17 “(3) EXCLUSIONS.—In this part, the term
18 ‘qualifying single source drug’ does not include any
19 of the following:

20 “(A) CERTAIN ORPHAN DRUGS.—A drug
21 that is designated as a drug for only one rare
22 disease or condition under section 526 of the
23 Federal Food, Drug, and Cosmetic Act and for
24 which the only approved indication (or indica-
25 tions) is for such disease or condition.

1 “(B) LOW SPEND MEDICARE DRUGS.—A
2 drug or biological product with respect to which
3 the total expenditures under parts B and D of
4 title XVIII, as determined by the Secretary,
5 during the most recent period for which data
6 are available of at least 12 months prior to the
7 selected drug publication date (but ending no
8 later than October 31 of the year prior to the
9 year of such drug publication date), with re-
10 spect to such year, is less than—

11 “(i) with respect to 2021,
12 \$200,000,000; or

13 “(ii) with respect to a subsequent
14 year, the dollar amount specified in this
15 subparagraph for the previous year in-
16 creased by the annual percentage increase
17 in the consumer price index for all urban
18 consumers (all items; United States city
19 average) for the 12-month period ending
20 with September of such previous year.

21 “(C) PLASMA-DERIVED PRODUCTS.—A bio-
22 logical product that is derived from human
23 whole blood or plasma.

24 “(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—
25 The determination of negotiation-eligible drugs under sub-

1 section (d), the determination of qualifying single source
2 drugs under subsection (e), and the selection of drugs
3 under this section are not subject to administrative or ju-
4 dicial review.

5 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

6 “(a) IN GENERAL.—For purposes of section
7 1191(a)(2), the Secretary shall enter into agreements with
8 manufacturers of selected drugs with respect to a price
9 applicability period, by not later than February 28 fol-
10 lowing the selected drug publication date with respect to
11 such selected drug, under which—

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

20 “(A) to maximum fair price eligible indi-
21 viduals who with respect to such drug are de-
22 scribed in subparagraph (A) of section
23 1191(c)(1) and are dispensed such drug (and to
24 pharmacies, mail order services, and other dis-
25 pensers, with respect to such maximum fair

1 price eligible individuals who are dispensed such
2 drugs) during, subject to paragraph (2), the
3 price applicability period; 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 fur-
9 nished or administered such drug during, sub-
10 ject to paragraph (2), the price applicability pe-
11 riod;

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

18 “(A) to maximum fair price eligible indi-
19 viduals who with respect to such drug are de-
20 scribed in subparagraph (A) of section
21 1191(c)(1) and are dispensed such drug (and to
22 pharmacies, mail order services, and other dis-
23 pensers, with respect to such maximum fair
24 price eligible individuals who are dispensed such
25 drugs) during any year during the price appli-

1 cability period (beginning after such renegoti-
2 ation) with respect to such selected drug; and

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

10 “(3) subject to subsection (d), access to the
11 maximum fair price (including as renegotiated pur-
12 suant to paragraph (2)), with respect to such a se-
13 lected drug, shall be provided by the manufacturer
14 to—

15 “(A) maximum fair price eligible individ-
16 uals, who with respect to such drug are de-
17 scribed in subparagraph (A) of section
18 1191(c)(1), at the pharmacy, mail order service,
19 or other dispenser at the point-of-sale of such
20 drug (and shall be provided by the manufac-
21 turer to the pharmacy, mail order service, or
22 other dispenser, with respect to such maximum
23 fair price eligible individuals who are dispensed
24 such drugs), as described in paragraph (1)(A)
25 or (2)(A), as applicable; 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 fur-
6 nished or administered such drug, as described
7 in paragraph (1)(B) or (2)(B), as applicable;

8 “(4) the manufacturer submits to the Sec-
9 retary, in a form and manner specified by the Sec-
10 retary, for the negotiation period for the price appli-
11 cability period (and, if applicable, before any period
12 of renegotiation pursuant to section 1194(f)) with
13 respect to 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
23 for purposes of administering the program and mon-
24 itoring 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 se-
4 lected drug, until such drug is no longer considered a se-
5 lected drug under section 1192(c).

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

13 “(d) NONDUPLICATION WITH 340B CEILING
14 PRICE.—Under an agreement entered into under this sec-
15 tion, the manufacturer of a selected drug shall not be re-
16 quired to provide access to the maximum fair price under
17 subsection (a)(3), with respect to such selected drug and
18 maximum fair price eligible individuals who are eligible to
19 be furnished, administered, or dispensed such selected
20 drug at a covered entity described in section 340B(a)(4)
21 of the Public Health Service Act, to such covered entity
22 if such selected drug is subject to an agreement described
23 in section 340B(a)(1) of such Act and the ceiling price
24 (defined in section 340B(a)(1) of such Act) is lower than
25 the maximum fair price for such selected drug, except that

1 the manufacturer shall provide for the maximum fair price
2 to such covered entity with respect to maximum fair price
3 eligible individuals who are eligible to be furnished, admin-
4 istered, or dispensed such selected drug at such entity at
5 such ceiling price in a nonduplicated amount to the ceiling
6 price if the maximum fair price is below the ceiling price
7 for such selected drug.

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

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

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

19 “(2) renegotiate, in accordance with the process
20 specified pursuant to subsection (f), such maximum
21 fair price for such drug for the purpose described in
22 section 1193(a)(2) if such drug is a renegotiation-el-
23 igible drug under such subsection.

24 “(b) NEGOTIATION PROCESS REQUIREMENTS.—

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

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

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

20 “(B) INITIAL OFFER BY SECRETARY.—Not
21 later than the June 1 following the selected
22 drug publication date, the Secretary shall pro-
23 vide the manufacturer of a selected drug with
24 a written initial offer that contains the Sec-
25 retary’s proposal for the maximum fair price of

1 the drug and a list of the factors described in
2 section 1194(e) that were used in developing
3 such offer.

4 “(C) RESPONSE TO INITIAL OFFER.—

5 “(i) IN GENERAL.—Not later than 30
6 days after the date of receipt of an initial
7 offer under subparagraph (B), the manu-
8 facturer shall either accept such offer or
9 propose a counteroffer to such offer.

10 “(ii) COUNTEROFFER REQUIRE-
11 MENTS.—If a manufacturer proposes a
12 counteroffer, such counteroffer—

13 “(I) shall be in writing; and

14 “(II) shall be justified based on
15 the factors described in subsection (e).

16 “(D) RESPONSE TO COUNTEROFFER.—
17 After receiving a counteroffer under subpara-
18 graph (C), the Secretary shall respond in writ-
19 ing to such counteroffer.

20 “(E) DEADLINE.—All negotiations between
21 the Secretary and the manufacturer of the se-
22 lected drug shall end prior to the first day of
23 November following the selected drug publica-
24 tion date, with respect to the initial price appli-
25 cability year.

1 “(F) LIMITATIONS ON OFFER AMOUNT.—

2 In negotiating the maximum fair price of a se-
3 lected drug, with respect to an initial price ap-
4 plicability year for the selected drug, and, as
5 applicable, in renegotiating the maximum fair
6 price for such drug, with respect to a subse-
7 quent year during the price applicability period
8 for such drug, the Secretary shall not offer (or
9 agree to a counteroffer for) a maximum fair
10 price for the selected drug that—

11 “(i) exceeds the ceiling determined
12 under subsection (c) for the selected drug
13 and year; or

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

17 “(G) TREATMENT OF DETERMINATION.—

18 The determination of a maximum fair price
19 under this section is not subject to administra-
20 tive or judicial review.

21 “(c) CEILING FOR MAXIMUM FAIR PRICE.—

22 “(1) GENERAL CEILING.—

23 “(A) IN GENERAL.—The maximum fair
24 price negotiated under this section for a se-
25 lected drug, with respect to the first year of the

1 price applicability period with respect to such
2 drug, shall not exceed the lower of the amount
3 under subparagraph (B) or the amount under
4 subparagraph (C).

5 “(B) SUBPARAGRAPH (B) AMOUNT.—An
6 amount equal to the following:

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

13 “(ii) PART B DRUG OR BIOLOGICAL.—
14 In the case of a drug or biological product
15 covered under part B of title XVIII, the
16 payment amount under section
17 1847A(b)(4) for the drug or biological
18 product for the year prior to the year of
19 the selected drug publication date with re-
20 spect to the initial price applicability year
21 for the drug or biological product.

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

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

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

24 “(2) PLAN SPECIFIC ENROLLMENT WEIGHTED
25 AMOUNT.—For purposes of paragraph (1)(B)(i), the

1 plan specific enrollment weighted amount for a pre-
2 scription drug plan or an MA–PD plan with respect
3 to a covered Part D drug is an amount equal to the
4 product of—

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

11 “(B) a fraction—

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

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

19 “(3) APPLICABLE PERCENT DESCRIBED.—For
20 purposes of this subsection, the applicable percent
21 described in this paragraph is the following:

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

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

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
8 to subparagraph (B), the term ‘extended-mo-
9 nopoly drug’ means, with respect to an initial
10 price applicability year, a selected drug for
11 which at least 12 years, but fewer than 16
12 years, have elapsed since the date of approval
13 of such drug under section 505(c) of the Fed-
14 eral Food, Drug, and Cosmetic Act or since the
15 date of licensure of such drug under section
16 351(a) of the Public Health Service Act, as ap-
17 plicable.

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

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

1 “(ii) A selected drug for which a man-
2 ufacturer had an agreement under this
3 part with the Secretary with respect to an
4 initial price applicability year that is before
5 2030.

6 “(C) CLARIFICATION.—Nothing in sub-
7 paragraph (B)(ii) shall limit the transition of a
8 selected drug described in paragraph (3)(A) to
9 a long-monopoly drug if the selected drug meets
10 the definition of a long-monopoly drug.

11 “(5) LONG-MONOPOLY DRUG DEFINED.—

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

22 “(B) EXCLUSION.—The term ‘long-monop-
23 oly drug’ shall not include a vaccine that is li-
24 censed under section 351 of the Public Health

1 Service Act and marketed pursuant to such sec-
2 tion.

3 “(6) AVERAGE NON-FEDERAL AVERAGE MANU-
4 FACTURER PRICE.—In this part, the term ‘average
5 non-Federal average manufacturer price’ means the
6 average of the non-Federal average manufacturer
7 price (as defined in section 8126(h)(5) of title 38,
8 United States Code) for the 4 calendar quarters of
9 the year involved.

10 “(d) TEMPORARY FLOOR FOR SMALL BIOTECH
11 DRUGS.—In the case of a selected drug that is a quali-
12 fying single source drug described in section 1192(d)(2)
13 and with respect to which the first initial price applica-
14 bility year of the price applicability period with respect to
15 such drug is 2029 or 2030, the maximum fair price nego-
16 tiated under this section for such drug for such initial
17 price applicability year may not be less than 66 percent
18 of the average non-Federal average manufacturer price for
19 such drug (as defined in subsection (c)(6)) for 2021 (or,
20 in the case that there is not an average non-Federal aver-
21 age manufacturer price available for such drug for 2021,
22 for the first full year following the market entry for such
23 drug), increased by the percentage increase in the con-
24 sumer price index for all urban consumers (all items;
25 United States city average) from September 2021 (or De-

1 cember of such first full year following the market entry),
2 as applicable, to September of the year prior to the se-
3 lected drug publication date with respect to the initial
4 price applicability year.

5 “(e) FACTORS.—For purposes of negotiating the
6 maximum fair price of a selected drug under this part with
7 the manufacturer of the drug, the Secretary shall consider
8 the following factors (and, with respect to extended-mo-
9 nopoly drugs and long-monopoly drugs, shall not, except
10 in making a determination of a material change under
11 subsection (f)(2)(D), consider factors other than those de-
12 scribed in subparagraphs (B) and (C) of paragraph (1)):

13 “(1) MANUFACTURER-SPECIFIC INFORMA-
14 TION.—The following information, with respect to
15 such selected drug, including as submitted by the
16 manufacturer:

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

21 “(B) Market data for the drug.

22 “(C) Unit costs of production and distribu-
23 tion of the drug.

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

4 “(E) Data on patents and on existing and
5 pending exclusivity for the drug.

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

7 “(G) Information on clinical trials for the
8 drug.

9 “(2) INFORMATION ON ALTERNATIVE TREAT-
10 MENTS.—The following information, with respect to
11 such selected drug and therapeutic alternatives to
12 such drug:

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

18 “(B) Approval by the Food and Drug Ad-
19 ministration of such drug and therapeutic alter-
20 natives of such drug.

21 “(C) Comparative effectiveness of such
22 drug and therapeutic alternatives to such drug,
23 taking into consideration the effects of such
24 drug and therapeutic alternatives of such drug
25 on specific populations, such as individuals with

1 disabilities, the elderly, the terminally ill, chil-
2 dren, and other patient populations.

3 “(D) The extent to which such drug and
4 therapeutic alternatives to such drug address
5 unmet medical needs for a condition for which
6 treatment or diagnosis is not addressed ade-
7 quately by available therapy.

8 In considering information described in subpara-
9 graph (C), the Secretary shall not use evidence or
10 findings from comparative clinical effectiveness re-
11 search in a manner that treats extending the life of
12 an elderly, disabled, or terminally ill individual as of
13 lower value than extending the life of an individual
14 who is younger, nondisabled, or not terminally ill.

15 “(f) RENEGOTIATION PROCESS.—

16 “(1) IN GENERAL.—In the case of a renegoti-
17 ation-eligible drug (as defined in paragraph (2)) that
18 is selected under paragraph (3), the Secretary shall
19 provide for a process of renegotiation (for years (be-
20 ginning with 2028) during the price applicability pe-
21 riod, with respect to such drug) of the maximum fair
22 price for such drug consistent with paragraph (4).

23 “(2) RENEGOTIATION-ELIGIBLE DRUG DE-
24 FINED.—In this section, the term ‘renegotiation-eli-

1 gible drug' means a selected drug that is any of the
2 following:

3 “(A) ADDITION OF NEW INDICATION.—A
4 selected drug for which a new indication is
5 added to the drug.

6 “(B) CHANGE OF STATUS TO AN EX-
7 TENDED-MONOPOLY DRUG.—A selected drug
8 that—

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

11 “(ii) for which there is a change in
12 status to that of an extended-monopoly
13 drug.

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

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

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

19 “(D) MATERIAL CHANGES.—A selected
20 drug for which the Secretary determines there
21 has been a material change of any of the fac-
22 tors described in paragraph (1) or (2) of sub-
23 section (e).

24 “(3) SELECTION OF DRUGS FOR RENEGOTI-
25 ATION.—Each year the Secretary shall select among

1 renegotiation-eligible drugs for renegotiation as fol-
2 lows:

3 “(A) ALL EXTENDED-MONOPOLY NEGOTIA-
4 TION-ELIGIBLE DRUGS.—The Secretary shall
5 select all renegotiation-eligible drugs described
6 in paragraph (2)(B).

7 “(B) ALL LONG-MONOPOLY NEGOTIATION-
8 ELIGIBLE DRUGS.—The Secretary shall select
9 all renegotiation-eligible drugs described in
10 paragraph (2)(C).

11 “(C) REMAINING DRUGS.—Among the re-
12 maining renegotiation-eligible drugs described
13 in subparagraphs (A) and (D) of paragraph (2),
14 the Secretary shall select renegotiation-eligible
15 drugs for which the Secretary expects renegoti-
16 ation is likely to result in a significant change
17 in the maximum fair price otherwise negotiated.

18 “(4) RENEGOTIATION PROCESS.—The Secretary
19 shall specify the process for renegotiation of max-
20 imum fair prices with the manufacturer of a renego-
21 tiation-eligible drug selected for renegotiation under
22 this subsection. Such process shall, to the extent
23 practicable, be consistent with the methodology and
24 process established under subsection (b) and in ac-
25 cordance with subsections (c) and (d), and for pur-

1 poses of applying subsections (c) and (d), the ref-
2 erence to the first initial price applicability year of
3 the price applicability period with respect to such
4 drug shall be treated as the first initial price appli-
5 cability year of such period for which the maximum
6 fair price established pursuant to such renegotiation
7 applies, including for applying subsection (c)(3)(B)
8 in the case of renegotiation-eligible drugs described
9 in paragraph (3)(A) of this subsection and sub-
10 section (c)(3)(C) in the case of renegotiation-eligible
11 drugs described in paragraph (3)(B) of this sub-
12 section.

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

18 “(6) NO ADMINISTRATIVE OR JUDICIAL RE-
19 VIEW.—The determination of renegotiation-eligible
20 drugs under paragraph (2) and the selection of re-
21 negotiation-eligible drugs under paragraph (3) are
22 not subject to administrative or judicial review.

23 “(g) LIMITATION.—

24 “(1) IN GENERAL.—In no case shall the max-
25 imum fair price negotiated under this section for a

1 selected drug that is a qualifying single source drug
2 described in section 1192(e)(1) apply before—

3 “(A) in the case the selected drug is a
4 qualifying single source drug described in sub-
5 paragraph (A) of section 1192(e)(1), the date
6 that is 9 years after the day on which the drug
7 was approved under section 505(c) of the Fed-
8 eral Food, Drug, and Cosmetic Act; and

9 “(B) in the case the selected drug is a
10 qualifying single source drug described in sub-
11 paragraph (B) of section 1192(e)(1), the date
12 that is 13 years after the day on which the
13 drug was licensed under section 351(a) of the
14 Public Health Service Act.

15 “(2) CLARIFICATION.—The maximum fair price
16 for a selected drug described in subparagraph (A) or
17 (B) of paragraph (1) shall take effect no later than
18 the first day of the first calendar quarter that begins
19 after the date described in subparagraph (A) or (B),
20 as applicable.

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

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

1 “(1) not later than November 30 of the year
2 that is 2 years prior to such initial price applicability
3 year, the Secretary shall publish the maximum fair
4 price for such drug negotiated with the manufac-
5 turer of such drug under this part; and

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

12 “(b) UPDATES.—

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

23 “(A) subject to subparagraph (B), the
24 amount equal to the maximum fair price pub-
25 lished for such drug for the previous year, in-

1 creased by the annual percentage increase in
2 the consumer price index for all urban con-
3 sumers (all items; United States city average)
4 for the 12-month period ending with September
5 of such previous year; or

6 “(B) in the case the maximum fair price
7 for such drug was renegotiated, for the first
8 year for which such price as so renegotiated ap-
9 plies, such renegotiated maximum fair price.

10 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

11 In the case of a selected drug with respect to an ini-
12 tial price applicability year for which the maximum
13 fair price is determined under this part after the
14 date of publication under this section, the Secretary
15 shall publish such maximum fair price by not later
16 than 30 days after the date such maximum price is
17 so determined.

18 **“SEC. 1196. ADMINISTRATIVE DUTIES AND COMPLIANCE**

19 **MONITORING.**

20 “(a) ADMINISTRATIVE DUTIES.—For purposes of
21 section 1191(a)(4), the administrative duties described in
22 this section are the following:

23 “(1) The establishment of procedures to ensure
24 that the maximum fair price for a selected drug is
25 applied before—

1 “(A) any coverage or financial assistance
2 under other health benefit plans or programs
3 that provide coverage or financial assistance for
4 the purchase or provision of prescription drug
5 coverage on behalf of maximum fair price eligi-
6 ble individuals; and

7 “(B) any other discounts.

8 “(2) The establishment of procedures to com-
9 pute and apply the maximum fair price across dif-
10 ferent strengths and dosage forms of a selected drug
11 and not based on the specific formulation or package
12 size or package type of such drug.

13 “(3) The establishment of procedures to carry
14 out the provisions of this part, as applicable, with
15 respect to—

16 “(A) maximum fair price eligible individ-
17 uals who are enrolled under a prescription drug
18 plan under part D of title XVIII or an MA-PD
19 plan under part C of such title; and

20 “(B) maximum fair price eligible individ-
21 uals who are enrolled under part B of such
22 title, including who are enrolled under an MA
23 plan under part C of such title.

1 “(4) The establishment of a negotiation process
2 and renegotiation process in accordance with section
3 1194.

4 “(5) The establishment of a process for manu-
5 facturers to submit information described in section
6 1194(b)(2)(A).

7 “(6) The sharing with the Secretary of the
8 Treasury of such information as is necessary to de-
9 termine the tax imposed by section 4192 of the In-
10 ternal Revenue Code of 1986 (relating to enforce-
11 ment of this part).

12 “(7) The establishment of procedures for pur-
13 poses of applying section 1192(d)(2)(B).

14 “(b) COMPLIANCE MONITORING.—The Secretary
15 shall monitor compliance by a manufacturer with the
16 terms of an agreement under section 1193 and establish
17 a mechanism through which violations of such terms shall
18 be reported.

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

20 “(a) VIOLATIONS RELATING TO OFFERING OF MAX-
21 IMUM FAIR PRICE.—Any manufacturer of a selected drug
22 that has entered into an agreement under section 1193,
23 with respect to a year during the price applicability period
24 with respect to such drug, that does not provide access

1 to a price that is not more than the maximum fair price
2 (or a lesser price) for such drug for such year—

3 “(1) to a maximum fair price eligible individual
4 who with respect to such drug is described in sub-
5 paragraph (A) of section 1191(c)(1) and who is dis-
6 pensed such drug during such year (and to phar-
7 macies, mail order services, and other dispensers,
8 with respect to such maximum fair price eligible in-
9 dividuals who are dispensed such drugs); or

10 “(2) to a hospital, physician, or other provider
11 of services or supplier with respect to maximum fair
12 price eligible individuals who with respect to such
13 drug is described in subparagraph (B) of such sec-
14 tion and is furnished or administered such drug by
15 such hospital, physician, or provider or supplier dur-
16 ing such year;

17 shall be subject to a civil monetary penalty equal to ten
18 times the amount equal to the product of the number of
19 units of such drug so furnished, dispensed, or adminis-
20 tered during such year and the difference between the
21 price for such drug made available for such year by such
22 manufacturer with respect to such individual or hospital,
23 physician, provider of services, or supplier and the max-
24 imum fair price for such drug for such year.

1 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
2 MENT.—Any manufacturer of a selected drug that has en-
3 tered into an agreement under section 1193, with respect
4 to a year during the price applicability period with respect
5 to such drug, that is in violation of a requirement imposed
6 pursuant to section 1193(a)(5), including the requirement
7 to submit information pursuant to section 1193(a)(4),
8 shall be subject to a civil monetary penalty equal to
9 \$1,000,000 for each day of such violation.

10 “(c) FALSE INFORMATION.—Any manufacturer that
11 knowingly provides false information pursuant to section
12 1196(a)(7) shall be subject to a civil monetary penalty
13 equal to \$100,000,000 for each item of such false informa-
14 tion.

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

20 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
21 CONFORMING AMENDMENTS.—

22 (1) UNDER MEDICARE.—

23 (A) APPLICATION TO PAYMENTS UNDER
24 PART B.—Section 1847A(b)(1)(B) of the Social
25 Security Act (42 U.S.C. 1395w-3a(b)(1)(B)) is

1 amended by inserting “or in the case of such a
2 drug or biological product that is a selected
3 drug (as referred to in section 1192(c)), with
4 respect to a price applicability period (as de-
5 fined in section 1191(b)(2)), 106 percent of the
6 maximum fair price (as defined in section
7 1191(c)(2)) applicable for such drug and a year
8 during such period” after “paragraph (4)”.

9 (B) APPLICATION UNDER MA OF COST-
10 SHARING FOR PART B DRUGS BASED OFF OF
11 NEGOTIATED PRICE.—Section
12 1852(a)(1)(B)(iv) of the Social Security Act
13 (42 U.S.C. 1395w–22(a)(1)(B)(iv)) is amend-
14 ed—

15 (i) by redesignating subclause (VII) as
16 subclause (VIII); and

17 (ii) by inserting after subclause (VI)
18 the following subclause:

19 “(VII) A drug or biological prod-
20 uct that is a selected drug (as referred
21 to in section 1192(c)).”.

22 (C) EXCEPTION TO PART D NON-INTER-
23 FERENCE.—Section 1860D–11(i) of the Social
24 Security Act (42 U.S.C. 1395w–111(i)) is
25 amended—

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

3 (ii) in paragraph (2), by striking the
4 period at the end and inserting “, except
5 as provided under section 1860D–
6 4(b)(3)(l); and”;

7 (iii) by adding at the end the fol-
8 lowing new paragraph:

9 “(3) may not institute a price structure for the
10 reimbursement of covered part D drugs, except as
11 provided under part E of title XI.”

12 (D) APPLICATION AS NEGOTIATED PRICE
13 UNDER PART D.—Section 1860D–2(d)(1) of the
14 Social Security Act (42 U.S.C. 1395w–
15 102(d)(1)) is amended—

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

19 (ii) by adding at the end the following
20 new subparagraph:

21 “(D) APPLICATION OF MAXIMUM FAIR
22 PRICE FOR SELECTED DRUGS.—In applying this
23 section, in the case of a covered part D drug
24 that is a selected drug (as referred to in section
25 1192(c)), with respect to a price applicability

1 period (as defined in section 1191(b)(2)), the
2 negotiated prices used for payment (as de-
3 scribed in this subsection) shall be no greater
4 than the maximum fair price (as defined in sec-
5 tion 1191(c)(2)) for such drug and for each
6 year during such period plus any dispensing
7 fees for such drug.”.

8 (E) COVERAGE OF SELECTED DRUGS.—
9 Section 1860D–4(b)(3) of the Social Security
10 Act (42 U.S.C. 1395w–104(b)(3)) is amended
11 by adding at the end the following new sub-
12 paragraph:

13 “(I) REQUIRED INCLUSION OF SELECTED
14 DRUGS.—

15 “(i) IN GENERAL.—For 2026 and
16 each subsequent year, the PDP sponsor of-
17 fering a prescription drug plan shall in-
18 clude each covered part D drug that is a
19 selected drug under section 1192 for which
20 an agreement for such drug is in effect
21 under section 1193 with respect to the
22 year.

23 “(ii) CLARIFICATION.—Nothing in
24 clause (i) shall be construed as prohibiting
25 a PDP sponsor from removing such a se-

1 lected drug from a formulary if such re-
2 moval would be permitted under section
3 423.120(b)(5)(iv) of title 42, Code of Fed-
4 eral Regulations (or any successor regula-
5 tion).”.

6 (F) INFORMATION FROM PRESCRIPTION
7 DRUG PLANS AND MA-PD PLANS REQUIRED.—

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

13 “(8) PROVISION OF INFORMATION RELATED TO
14 MAXIMUM FAIR PRICES.—Each contract entered into
15 with a PDP sponsor under this part with respect to
16 a prescription drug plan offered by such sponsor
17 shall require the sponsor to provide information to
18 the Secretary as requested by the Secretary in ac-
19 cordance with section 1194(g).”.

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

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

4 (2) DRUG PRICE NEGOTIATION PROGRAM
5 PRICES INCLUDED IN BEST PRICE.—Section
6 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
7 1396r–8(c)(1)(C)) 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 fol-
18 lowing new subclause:

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

1 1191(e)(2)) for such drug with re-
2 spect to such period.”.

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

7 (A) in subclause (IV) by striking “; and”
8 at 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.—
18 The Secretary of Health and Human Services shall imple-
19 ment this section, including the amendments made by this
20 section, for 2026, 2027, and 2028 by program instruction
21 or other forms of program guidance.

1 **SEC. 129002. 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
5 Security Act, as added by section 129001, is amended—

6 (1) in section 1192—

7 (A) in subsection (a), in the flush matter
8 following paragraph (2), 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 mak-
19 ing the selections under subparagraph (B).”;
20 and

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

23 “(3) INCLUSION OF DELAYED BIOLOGICAL
24 PRODUCTS.—Pursuant to subparagraphs (B)(ii)(I)
25 and (C)(i) of subsection (f)(2), the Secretary shall
26 select and include on the list published under sub-

1 section (a) the biological products described in such
2 subparagraphs. Such biological products shall count
3 towards the required number of drugs to be selected
4 under subsection (a)(1).”;

5 (C) by redesignating subsection (f) as sub-
6 section (g);

7 (D) by inserting after subsection (e) the
8 following new subsection:

9 “(f) SPECIAL RULE TO DELAY SELECTION AND NE-
10 GOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET
11 ENTRY.—

12 “(1) APPLICATION.—

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

1 351(k) of the Public Health Service Act before
2 the date that is 2 years after the selected drug
3 publication date with respect to such initial
4 price applicability year.

5 “(B) REQUEST REQUIRED.—

6 “(i) IN GENERAL.—The Secretary
7 shall not provide for a delay under—

8 “(I) paragraph (2)(A) unless a
9 request is made for such a delay by a
10 manufacturer of a biosimilar biological
11 product prior to the selected drug
12 publication date for the list published
13 under subsection (a) with respect to
14 the initial price applicability year for
15 which the biological product would
16 have been included as a selected drug
17 on such list but for subparagraph
18 (2)(A); or

19 “(II) paragraph (2)(B)(iii) unless
20 a request is made for such a delay by
21 such a manufacturer prior to the se-
22 lected drug publication date for the
23 list published under subsection (a)
24 with respect to the initial price appli-
25 cability year that is 1 year after the

1 initial price applicability year for
2 which the biological product described
3 in subsection (a) would have been in-
4 cluded as a selected drug on such list
5 but for paragraph (2)(A).

6 “(ii) INFORMATION AND DOCU-
7 MENTS.—

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

14 “(aa) information and docu-
15 ments necessary for the Sec-
16 retary to make determinations
17 under this subsection, as speci-
18 fied by the Secretary; 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 Prescrip-

1 tion Drug, Improvement, and
2 Modernization Act of 2003.

3 “(II) ADDITIONAL INFORMATION
4 AND DOCUMENTS.—After the Sec-
5 retary has reviewed the request and
6 materials submitted under subclause
7 (I), the manufacturer shall submit
8 any additional information and docu-
9 ments requested by the Secretary nec-
10 essary to make determinations under
11 this subsection.

12 “(C) AGGREGATION RULE.—

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

19 “(ii) PARTNERSHIP DEFINED.—In
20 clause (i), the term ‘partnership’ means a
21 syndicate, group, pool, joint venture, or
22 other organization through or by means of
23 which any business, financial operation, or
24 venture is carried on by the manufacturer

1 of the biological product and the manufac-
2 turer of the biosimilar biological product.

3 “(2) RULES DESCRIBED.—The rules described
4 in this paragraph are the following:

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

16 “(B) IF NOT LICENSED AND MARKETED
17 DURING THE INITIAL DELAY.—

18 “(i) IN GENERAL.—If, during the
19 time period between the selected drug pub-
20 lication date on which the biological prod-
21 uct would have been included on the list as
22 a selected drug pursuant to subsection (a)
23 but for subparagraph (A) and the selected
24 drug publication date with respect to the
25 initial price applicability year that is 1

1 year after the initial price applicability
2 year for which such biological product
3 would have been included as a selected
4 drug on such list, the Secretary determines
5 that the biosimilar biological product for
6 which the manufacturer submitted the re-
7 quest under paragraph (1)(B)(i)(II) (and
8 for which the Secretary previously made a
9 high likelihood determination under para-
10 graph (3)) has not been licensed and mar-
11 keted under such section 351(k), the Sec-
12 retary shall, at the request of such manu-
13 facturer—

14 “(I) reevaluate whether there is a
15 high likelihood (as described in para-
16 graph (3)) that such biosimilar bio-
17 logical product will be licensed and
18 marketed under such section 351(k)
19 before the selected drug publication
20 date that is 2 years after the selected
21 drug publication date for which such
22 biological product would have been in-
23 cluded as a selected drug on such list
24 published but for subparagraph (A);
25 and

1 after the initial price applicability year
2 for which such biological product
3 would have been included as a selected
4 drug on such list but for subpara-
5 graph (A); and

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

13 “(iii) SECOND 1-YEAR DELAY.—If the
14 Secretary determines that there is a high
15 likelihood that such biosimilar biological
16 product will be licensed and marketed (as
17 described in clause (i)(I)) and a significant
18 amount of progress has been made by the
19 manufacturer of such biosimilar biological
20 product towards such licensure and mar-
21 keting (as described in clause (i)(II)), the
22 Secretary shall delay the inclusion of the
23 biological product as a selected drug on the
24 list published under subsection (a) until
25 the selected drug publication date of 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
5 as a selected drug on such list but for this
6 subsection.

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

21 “(i) the Secretary shall include such
22 biological product as a selected drug on
23 such list with respect to the initial price
24 applicability year that is 2 years after the
25 initial price applicability year for which

1 such biological product would have been in-
2 cluded as a selected drug on such list; and

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

10 “(D) LIMITATIONS ON DELAYS.—

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

16 “(ii) EXCLUSION OF BIOLOGICAL
17 PRODUCTS THAT TRANSITIONED TO A
18 LONG-MONOPOLY DRUG DURING THE
19 DELAY.—In the case of a biological prod-
20 uct for which the inclusion on the list pub-
21 lished pursuant to subsection (a) was de-
22 layed by 1 year under subparagraph (A)
23 and for which there would have been a
24 change in status to a long-monopoly drug
25 (as defined in section 1194(c)(5)) if such

1 biological product had been a selected
2 drug, in no case may the Secretary provide
3 for a second 1-year delay under subpara-
4 graph (B)(iii).

5 “(iii) EXCLUSION OF BIOLOGICAL
6 PRODUCTS IF MORE THAN 1 YEAR SINCE
7 LICENSURE.—In no case shall the Sec-
8 retary delay the inclusion of a biological
9 product on the list published under sub-
10 section (a) if more than 1 year has elapsed
11 since the biosimilar biological product has
12 been licensed under section 351(k) and
13 marketing has not commenced for such
14 biosimilar biological product.

15 “(iv) CERTAIN MANUFACTURERS OF
16 BIOSIMILAR BIOLOGICAL PRODUCTS EX-
17 CLUDED.—In no case shall the Secretary
18 delay the inclusion of a biological product
19 as a selected drug on the list published
20 under subsection (a) if the manufacturer
21 of the biosimilar biological product de-
22 scribed in paragraph (1)(A)—

23 “(I) is the same as the manufac-
24 turer of the reference product de-
25 scribed in such paragraph or is treat-

1 ed as being the same pursuant to
2 paragraph (1)(C);

3 “(II) has—

4 “(aa) in the past 5 years,
5 been subject to exclusion under
6 section 1128(b)(7) or to the im-
7 position of civil monetary pen-
8 alties under section 1128A; or

9 “(bb) an integrity agreement
10 in effect with the Inspector Gen-
11 eral of the Department of Health
12 and Human Services that was
13 entered into in lieu of exclusion
14 under section 1128(b)(7);

15 “(III) is currently subject to a
16 cease and desist order or an injunc-
17 tion in a proceeding or civil action
18 brought by the Federal Trade Com-
19 mission except for proceedings or ac-
20 tions related solely to a merger or ac-
21 quisition; or

22 “(IV) has entered into any agree-
23 ment described in paragraph
24 (1)(B)(ii)(I)(bb) with the manufac-
25 turer of the reference product de-

1 scribed in paragraph (1)(A) that re-
2 quires or incentivizes the manufac-
3 turer of the biosimilar biological prod-
4 uct to submit a request described in
5 paragraph (1)(B).

6 “(E) PUBLIC NOTIFICATION.—If the Sec-
7 retary delays the inclusion of a biological prod-
8 uct as a selected drug on the list published
9 under this section pursuant to subparagraph
10 (A) or (B)(iii), the Secretary shall, within 30
11 days of making the determination with respect
12 to such delay, provide notification to the public
13 of such delay in a form and manner determined
14 by the Secretary.

15 “(3) HIGH LIKELIHOOD.—

16 “(A) IN GENERAL.—For purposes of this
17 subsection, there is a high likelihood described
18 in paragraph (1) or paragraph (2), as applica-
19 ble, if the Secretary finds that—

20 “(i) an application for licensure under
21 such section 351(k) for the biosimilar bio-
22 logical product has been accepted for re-
23 view or approved by the Food and Drug
24 Administration; and

1 “(ii) information from documents de-
2 scribed in paragraph (1)(B)(ii) submitted
3 by the manufacturer requesting a delay
4 under paragraph (1)(B) to the Secretary
5 provides clear and convincing evidence that
6 such biosimilar biological product will,
7 within the time period specified under
8 paragraph (1)(A) or (2)(B)(i)(I), be mar-
9 keted.

10 “(B) ITEMS DESCRIBED.—The items de-
11 scribed in this subparagraph are the following:

12 “(i) The manufacturing schedule for
13 such biosimilar biological product sub-
14 mitted to the Food and Drug Administra-
15 tion during its review of the application
16 under such section 351(k).

17 “(ii) Disclosures (in filings by the
18 manufacturer of such biosimilar biological
19 product with the Securities and Exchange
20 Commission required under section 12(b),
21 12(g), 13(a), or 15(d) of the Securities Ex-
22 change Act of 1934 about capital invest-
23 ment, revenue expectations, and actions
24 taken by the manufacturer that are typical
25 of the normal course of business in the

1 year (or the 2 years, as applicable) before
2 marketing of a biosimilar biological prod-
3 uct) that pertain to the marketing of such
4 biosimilar biological product, or com-
5 parable documentation that is distributed
6 to the shareholders of privately held com-
7 panies.

8 “(iii) Agreements filed with the Fed-
9 eral Trade Commission or the Assistant
10 Attorney General pursuant to subsections
11 (a) and (c) of section 1112 of the Medicare
12 Prescription Drug, Improvement, and
13 Modernization Act of 2003.

14 “(4) REBATE.—

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

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

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

9 “(I) 75 percent of the amount by
10 which—

11 “(aa) the average manufac-
12 turer price, as reported by the
13 manufacturer of such covered
14 part D drug under section 1927
15 (or, if not reported by such man-
16 ufacturer under section 1927, as
17 reported by such manufacturer to
18 the Secretary pursuant to the
19 agreement under section
20 1193(a)) for such biological prod-
21 uct, with respect to each of the
22 calendar quarters of the price ap-
23 plicability period that would have
24 applied but for this subsection;
25 exceeds

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

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

10 “(BB) paragraph
11 (2)(B)(iii), such maximum
12 fair price, increased by the
13 annual percentage increase
14 in the consumer price index
15 for all urban consumers (all
16 items; United States city av-
17 erage) for the 12-month pe-
18 riod ending with September
19 of such previous year; and

20 “(II) the number of units dis-
21 pensed under part D of title XVIII
22 for such covered part D drug during
23 each such quarter of such price appli-
24 cability period; and

1 in the consumer price index
2 for all urban consumers (all
3 items; United States city av-
4 erage) for the 12-month pe-
5 riod ending with September
6 of such previous year; and

7 “(II) the number of units (ex-
8 cluding units that are packaged into
9 the payment amount for an item or
10 service and are not separately payable
11 under such part B) of the billing and
12 payment code of such biological prod-
13 uct administered or furnished under
14 such part B during each such cal-
15 endar quarter of such price applica-
16 bility period.

17 “(C) SPECIAL RULE FOR DELAYED BIO-
18 LOGICAL PRODUCTS THAT ARE LONG-MONOP-
19 OLY DRUGS.—

20 “(i) IN GENERAL.—In the case of a
21 biological product with respect to which a
22 rebate is required to be paid under this
23 paragraph, if such biological product quali-
24 fies as a long-monopoly drug (as defined in
25 section 1194(c)(5)) at the time of its inclu-

1 sion on the list published under subsection
2 (a), in determining the amount of the re-
3 bate for such biological product under sub-
4 paragraph (B), the amount described in
5 clause (ii) shall be substituted for the max-
6 imum fair price described in clause (i)(I)
7 or (ii)(I) of such subparagraph (B), as ap-
8 plicable.

9 “(ii) AMOUNT DESCRIBED.—The
10 amount described in this clause is an
11 amount equal to 65 percent of the average
12 non-Federal average manufacturer price
13 for the biological product for 2021 (or, in
14 the case that there is not an average non-
15 Federal average manufacturer price avail-
16 able for such biological product for 2021,
17 for the first full year following the market
18 entry for such biological product), in-
19 creased by the percentage increase in the
20 consumer price index for all urban con-
21 sumers (all items; United States city aver-
22 age) from September 2021 (or December
23 of such first full year following the market
24 entry), as applicable, to September of the
25 year prior to the selected drug publication

1 date with respect to the initial price appli-
2 cability year that would have applied but
3 for this subsection.

4 “(D) REBATE DEPOSITS.—Amounts paid
5 as rebates under this paragraph shall be depos-
6 ited into—

7 “(i) in the case payment is made for
8 such biological product under part B of
9 title XVIII, the Federal Supplementary
10 Medical Insurance Trust Fund established
11 under section 1841; and

12 “(ii) in the case such biological prod-
13 uct is a covered part D drug (as defined in
14 section 1860D–2(e)), the Medicare Pre-
15 scription Drug Account under section
16 1860D–16 in such Trust Fund.

17 “(5) DETERMINATIONS.—The determinations of
18 high likelihood and significant amount of progress
19 under this subsection and the determinations re-
20 quired under paragraph (2)(D)(iv) shall be based on
21 information available to the Secretary, including in-
22 formation required by the Secretary from the manu-
23 facturer of the biosimilar biological product making
24 a request for a delay under this subsection.

1 “(6) DEFINITIONS OF BIOSIMILAR BIOLOGICAL
2 PRODUCT.—In this subsection, the term ‘biosimilar
3 biological product’ has the meanings given such term
4 in section 1847A(c)(6).”; and

5 (E) in subsection (g), as redesignated by
6 subparagraph (C), by inserting “the application
7 of subsection (f),” after “subsection (e),”;
8 (2) in section 1193(a)(4)—

9 (A) in the matter preceding subparagraph
10 (A), by inserting “and for section 1192(f)”
11 after “section 1194(f)”;

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

14 (C) by adding at the end the following new
15 subparagraph:

16 “(C) information that the Secretary re-
17 quires to carry out section 1192(f), including
18 rebates under paragraph (4) of such section;
19 and”;

20 (3) in section 1196(a)(7), by inserting “,
21 1192(f)(1)(C),” after “sections 1192(d)(2)(B)”;

22 (4) in section 1197—

23 (A) by redesignating subsections (b), (c),
24 and (d) as subsections (c), (d), and (e), respec-
25 tively; and

1 (B) by inserting after subsection (a) the
2 following new subsection:

3 “(b) VIOLATIONS RELATING TO PROVIDING RE-
4 BATES.—Any manufacturer that fails to comply with the
5 rebate requirements under section 1192(f)(4) shall be sub-
6 ject to a civil monetary penalty equal to 10 times the
7 amount of the rebate the manufacturer failed to pay under
8 such section.”.

9 (b) CONFORMING AMENDMENTS FOR DISCLOSURE
10 OF CERTAIN INFORMATION.—Section 1927(b)(3)(D) of
11 the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)) is
12 amended—

13 (1) in clause (vi), by striking “and” at the end;

14 (2) in clause (vii), by striking the period at the
15 end and inserting “; and”; and

16 (3) by inserting after clause (vii) the following
17 new clause:

18 “(viii) as the Secretary determines
19 necessary to carry out section 1192(f), in-
20 cluding rebates under paragraph (4) of
21 such section.”.

22 (c) IMPLEMENTATION FOR 2026 THROUGH 2028.—
23 The Secretary of Health and Human Services shall imple-
24 ment this section, including the amendments made by this

1 section, for 2026, 2027, and 2028 by program instruction
2 or other forms of program guidance.

3 **SEC. 129003. SELECTED DRUG MANUFACTURER EXCISE TAX**
4 **IMPOSED DURING NONCOMPLIANCE PERI-**
5 **ODS.**

6 (a) IN GENERAL.—Subtitle D of the Internal Rev-
7 enue Code of 1986 is amended by adding at the end the
8 following new chapter:

9 **“CHAPTER 50A—SELECTED DRUGS**

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

10 **“SEC. 5000D. SELECTED DRUGS DURING NONCOMPLIANCE**
11 **PERIODS.**

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

17 “(1) such tax, divided by

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

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

23 “(1) The period beginning on the March 1st

24 (or, in the case of initial price applicability year

1 2026, the October 2nd) immediately following the
2 selected drug publication date and ending on the
3 first date during which the manufacturer of the drug
4 has in place an agreement described in subsection
5 (a) of section 1193 of the Social Security Act with
6 respect to such drug.

7 “(2) The period beginning on the November
8 2nd immediately following the March 1st described
9 in paragraph (1) (or, in the case of initial price ap-
10 plicability year 2026, the August 2nd immediately
11 following the October 2nd described in such para-
12 graph) and ending on the first date during which the
13 manufacturer of the drug and the Secretary of
14 Health and Human Services have agreed to a max-
15 imum fair price under such agreement.

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

24 “(4) With respect to information that is re-
25 quired to be submitted to the Secretary of Health

1 and Human Services under such agreement, the pe-
2 riod beginning on the date on which such Secretary
3 certifies that such information is overdue and ending
4 on the date that such information is so submitted.

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

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

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

13 “(3) in the case of sales of such drug during
14 the 181st day through the 270th day described in
15 subsection (b) with respect to such drug, 85 percent,
16 and

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

19 “(d) SELECTED DRUG.—For purposes of this sec-
20 tion—

21 “(1) IN GENERAL.—The term ‘selected drug’
22 means any selected drug (within the meaning of sec-
23 tion 1192(e) of the Social Security Act) which is
24 manufactured or produced in the United States or

1 entered into the United States for consumption, use,
2 or warehousing.

3 “(2) UNITED STATES.—The term ‘United
4 States’ has the meaning given such term by section
5 4612(a)(4).

6 “(3) COORDINATION WITH RULES FOR POSSES-
7 SIONS OF THE UNITED STATES.—Rules similar to
8 the rules of paragraphs (2) and (4) of section
9 4132(c) shall apply for purposes of this section.

10 “(e) OTHER DEFINITIONS.—For purposes of this
11 section, the terms ‘initial price applicability year’, ‘selected
12 drug publication date’, and ‘maximum fair price’ have the
13 meaning given such terms in section 1191 of the Social
14 Security Act.

15 “(f) SPECIAL RULES.—

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

21 “(2) PROHIBITION ON ADMINISTRATIVE AP-
22 PEALS.—Any tax controversy with respect to the tax
23 imposed by this section shall not be referred to, or
24 considered by, the Internal Revenue Service Inde-
25 pendent Office of Appeals.

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 or appropriate 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
9 is amended by inserting “50A,” after “46,”.

10 (c) CIVIL ACTIONS FOR REFUND.—Section 7422 of
11 the Internal Revenue Code of 1986 is amended by insert-
12 ing after subsection (g) the following new subsection:

13 “(h) SPECIAL RULES FOR EXCISE TAX IMPOSED BY
14 CHAPTER 50A.—No suit or proceeding shall be main-
15 tained in any court for the recovery of any tax imposed
16 under section 5000D until payment has been made by the
17 taxpayer in an amount equal to the full amount of the
18 tax imposed under such section (including any interest or
19 penalties in connection with such tax) with respect to any
20 sales of a selected drug (as defined in section
21 5000D(d)(1)) during the period for which a return is re-
22 quired to be made with respect to such tax (as determined
23 under regulations prescribed by the Secretary).”.

1 (d) CLERICAL AMENDMENT.—The table of chapters
2 for subtitle D of the Internal Revenue Code of 1986 is
3 amended by adding at the end the following new item:

“CHAPTER 50A—SELECTED DRUGS”.

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

7 **SEC. 129004. FUNDING.**

8 In addition to amounts otherwise available, there is
9 appropriated to the Centers for Medicare & Medicaid Serv-
10 ices, out of any money in the Treasury not otherwise ap-
11 propriated, \$3,000,000,000 for fiscal year 2022, to remain
12 available until expended, to carry out the provisions of,
13 including the amendments made by, this part.

14 **PART 2—PRESCRIPTION DRUG INFLATION**

15 **REBATES**

16 **SEC. 129101. MEDICARE PART B REBATE BY MANUFACTUR-**
17 **ERS.**

18 (a) IN GENERAL.—Section 1847A of the Social Secu-
19 rity Act (42 U.S.C. 1395w–3a) is amended—

20 (1) by redesignating subsection (i) as subsection
21 (j) and by inserting after subsection (h) the fol-
22 lowing subsection:

23 “(i) REBATE BY MANUFACTURERS FOR SINGLE
24 SOURCE DRUGS AND BIOLOGICALS WITH PRICES IN-
25 CREASING FASTER THAN INFLATION.—

1 “(1) REQUIREMENTS.—

2 “(A) SECRETARIAL PROVISION OF INFOR-
3 MATION.—Not later than 6 months after the
4 end of each calendar quarter beginning on or
5 after January 1, 2023, the Secretary shall, for
6 each part B rebatable drug, report to each
7 manufacturer of such part B rebatable drug the
8 following for such calendar quarter:

9 “(i) Information on the total number
10 of billing units of the billing and payment
11 code described in subparagraph (A)(i) of
12 paragraph (3) with respect to such drug
13 and calendar quarter.

14 “(ii) Information on the amount (if
15 any) of the excess average sales price in-
16 crease described in subparagraph (A)(ii) of
17 such paragraph for such drug and calendar
18 quarter.

19 “(iii) The rebate amount specified
20 under such paragraph for such part B
21 rebatable drug and calendar quarter.

22 “(B) MANUFACTURER REQUIREMENT.—
23 For each calendar quarter beginning on or after
24 January 1, 2023, the manufacturer of a part B
25 rebatable drug shall, for such drug, not later

1 than 30 days after the date of receipt from the
2 Secretary of the information described in sub-
3 paragraph (A) for such calendar quarter, pro-
4 vide to the Secretary a rebate that is equal to
5 the amount specified in paragraph (3) for such
6 drug for such calendar quarter.

7 “(C) TRANSITION RULE FOR REPORT-
8 ING.—The Secretary may, for each part B
9 rebatable drug, delay the timeframe for report-
10 ing the information described in subparagraph
11 (A) for calendar quarters beginning in 2023
12 and 2024 until not later than September 30,
13 2025.

14 “(2) PART B REBATABLE DRUG DEFINED.—

15 “(A) IN GENERAL.—In this subsection, the
16 term ‘part B rebatable drug’ means a single
17 source drug or biological (as defined in sub-
18 paragraph (D) of subsection (c)(6)), including a
19 biosimilar biological product (as defined in sub-
20 paragraph (H) of such subsection) but exclud-
21 ing a qualifying biosimilar biological product
22 (as defined in subsection (b)(8)(B)(iii)), that
23 would be payable under this part if such drug
24 were furnished to an individual enrolled under

1 this part, except such term shall not include
2 such a drug or biological—

3 “(i) if, as determined by the Sec-
4 retary, the average total allowed charges
5 for such drug or biological under this part
6 for a year per individual that uses such a
7 drug or biological are less than, subject to
8 subparagraph (B), \$100; or

9 “(ii) that is a vaccine described in
10 subparagraph (A) or (B) of section
11 1861(s)(10).

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

14 “(i) for 2024, shall be the dollar
15 amount specified under such subparagraph
16 for 2023, increased by the percentage in-
17 crease in the consumer price index for all
18 urban consumers (United States city aver-
19 age) for the 12-month period ending with
20 June of the previous year; and

21 “(ii) for a subsequent year, shall be
22 the dollar amount specified in this clause
23 (or clause (i)) for the previous year (with-
24 out application of subparagraph (C)), in-
25 creased by the percentage increase in the

1 consumer price index for all urban con-
2 sumers (United States city average) for
3 the 12-month period ending with June of
4 the previous year.

5 “(C) ROUNDING.—Any dollar amount de-
6 termined under subparagraph (B) that is not a
7 multiple of \$10 shall be rounded to the nearest
8 multiple of \$10.

9 “(3) REBATE AMOUNT.—

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

17 “(i) the total number of billing units
18 determined under subparagraph (B) for
19 the billing and payment code of such drug;
20 and

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

22 “(I) the amount equal to—

23 “(aa) in the case of a part B
24 rebatable drug described in para-
25 graph (1)(B) of section

1 1847A(b), 106 percent of the
2 amount determined under para-
3 graph (4) of such section for
4 such drug during the calendar
5 quarter; or

6 “(bb) in the case of a part B
7 rebatable drug described in para-
8 graph (1)(C) of such section, the
9 payment amount under such
10 paragraph for such drug during
11 the calendar quarter; exceeds

12 “(II) the inflation-adjusted pay-
13 ment amount determined under sub-
14 paragraph (C) for such part B
15 rebatable drug during the calendar
16 quarter.

17 “(B) TOTAL NUMBER OF BILLING
18 UNITS.—For purposes of subparagraph (A)(i),
19 the total number of billing units with respect to
20 a part B rebatable drug is determined as fol-
21 lows:

22 “(i) Determine the total number of
23 units equal to—

24 “(I) the total number of units, as
25 reported under subsection (c)(1)(B)

1 for each National Drug Code of such
2 drug during the calendar quarter that
3 is two calendar quarters prior to the
4 calendar quarter as described in sub-
5 paragraph (A), minus

6 “(II) the total number of units
7 with respect to each National Drug
8 Code of such drug for which payment
9 was made under a State plan under
10 title XIX (or waiver of such plan), as
11 reported by States under section
12 1927(b)(2)(A) for the rebate period
13 that is the same calendar quarter as
14 described in subclause (I).

15 “(ii) Convert the units determined
16 under clause (i) to billing units for the bill-
17 ing and payment code of such drug, using
18 a methodology similar to the methodology
19 used under this section, by dividing the
20 units determined under clause (i) for each
21 National Drug Code of such drug by the
22 billing unit for the billing and payment
23 code of such drug.

1 “(iii) Compute the sum of the billing
2 units for each National Drug Code of such
3 drug in clause (ii).

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

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

13 “(ii) the percentage by which the re-
14 bate period CPI-U (as defined in subpara-
15 graph (F)) for the calendar quarter ex-
16 ceeds the benchmark period CPI-U (as de-
17 fined in subparagraph (E)).

18 “(D) PAYMENT AMOUNT BENCHMARK
19 QUARTER.—The term ‘payment amount bench-
20 mark quarter’ means the calendar quarter be-
21 ginning July 1, 2021.

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

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

10 “(G) REDUCTION OR WAIVER FOR SHORT-
11 AGES AND SEVERE SUPPLY CHAIN DISRUP-
12 TIONS.—The Secretary shall reduce or waive
13 the amount under subparagraph (A) with re-
14 spect to a part B rebatable drug and a calendar
15 quarter—

16 “(i) in the case of a part B rebatable
17 drug that is described as currently in
18 shortage on the shortage list in effect
19 under section 506E of the Federal Food,
20 Drug, and Cosmetic Act at any point dur-
21 ing the calendar quarter; or

22 “(ii) in the case of a biosimilar bio-
23 logical product, when the Secretary deter-
24 mines there is a severe supply chain dis-
25 ruption during the calendar quarter, such

1 as that caused by a natural disaster or
2 other unique or unexpected event.

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

5 “(A) SUBSEQUENTLY APPROVED DRUGS.—

6 In the case of a part B rebatable drug first ap-
7 proved or licensed by the Food and Drug Ad-
8 ministration after December 1, 2020, clause (i)
9 of paragraph (3)(C) shall be applied as if the
10 term ‘payment amount benchmark quarter’
11 were defined under paragraph (3)(D) as the
12 third full calendar quarter after the day on
13 which the drug was first marketed and clause
14 (ii) of paragraph (3)(C) shall be applied as if
15 the term ‘benchmark period CPI-U’ were de-
16 fined under paragraph (3)(E) as if the ref-
17 erence to ‘January 2021’ under such paragraph
18 were a reference to ‘the first month of the first
19 full calendar quarter after the day on which the
20 drug was first marketed’.

21 “(B) TIMELINE FOR PROVISION OF RE-
22 BATES FOR SUBSEQUENTLY APPROVED
23 DRUGS.—In the case of a part B rebatable drug
24 first approved or licensed by the Food and
25 Drug Administration after December 1, 2020,

1 paragraph (1)(B) shall be applied as if the ref-
2 erence to ‘January 1, 2023’ under such para-
3 graph were a reference to ‘the later of the 6th
4 full calendar quarter after the day on which the
5 drug was first marketed or January 1, 2023’.

6 “(C) SELECTED DRUGS.—In the case of a
7 part B rebatable drug that is a selected drug
8 (as defined in section 1192(c)) with respect to
9 a price applicability period (as defined in sec-
10 tion 1191(b)(2)), in the case such drug is no
11 longer considered to be a selected drug under
12 section 1192(c), for each applicable period (as
13 defined under subsection (g)(7)) beginning after
14 the price applicability period with respect to
15 such drug, clause (i) of paragraph (3)(C) shall
16 be applied as if the term ‘payment amount
17 benchmark quarter’ were defined under para-
18 graph (3)(D) as the calendar quarter beginning
19 January 1 of the last year during such price
20 applicability period with respect to such selected
21 drug and clause (ii) of paragraph (3)(C) shall
22 be applied as if the term ‘benchmark period
23 CPI–U’ were defined under paragraph (3)(E)
24 as if the reference to ‘January 2021’ under

1 such paragraph were a reference to ‘the July of
2 the year preceding such last year’.

3 “(5) APPLICATION TO BENEFICIARY COINSUR-
4 ANCE.—In the case of a part B rebatable drug fur-
5 nished on or after April 1, 2023, if the payment
6 amount described in paragraph (3)(A)(ii)(I) (or, in
7 the case of a part B rebatable drug that is a selected
8 drug (as defined in section 1192(c)), the payment
9 amount described in subsection (b)(1)(B) for such
10 drug) for a calendar quarter exceeds the inflation
11 adjusted payment for such quarter—

12 “(A) in computing the amount of any coin-
13 surance applicable under this part to an indi-
14 vidual to whom such drug is furnished, the
15 computation of such coinsurance shall be equal
16 to 20 percent of the inflation-adjusted payment
17 amount determined under paragraph (3)(C) for
18 such part B rebatable drug; and

19 “(B) the amount of such coinsurance for
20 such calendar quarter, as computed under sub-
21 paragraph (A), shall be applied as a percent, as
22 determined by the Secretary, to the payment
23 amount that would otherwise apply under sub-
24 paragraphs (B) or (C) of subsection (b)(1).

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

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

20 (2) in subsection (j), as redesignated by para-
21 graph (1)—

22 (A) in paragraph (4), by striking at the
23 end “and”;

24 (B) in paragraph (5), by striking at the
25 end the period and inserting a semicolon; and

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

3 “(6) the determination of units under sub-
4 section (i);

5 “(7) the determination of whether a drug is a
6 part B rebatable drug under subsection (i);

7 “(8) the calculation of the rebate amount under
8 subsection (i); and

9 “(9) the computation of coinsurance under sub-
10 section (i)(5); and

11 “(10) the computation of amounts paid under
12 section 1833(a)(1)(EE).”.

13 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
14 1833 of the Social Security Act (42 U.S.C. 1395l) is
15 amended—

16 (1) in subsection (a)(1)—

17 (A) in subparagraph (G), by inserting “,
18 subject to subsection (i)(9),” after “the
19 amounts paid”;

20 (B) in subparagraph (S), by striking “with
21 respect to” and inserting “subject to subpara-
22 graph (EE), with respect to”;

23 (C) by striking “and (DD)” and inserting
24 “(DD)”; and

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

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

23 “(9) In the case of a part B rebatable drug (as de-
24 fined in paragraph (2) of section 1847A(i)) for which pay-
25 ment under this subsection is not packaged into a payment

1 for a service furnished on or after April 1, 2023, under
2 the revised payment system under this subsection, in lieu
3 of calculation of coinsurance and the amount of payment
4 otherwise applicable under this subsection, the provisions
5 of section 1847A(i)(5) and paragraph (1)(EE) of sub-
6 section (a), shall, as determined appropriate by the Sec-
7 retary, apply under this subsection in the same manner
8 as such provisions of section 1847A(i)(5) and subsection
9 (a) apply under such section and subsection.”; and

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

12 “(F) PART B REBATABLE DRUGS.—In the
13 case of a part B rebatable drug (as defined in
14 paragraph (2) of section 1847A(i), except if
15 such drug does not have a copayment amount
16 as a result of application of subparagraph (E))
17 for which payment under this part is not pack-
18 aged into a payment for a covered OPD service
19 (or group of services) furnished on or after
20 April 1, 2023, and the payment for such drug
21 under this subsection is the same as the
22 amount for a calendar quarter under paragraph
23 (3)(A)(ii)(I) of section 1847A(i), under the sys-
24 tem under this subsection, in lieu of calculation
25 of the copayment amount and the amount of

1 payment otherwise applicable under this sub-
2 section (other than the application of the limita-
3 tion described in subparagraph (C)), the provi-
4 sions of section 1847A(i)(5) and paragraph
5 (1)(EE) of subsection (a), shall, as determined
6 appropriate by the Secretary, apply under this
7 subsection in the same manner as such provi-
8 sions of section 1847A(i)(5) and subsection (a)
9 apply under such section and subsection.”.

10 (c) CONFORMING AMENDMENTS.—

11 (1) TO PART B ASP CALCULATION.—Section
12 1847A(c)(3) of the Social Security Act (42 U.S.C.
13 1395w–3a(c)(3)) is amended by inserting “sub-
14 section (i) or” before “section 1927”.

15 (2) EXCLUDING PART B DRUG INFLATION RE-
16 BATE FROM BEST PRICE.—Section
17 1927(e)(1)(C)(ii)(I) of the Social Security Act (42
18 U.S.C. 1396r–8(e)(1)(C)(ii)(I)) is amended by in-
19 serting “or section 1847A(i)” after “this section”.

20 (3) COORDINATION WITH MEDICAID REBATE IN-
21 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
22 of the Social Security Act (42 U.S.C. 1396r–
23 8(b)(3)(D)(i)) is amended by inserting “and the re-
24 bate” after “the payment amount”.

1 (4) EXCLUDING PART B DRUG INFLATION RE-
2 BATES FROM AVERAGE MANUFACTURER PRICE.—
3 Section 1927(k)(1)(B)(i) of the Social Security Act
4 (42 U.S.C. 1396r–8(k)(1)(B)(i)), as amended by
5 section 129001(b)(4), is amended—

6 (A) in subclause (V), by striking “and” at
7 the end;

8 (B) in subclause (VI), by striking the pe-
9 riod at the end and inserting a semicolon; and

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

12 “(VII) rebates paid by manufac-
13 turers under section 1847A(i); and”.

14 (d) FUNDING.—In addition to amounts otherwise
15 available, there are appropriated to the Centers for Medi-
16 care & Medicaid Services, out of any money in the Treas-
17 ury not otherwise appropriated, \$80,000,000 for fiscal
18 year 2022, including \$12,500,000 to carry out the provi-
19 sions of, including the amendments made by, this section
20 in fiscal year 2022, and \$7,500,000 to carry out the provi-
21 sions of, including the amendments made by, this section
22 in each of fiscal years 2023 through 2031, to remain avail-
23 able until expended.

1 **SEC. 129102. MEDICARE PART D REBATE BY MANUFACTUR-**
2 **ERS.**

3 (a) IN GENERAL.—Part D of title XVIII of the Social
4 Security Act is amended by inserting after section 1860D–
5 14A (42 U.S.C. 1395w–114a) the following new section:

6 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
7 **DRUGS WITH PRICES INCREASING FASTER**
8 **THAN INFLATION.**

9 “(a) REQUIREMENTS.—

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

17 “(A) The amount (if any) of the excess an-
18 nual manufacturer price increase described in
19 subsection (b)(1)(A)(ii) for each dosage form
20 and strength with respect to such drug and pe-
21 riod.

22 “(B) The rebate amount specified under
23 subsection (b) for each dosage form and
24 strength with respect to such drug and period.

25 “(2) MANUFACTURER REQUIREMENTS.—For
26 each applicable period, the manufacturer of a part D

1 rebatable drug, for each dosage form and strength
2 with respect to such drug, not later than 30 days
3 after the date of receipt from the Secretary of the
4 information described in paragraph (1) for such pe-
5 riod, shall provide to the Secretary a rebate that is
6 equal to the amount specified in subsection (b) for
7 such dosage form and strength with respect to such
8 drug for such period.

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

16 “(b) REBATE AMOUNT.—

17 “(1) IN GENERAL.—

18 “(A) CALCULATION.—For purposes of this
19 section, the amount specified in this subsection
20 for a dosage form and strength with respect to
21 a part D rebatable drug and applicable period
22 is, subject to subparagraph (C), paragraph
23 (5)(B), and paragraph (6), the estimated
24 amount equal to the product of—

1 “(i) subject to subparagraph (B) of
2 this paragraph, the total number of units
3 that are used to calculate the average man-
4 ufacturer price of such dosage form and
5 strength with respect to such part D
6 rebtable drug, as reported by the manu-
7 facturer of such drug under section 1927
8 for each month, with respect to such pe-
9 riod; and

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

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

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

21 “(B) EXCLUDED UNITS.—For purposes of
22 subparagraph (A)(i), the Secretary shall exclude
23 from the total number of units for a dosage
24 form and strength with respect to a part D

1 rebatable drug, with respect to an applicable pe-
2 riod, the following:

3 “(i) Units of each dosage form and
4 strength of such part D rebatable drug for
5 which payment was made under a State
6 plan under title XIX (or waiver of such
7 plan), as reported by States under section
8 1927(b)(2)(A).

9 “(ii) Units of each dosage form and
10 strength of such part D rebatable drug for
11 which a rebate is paid under section
12 1847A(i).

13 “(C) REDUCTION OR WAIVER FOR SHORT-
14 AGES AND SEVERE SUPPLY CHAIN DISRUP-
15 TIONS.—The Secretary shall reduce or waive
16 the amount under subparagraph (A) with re-
17 spect to a part D rebatable drug and an appli-
18 cable period—

19 “(i) in the case of a part D rebatable
20 drug that is described as currently in
21 shortage on the shortage list in effect
22 under section 506E of the Federal Food,
23 Drug, and Cosmetic Act at any point dur-
24 ing the applicable period;

1 “(ii) in the case of a generic part D
2 rebatable drug (described in subsection
3 (g)(1)(C)(ii)) or a biosimilar (defined as a
4 biological product licensed under section
5 351(k) of the Public Health Service Act),
6 when the Secretary determines there is a
7 severe supply chain disruption during the
8 applicable period, such as that caused by a
9 natural disaster or other unique or unex-
10 pected event; and

11 “(iii) in the case of a generic Part D
12 rebatable drug (as so described), if the
13 Secretary determines that without such re-
14 duction or waiver, the drug is likely to be
15 described as in shortage on such shortage
16 list during a subsequent applicable period.

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

23 “(A) the average manufacturer price (as
24 defined in subsection (g)(6)) of such dosage
25 form and strength, as calculated for a unit of

1 such drug, with respect to each of the calendar
2 quarters of such period; and

3 “(B) the ratio of—

4 “(i) the total number of units of such
5 dosage form and strength reported under
6 section 1927 with respect to each such cal-
7 endar quarter of such period; to

8 “(ii) the total number of units of such
9 dosage form and strength reported under
10 section 1927 with respect to such period,
11 as determined by the Secretary.

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

18 “(A) the benchmark period manufacturer
19 price determined under paragraph (4) for such
20 dosage form and strength with respect to such
21 drug and period; increased by

22 “(B) the percentage by which the applica-
23 ble period CPI-U (as defined in subsection
24 (g)(5)) for the period exceeds the benchmark
25 period CPI-U (as defined in subsection (g)(4)).

1 “(4) DETERMINATION OF BENCHMARK PERIOD
2 MANUFACTURER PRICE.—The benchmark period
3 manufacturer price determined under this paragraph
4 for a dosage form and strength, with respect to a
5 part D rebatable drug and an applicable period, is
6 the sum of the products of—

7 “(A) the average manufacturer price (as
8 defined in subsection (g)(6)) of such dosage
9 form and strength, as calculated for a unit of
10 such drug, with respect to each of the calendar
11 quarters of the payment amount benchmark pe-
12 riod (as defined in subsection (g)(3)); and

13 “(B) the ratio of—

14 “(i) the total number of units re-
15 ported under section 1927 of such dosage
16 form and strength with respect to each
17 such calendar quarter of such payment
18 amount benchmark period; to

19 “(ii) the total number of units re-
20 ported under section 1927 of such dosage
21 form and strength with respect to such
22 payment amount benchmark period.

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

1 “(A) SUBSEQUENTLY APPROVED DRUGS.—

2 In the case of a part D rebatable drug first ap-
3 proved or licensed by the Food and Drug Ad-
4 ministration after October 1, 2021, subpara-
5 graphs (A) and (B) of paragraph (4) shall be
6 applied as if the term ‘payment amount bench-
7 mark period’ were defined under subsection
8 (g)(3) as the first calendar year beginning after
9 the day on which the drug was first marketed
10 and subparagraph (B) of paragraph (3) shall be
11 applied as if the term ‘benchmark period CPI-
12 U’ were defined under subsection (g)(4) as if
13 the reference to ‘January 2021’ under such
14 subsection were a reference to ‘January of the
15 first year beginning after the date on which the
16 drug was first marketed’.

17 “(B) TREATMENT OF NEW FORMULA-
18 TIONS.—

19 “(i) IN GENERAL.—In the case of a
20 part D rebatable drug that is a line exten-
21 sion of a part D rebatable drug that is an
22 oral solid dosage form, the Secretary shall
23 establish a formula for determining the re-
24 bate amount under paragraph (1) and the
25 inflation adjusted payment amount under

1 paragraph (3) with respect to such part D
2 rebatable drug and an applicable period,
3 consistent with the formula applied under
4 subsection (c)(2)(C) of section 1927 for
5 determining a rebate obligation for a re-
6 bate period under such section.

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

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

1 such drug, subparagraphs (A) and (B) of para-
2 graph (4) shall be applied as if the term ‘pay-
3 ment amount benchmark period’ were defined
4 under subsection (g)(3) as the last year begin-
5 ning during such price applicability period with
6 respect to such selected drug and subparagraph
7 (B) of paragraph (3) shall be applied as if the
8 term ‘benchmark period CPI-U’ were defined
9 under subsection (g)(4) as if the reference to
10 ‘January 2021’ under such subsection were a
11 reference to ‘January of the last year beginning
12 during such price applicability period with re-
13 spect to such drug’.

14 “(6) RECONCILIATION IN CASE OF REVISED
15 AMP REPORTS.—The Secretary shall provide for a
16 method and process under which, in the case of a
17 manufacturer of a part D rebatable drug that sub-
18 mits revisions to information submitted under sec-
19 tion 1927 by the manufacturer with respect to such
20 drug, the Secretary determines, pursuant to such re-
21 visions, adjustments, if any, to the calculation of the
22 amount specified in this subsection for a dosage
23 form and strength with respect to such part D
24 rebatable drug and an applicable period and rec-
25 onciles any overpayments or underpayments in

1 amounts paid as rebates under this subsection. Any
2 identified underpayment shall be rectified by the
3 manufacturer not later than 30 days after the date
4 of receipt from the Secretary of information on such
5 underpayment.

6 “(c) REBATE DEPOSITS.—Amounts paid as rebates
7 under subsection (b) shall be deposited into the Medicare
8 Prescription Drug Account in the Federal Supplementary
9 Medical Insurance Trust Fund established under section
10 1841.

11 “(d) INFORMATION.—For purposes of carrying out
12 this section, the Secretary shall use information submitted
13 by manufacturers under section 1927(b)(3) and informa-
14 tion submitted by States under section 1927(b)(2)(A).

15 “(e) CIVIL MONEY PENALTY.—If a manufacturer of
16 a part D rebatable drug has failed to comply with the re-
17 quirement under subsection (a)(2) with respect to such
18 drug for an applicable period, the manufacturer shall be
19 subject to, in accordance with a process established by the
20 Secretary pursuant to regulations, a civil money penalty
21 in an amount equal to 125 percent of the amount specified
22 in subsection (b) for such drug for such period. The provi-
23 sions of section 1128A (other than subsections (a) (with
24 respect to amounts of penalties or additional assessments)
25 and (b)) shall apply to a civil money penalty under this

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

3 “(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—

4 There shall be no administrative or judicial review of the
5 following:

6 “(1) The determination of units under this sec-
7 tion.

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

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

12 “(g) DEFINITIONS.—In this section:

13 “(1) PART D REBATABLE DRUG.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (B), the term ‘part D rebatable
16 drug’ means, with respect to an applicable pe-
17 riod, a drug or biological described in subpara-
18 graph (C) that would (without application of
19 this section) be a covered part D drug (as such
20 term is defined under section 1860D–2(e)).

21 “(B) EXCLUSION.—

22 “(i) IN GENERAL.—Such term shall,
23 with respect to an applicable period, not
24 include a drug or biological if the average
25 annual total cost under this part for such

1 period per individual who uses such a drug
2 or biological, as determined by the Sec-
3 retary, is less than, subject to clause (ii),
4 \$100, as determined by the Secretary
5 using the most recent data available or, if
6 data is not available, as estimated by the
7 Secretary.

8 “(ii) INCREASE.—The dollar amount
9 applied under clause (i)—

10 “(I) for the applicable period be-
11 ginning October 1, 2023, shall be the
12 dollar amount specified under such
13 clause for the applicable period begin-
14 ning October 1, 2022, increased by
15 the percentage increase in the con-
16 sumer price index for all urban con-
17 sumers (United States city average)
18 for the 12-month period beginning
19 with October of 2023; and

20 “(II) for a subsequent applicable
21 period, shall be the dollar amount
22 specified in this clause for the pre-
23 vious applicable period, increased by
24 the percentage increase in the con-
25 sumer price index for all urban con-

1 sumers (United States city average)
2 for the 12-month period beginning
3 with October of the previous period.

4 Any dollar amount specified under this
5 clause that is not a multiple of \$10 shall
6 be rounded to the nearest multiple of \$10.

7 “(C) DRUG OR BIOLOGICAL DESCRIBED.—

8 A drug or biological described in this subpara-
9 graph is a drug or biological that, as of the first
10 day of the applicable period involved, is—

11 “(i) a drug approved under a new
12 drug application under section 505(c) of
13 the Federal Food, Drug, and Cosmetic
14 Act;

15 “(ii) a drug approved under an abbrevi-
16 ated new drug application under section
17 505(j) of the Federal Food, Drug, and
18 Cosmetic Act, in the case where—

19 “(I) the reference listed drug ap-
20 proved under section 505(c) of the
21 Federal Food, Drug, and Cosmetic
22 Act, including any ‘authorized generic
23 drug’ (as that term is defined in sec-
24 tion 505(t)(3) of the Federal Food,
25 Drug, and Cosmetic Act), is not being

1 marketed, as identified in the Food
2 and Drug Administration’s National
3 Drug Code Directory;

4 “(II) there is no other drug ap-
5 proved under section 505(j) of the
6 Federal Food, Drug, and Cosmetic
7 Act that is rated as therapeutically
8 equivalent (under the Food and Drug
9 Administration’s most recent publica-
10 tion of ‘Approved Drug Products with
11 Therapeutic Equivalence Evaluations’)
12 and that is being marketed, as identi-
13 fied in the Food and Drug Adminis-
14 tration’s National Drug Code Direc-
15 tory;

16 “(III) the manufacturer is not a
17 ‘first applicant’ during the ‘180-day
18 exclusivity period’, as those terms are
19 defined in section 505(j)(5)(B)(iv) of
20 the Federal Food, Drug, and Cos-
21 metic Act; and

22 “(IV) the manufacturer is not a
23 ‘first approved applicant’ for a com-
24 petitive generic therapy, as that term
25 is defined in section 505(j)(5)(B)(v)

1 of the Federal Food, Drug, and Cos-
2 metic Act; or

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

5 “(2) UNIT.—The term ‘unit’ means, with re-
6 spect to a part D rebatable drug, the lowest dispen-
7 sable amount (such as a capsule or tablet, milligram
8 of molecules, or grams) of the part D rebatable
9 drug, as reported under section 1927.

10 “(3) PAYMENT AMOUNT BENCHMARK PE-
11 RIOD.—The term ‘payment amount benchmark pe-
12 riod’ means the period beginning January 1, 2021,
13 and ending in the month immediately prior to Octo-
14 ber 1, 2021.

15 “(4) BENCHMARK PERIOD CPI-U.—The term
16 ‘benchmark period CPI-U’ means the consumer
17 price index for all urban consumers (United States
18 city average) for January 2021.

19 “(5) APPLICABLE PERIOD CPI-U.—The term
20 ‘applicable period CPI-U’ means, with respect to an
21 applicable period, the consumer price index for all
22 urban consumers (United States city average) for
23 the first month of such applicable period.

24 “(6) AVERAGE MANUFACTURER PRICE.—The
25 term ‘average manufacturer price’ has the meaning,

1 with respect to a part D rebatable drug of a manu-
2 facturer, given such term in section 1927(k)(1), with
3 respect to a covered outpatient drug of a manufac-
4 turer for a rebate period under section 1927.

5 “(7) APPLICABLE PERIOD.—The term ‘applica-
6 ble period’ means a 12-month period beginning with
7 October 1 of a year (beginning with October 1,
8 2022).

9 “(h) IMPLEMENTATION FOR 2022, 2023, AND
10 2024.—The Secretary shall implement this section for
11 2022, 2023, and 2024 by program instruction or other
12 forms of program guidance.”

13 (b) CONFORMING AMENDMENTS.—

14 (1) TO PART B ASP CALCULATION.—Section
15 1847A(c)(3) of the Social Security Act (42 U.S.C.
16 1395w–3a(c)(3)), as amended by section
17 129101(c)(1), is amended by striking “subsection (i)
18 or section 1927” and inserting “subsection (i), sec-
19 tion 1927, or section 1860D–14B”.

20 (2) EXCLUDING PART D DRUG INFLATION RE-
21 BATE FROM BEST PRICE.—Section
22 1927(e)(1)(C)(ii)(I) of the Social Security Act (42
23 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
24 tion 129101(c)(2), is amended by striking “or sec-

1 tion 1847A(i)” and inserting “, section 1847A(i), or
2 section 1860D–14B”.

3 (3) COORDINATION WITH MEDICAID REBATE IN-
4 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
5 of the Social Security Act (42 U.S.C. 1396r-
6 8(b)(3)(D)(i)), as amended by section 129101(c)(3),
7 is amended by striking “or to carry out section
8 1847B” and inserting “or to carry out section
9 1847B or section 1860D–14B”.

10 (4) EXCLUDING PART D DRUG INFLATION RE-
11 BATES FROM AVERAGE MANUFACTURER PRICE.—
12 Section 1927(k)(1)(B)(i) of the Social Security Act
13 (42 U.S.C. 1396r-8(k)(1)(B)(i)), as amended by
14 section 129001(b)(4) and section 129101(c)(4), is
15 amended by adding at the end the following new
16 subclause:

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

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

21 (C) by adding at the end the following new
22 subclause:

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

1 (c) FUNDING.—In addition to amounts otherwise
2 available, there are appropriated to the Centers for Medi-
3 care & Medicaid Services, out of any money in the Treas-
4 ury not otherwise appropriated, \$80,000,000 for fiscal
5 year 2022, including \$12,500,000 to carry out the provi-
6 sions of, including the amendments made by, this section
7 in fiscal year 2022, and \$7,500,000 to carry out the provi-
8 sions of, including the amendments made by, this section
9 in each of fiscal years 2023 through 2031, to remain avail-
10 able until expended.

11 **PART 3—PART D IMPROVEMENTS AND MAXIMUM**
12 **OUT-OF-POCKET CAP FOR MEDICARE BENE-**
13 **FICIARIES**

14 **SEC. 129201. MEDICARE PART D BENEFIT REDESIGN.**

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

18 (1) in paragraph (2)—

19 (A) in subparagraph (A), in the matter
20 preceding clause (i), by inserting “for a year
21 preceding 2025 and for costs above the annual
22 deductible specified in paragraph (1) and up to
23 the annual out-of-pocket threshold specified in
24 paragraph (4)(B) for 2025 and each subsequent
25 year” after “paragraph (3)”;

1 (B) in subparagraph (C)—

2 (i) in clause (i), in the matter pre-
3 ceding subclause (I), by inserting “for a
4 year preceding 2025,” after “paragraph
5 (4),”; and

6 (ii) in clause (ii)(III), by striking
7 “and each subsequent year” and inserting
8 “through 2024”; and

9 (C) in subparagraph (D)—

10 (i) in clause (i)—

11 (I) in the matter preceding sub-
12 clause (I), by inserting “for a year
13 preceding 2025,” after “paragraph
14 (4),”; and

15 (II) in subclause (I)(bb), by
16 striking “a year after 2018” and in-
17 serting “each of years 2019 through
18 2024”; and

19 (ii) in clause (ii)(V), by striking
20 “2019 and each subsequent year” and in-
21 serting “each of years 2019 through
22 2024”;

23 (2) in paragraph (3)(A)—

1 (A) in the matter preceding clause (i), by
2 inserting “for a year preceding 2025,” after
3 “and (4),”; and

4 (B) in clause (ii), by striking “for a subse-
5 quent year” and inserting “for each of years
6 2007 through 2024”; and

7 (3) in paragraph (4)—

8 (A) in subparagraph (A)—

9 (i) in clause (i)—

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

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

19 “(I) for a year preceding 2024,
20 the greater of—”;

21 (III) by striking the period at the
22 end of item (bb), as redesignated by
23 subclause (I), and inserting “; and”;
24 and

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1 (IV) by adding at the end the fol-
2 lowing:

3 “(II) for 2024 and each suc-
4 ceeding year, \$0.”; and

5 (ii) in clause (ii)—

6 (I) by striking “clause (i)(I)” and
7 inserting “clause (i)(I)(aa)”;

8 (II) by adding at the end the fol-
9 lowing new sentence: “The Secretary
10 shall continue to calculate the dollar
11 amounts specified in clause (i)(I)(aa),
12 including with the adjustment under
13 this clause, after 2023 for purposes of
14 section 1860D–14(a)(1)(D)(iii).”;

15 (B) in subparagraph (B)—

16 (i) in clause (i)—

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

19 (II) in subclause (VI)—

20 (aa) by striking “for a sub-
21 sequent year” and inserting “for
22 each of years 2021 through
23 2024”; and

1 (bb) by striking the period
2 at the end and inserting a semi-
3 colon; and

4 (III) by adding at the end the
5 following new subclauses:

6 “(VII) for 2025, is equal to
7 \$2,000; or

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

14 (ii) in clause (ii), by striking “clause
15 (i)(II)” and inserting “clause (i)”;
16 (C) in subparagraph (C)—

17 (i) in clause (i), by striking “and for
18 amounts” and inserting “and, for a year
19 preceding 2025, for amounts”; and

20 (ii) in clause (iii)—

21 (I) by redesignating subclauses
22 (I) through (IV) as items (aa)
23 through (dd) and indenting appro-
24 priately;

1 (II) by striking “if such costs are
2 borne or paid” and inserting “if such
3 costs—

4 “(I) are borne or paid—”; and

5 (III) in item (dd), by striking the
6 period at the end and inserting “; or”;
7 and

8 (IV) by adding at the end the fol-
9 lowing new subclause:

10 “(II) for 2025 and subsequent
11 years, are reimbursed through insur-
12 ance, a group health plan, or certain
13 other third party payment arrange-
14 ments, but not including the coverage
15 provided by a prescription drug plan
16 or an MA–PD plan that is basic pre-
17 scription drug coverage (as defined in
18 subsection (a)(3)) or any payments by
19 a manufacturer under the manufac-
20 turer discount program under section
21 1860D–14C.”; and

22 (D) in subparagraph (E), by striking “In
23 applying” and inserting “For each of years
24 2011 through 2024, in applying”.

1 (b) REINSURANCE PAYMENT AMOUNT.—Section
2 1860D–15(b) of the Social Security Act (42 U.S.C.
3 1395w–115(b)) is amended—

4 (1) in paragraph (1)—

5 (A) by striking “equal to 80 percent” and
6 inserting “equal to—

7 “(A) for a year preceding 2025, 80 per-
8 cent”;

9 (B) in subparagraph (A), as added by sub-
10 paragraph (A), by striking the period at the
11 end and inserting “; and”; and

12 (C) by adding at the end the following new
13 subparagraph:

14 “(B) for 2025 and each subsequent year,
15 the sum of—

16 “(i) with respect to applicable drugs
17 (as defined in section 1860D–14C(g)(2)),
18 an amount equal to 20 percent of such al-
19 lowable reinsurance costs attributable to
20 that portion of gross covered prescription
21 drug costs as specified in paragraph (3) in-
22 curred in the coverage year after such indi-
23 vidual has incurred costs that exceed the
24 annual out-of-pocket threshold specified in
25 section 1860D–2(b)(4)(B); and

1 “(ii) with respect to covered part D
2 drugs that are not applicable drugs (as so
3 defined), an amount equal to 40 percent of
4 such allowable reinsurance costs attrib-
5 utable to that portion of gross covered pre-
6 scription drug costs as specified in para-
7 graph (3) incurred in the coverage year
8 after such individual has incurred costs
9 that exceed the annual out-of-pocket
10 threshold specified in section 1860D-
11 2(b)(4)(B).”;

12 (2) in paragraph (2)—

13 (A) by striking “COSTS.—For purposes”
14 and inserting “COSTS.—

15 “(A) IN GENERAL.—Subject to subpara-
16 graph (B), for purposes”; and

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

19 “(B) INCLUSION OF MANUFACTURER DIS-
20 COUNTS ON APPLICABLE DRUGS.—For purposes
21 of applying subparagraph (A), the term ‘allow-
22 able reinsurance costs’ shall include the portion
23 of the negotiated price (as defined in section
24 1860D-14C(g)(6)) of an applicable drug (as
25 defined in section 1860D-14C(g)(2)) that was

1 paid by a manufacturer under the manufacturer
2 discount program under section 1860D–14C.”;
3 and

4 (3) in paragraph (3)—

5 (A) in the first sentence, by striking “For
6 purposes” and inserting “Subject to paragraph
7 (2)(B), for purposes”; and

8 (B) in the second sentence, by inserting
9 “(or, with respect to 2025 and subsequent
10 years, in the case of an applicable drug, as de-
11 fined in section 1860D–14C(g)(2), by a manu-
12 facturer)” after “by the individual or under the
13 plan”.

14 (c) MANUFACTURER DISCOUNT PROGRAM.—

15 (1) IN GENERAL.—Part D of title XVIII of the
16 Social Security Act (42 U.S.C. 1395w–101 through
17 42 U.S.C. 1395w–153), as amended by section
18 129102, is amended by inserting after section
19 1860D–14B the following new sections:

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

21 “(a) ESTABLISHMENT.—The Secretary shall estab-
22 lish a manufacturer discount program (in this section re-
23 ferred to as the ‘program’). Under the program, the Sec-
24 retary shall enter into agreements described in subsection

1 (b) with manufacturers and provide for the performance
2 of the duties described in subsection (c).

3 “(b) TERMS OF AGREEMENT.—

4 “(1) IN GENERAL.—

5 “(A) AGREEMENT.—An agreement under
6 this section shall require the manufacturer to
7 provide, in accordance with this section, dis-
8 counted prices for applicable drugs of the man-
9 ufacturer that are dispensed to applicable bene-
10 ficiaries on or after January 1, 2025.

11 “(B) CLARIFICATION.—Nothing in this
12 section shall be construed as affecting—

13 “(i) the application of a coinsurance
14 of 25 percent of the negotiated price, as
15 applied under paragraph (2)(A) of section
16 1860D–2(b), for costs described in such
17 paragraph; or

18 “(ii) the application of the copayment
19 amount described in paragraph (4)(A) of
20 such section, with respect to costs de-
21 scribed in such paragraph.

22 “(C) TIMING OF AGREEMENT.—

23 “(i) SPECIAL RULE FOR 2025.—In
24 order for an agreement with a manufac-
25 turer to be in effect under this section with

1 respect to the period beginning on January
2 1, 2025, and ending on December 31,
3 2025, the manufacturer shall enter into
4 such agreement not later than March 1,
5 2024.

6 “(ii) 2026 AND SUBSEQUENT
7 YEARS.—In order for an agreement with a
8 manufacturer to be in effect under this
9 section with respect to plan year 2026 or
10 a subsequent plan year, the manufacturer
11 shall enter into such agreement not later
12 than a calendar quarter or semi-annual
13 deadline established by the Secretary.

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

20 “(3) COMPLIANCE WITH REQUIREMENTS FOR
21 ADMINISTRATION OF PROGRAM.—Each manufac-
22 turer with an agreement in effect under this section
23 shall comply with requirements imposed by the Sec-
24 retary, as applicable, for purposes of administering
25 the program, including any determination under

1 subparagraph (A) of subsection (c)(1) or procedures
2 established under such subsection (c)(1).

3 “(4) LENGTH OF AGREEMENT.—

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

10 “(B) TERMINATION.—

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

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

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

6 “(B) the establishment of procedures to
7 ensure that, not later than the applicable num-
8 ber of calendar days after the dispensing of an
9 applicable drug by a pharmacy or mail order
10 service, the pharmacy or mail order service is
11 reimbursed for an amount equal to the dif-
12 ference between—

13 “(i) the negotiated price of the appli-
14 cable drug; and

15 “(ii) the discounted price of the appli-
16 cable drug;

17 “(C) the establishment of procedures to
18 ensure that the discounted price for an applica-
19 ble drug under this section is applied before any
20 coverage or financial assistance under other
21 health benefit plans or programs that provide
22 coverage or financial assistance for the pur-
23 chase or provision of prescription drug coverage
24 on behalf of applicable beneficiaries as specified
25 by the Secretary; and

1 “(D) providing a reasonable dispute resolu-
2 tion mechanism to resolve disagreements be-
3 tween manufacturers, prescription drug plans
4 and MA–PD plans, and the Secretary.

5 “(2) MONITORING COMPLIANCE.—The Sec-
6 retary shall monitor compliance by a manufacturer
7 with the terms of an agreement under this section.

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

14 “(d) ADMINISTRATION.—

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

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

23 “(e) ENFORCEMENT.—

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

4 “(2) CIVIL MONEY PENALTY.—

5 “(A) IN GENERAL.—A manufacturer that
6 fails to provide discounted prices for applicable
7 drugs of the manufacturer dispensed to applica-
8 ble beneficiaries in accordance with such agree-
9 ment shall be subject to a civil money penalty
10 for each such failure in an amount the Sec-
11 retary determines is equal to the sum of—

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

18 “(ii) 25 percent of such amount.

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

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

8 “(g) DEFINITIONS.—In this section:

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

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

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

16 “(C) has incurred costs, as determined in
17 accordance with section 1860D–2(b)(4)(C), for
18 covered part D drugs in the year that exceed
19 the annual deductible specified in section
20 1860D–2(b)(1).

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

23 “(A) means a covered part D drug—

24 “(i) approved under a new drug appli-
25 cation under section 505(c) of the Federal

1 Food, Drug, and Cosmetic Act or, in the
2 case of a biologic product, licensed under
3 section 351 of the Public Health Service
4 Act; and

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

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

19 “(III) is provided through an excep-
20 tion or appeal; and

21 “(B) does not include a selected drug (as
22 referred to under section 1192(c)) during a
23 price applicability period (as defined in section
24 1191(b)(2)) with respect to such drug.

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

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

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

8 “(4) DISCOUNTED PRICE.—

9 “(A) IN GENERAL.—The term ‘discounted
10 price’ means, subject to subparagraphs (B) and
11 (C), with respect to an applicable drug of a
12 manufacturer dispensed during a year to an ap-
13 plicable beneficiary—

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

22 “(ii) who has incurred such costs, as
23 so determined, in the year that are equal
24 to or exceed such threshold for the year,

1 80 percent of the negotiated price of such
2 drug.

3 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-
4 PENSED TO LIS BENEFICIARIES.—

5 “(i) IN GENERAL.—In the case of an
6 applicable drug of a specified manufacturer
7 (as defined in clause (ii)) that is marketed
8 as of the date of enactment of this sub-
9 paragraph and dispensed for an applicable
10 beneficiary who is a subsidy eligible indi-
11 vidual (as defined in section 1860D-
12 14(a)(3)), the term ‘discounted price’
13 means the specified LIS percent (as de-
14 fined in clause (iii)) of the negotiated price
15 of the applicable drug of the manufacturer.

16 “(ii) SPECIFIED MANUFACTURER.—

17 “(I) IN GENERAL.—In this sub-
18 paragraph, subject to subclause (II),
19 the term ‘specified manufacturer’
20 means a manufacturer of an applica-
21 ble drug for which, in 2021—

22 “(aa) the manufacturer had
23 a coverage gap discount agree-
24 ment under section 1860D-14A;

1 “(bb) the total expenditures
2 for all of the specified drugs of
3 the manufacturer covered by
4 such agreement or agreements
5 for such year and covered under
6 this part during such year rep-
7 resented less than 1.0 percent of
8 the total expenditures under this
9 part for all covered Part D drugs
10 during such year; and

11 “(cc) the total expenditures
12 for all of the specified drugs of
13 the manufacturer that are single
14 source drugs and biological prod-
15 ucts covered under part B during
16 such year represented less than
17 1.0 percent of the total expendi-
18 tures under part B for all drugs
19 or biological products covered
20 under such part during such
21 year.

22 “(II) SPECIFIED DRUGS.—

23 “(aa) IN GENERAL.—For
24 purposes of this clause, the term
25 ‘specified drug’ means, with re-

1 spect to a specified manufac-
2 turer, for 2021, an applicable
3 drug that is produced, prepared,
4 propagated, compounded, con-
5 verted, or processed by the man-
6 ufacturer.

7 “(bb) AGGREGATION
8 RULE.—All persons treated as a
9 single employer under subsection
10 (a) or (b) of section 52 of the In-
11 ternal Revenue Code of 1986
12 shall be treated as one manufac-
13 turer for purposes of this sub-
14 paragraph. For purposes of mak-
15 ing a determination pursuant to
16 the previous sentence, an agree-
17 ment under this section shall re-
18 quire that a manufacturer pro-
19 vide and attest to such informa-
20 tion as specified by the Secretary
21 as necessary.

22 “(III) LIMITATION.—The term
23 ‘specified manufacturer’ shall not in-
24 clude a manufacturer described in
25 subclause (I) if such manufacturer is

1 acquired after 2021 by another manu-
2 facturer that is not a specified manu-
3 facturer, effective at the beginning of
4 the plan year immediately following
5 such acquisition or, in the case of an
6 acquisition before 2025, effective Jan-
7 uary 1, 2025.

8 “(iii) SPECIFIED LIS PERCENT.—In
9 this subparagraph, the ‘specified LIS per-
10 cent’ means, with respect to a year—

11 “(I) for an applicable drug dis-
12 pensed for an applicable beneficiary
13 described in clause (i) who has not in-
14 curred costs, as determined in accord-
15 ance with section 1860D–2(b)(4)(C),
16 for covered part D drugs in the year
17 that are equal to or exceed the annual
18 out-of-pocket threshold specified in
19 section 1860D–2(b)(4)(B)(i) for the
20 year—

21 “(aa) for 2025, 99 percent;

22 “(bb) for 2026, 98 percent;

23 “(cc) for 2027, 95 percent;

24 “(dd) for 2028, 92 percent;

25 and

1 “(ee) for 2029 and each
2 subsequent year, 90 percent; and

3 “(II) for an applicable drug dis-
4 pensed for an applicable beneficiary
5 described in clause (i) who has in-
6 curred costs, as determined in accord-
7 ance with section 1860D–2(b)(4)(C),
8 for covered part D drugs in the year
9 that are equal to or exceed the annual
10 out-of-pocket threshold specified in
11 section 1860D–2(b)(4)(B)(i) for the
12 year—

13 “(aa) for 2025, 99 percent;
14 “(bb) for 2026, 98 percent;
15 “(cc) for 2027, 95 percent;
16 “(dd) for 2028, 92 percent;
17 “(ee) for 2029, 90 percent;
18 “(ff) for 2030, 85 percent;

19 and

20 “(gg) for 2031 and each
21 subsequent year, 80 percent.

22 “(C) PHASE-IN FOR SPECIFIED SMALL
23 MANUFACTURERS.—

24 “(i) IN GENERAL.—In the case of an
25 applicable drug of a specified small manu-

1 manufacturer (as defined in clause (ii)) that is
2 marketed as of the date of enactment of
3 this subparagraph and dispensed for an
4 applicable beneficiary, the term ‘discounted
5 price’ means the specified small manufac-
6 turer percent (as defined in clause (iii)) of
7 the negotiated price of the applicable drug
8 of the manufacturer.

9 “(ii) SPECIFIED SMALL MANUFAC-
10 TURER.—

11 “(I) IN GENERAL.—In this sub-
12 paragraph, subject to subclause (III),
13 the term ‘specified small manufac-
14 turer’ means a manufacturer of an
15 applicable drug for which, in 2021—

16 “(aa) the manufacturer is a
17 specified manufacturer (as de-
18 fined in subparagraph (B)(ii));
19 and

20 “(bb) the total expenditures
21 under part D for any one of the
22 specified small manufacturer
23 drugs of the manufacturer that
24 are covered by the agreement or
25 agreements under section

1 1860D–14A of such manufac-
2 turer for such year and covered
3 under this part during such year
4 are equal to or more than 80 per-
5 cent of the total expenditures
6 under this part for all specified
7 small manufacturer drugs of the
8 manufacturer that are covered by
9 such agreement or agreements
10 for such year and covered under
11 this part during such year.

12 “(II) SPECIFIED SMALL MANU-
13 FACTURER DRUGS.—

14 “(aa) IN GENERAL.—For
15 purposes of this clause, the term
16 ‘specified small manufacturer
17 drugs’ means, with respect to a
18 specified small manufacturer, for
19 2021, an applicable drug that is
20 produced, prepared, propagated,
21 compounded, converted, or proc-
22 essed by the manufacturer.

23 “(bb) AGGREGATION
24 RULE.—All persons treated as a
25 single employer under subsection

1 (a) or (b) of section 52 of the In-
2 ternal Revenue Code of 1986
3 shall be treated as one manufac-
4 turer for purposes of this sub-
5 paragraph. For purposes of mak-
6 ing a determination pursuant to
7 the previous sentence, an agree-
8 ment under this section shall re-
9 quire that a manufacturer pro-
10 vide and attest to such informa-
11 tion as specified by the Secretary
12 as necessary.

13 “(III) LIMITATION.—The term
14 ‘specified small manufacturer’ shall
15 not include a manufacturer described
16 in subclause (I) if such manufacturer
17 is acquired after 2021 by another
18 manufacturer that is not a specified
19 small manufacturer, effective at the
20 beginning of the plan year imme-
21 diately following such acquisition or,
22 in the case of an acquisition before
23 2025, effective January 1, 2025.

24 “(iii) SPECIFIED SMALL MANUFAC-
25 Turer Percent.—In this subparagraph,

1 the term ‘specified small manufacturer per-
2 cent’ means, with respect to a year—

3 “(I) for an applicable drug dis-
4 pensed for an applicable beneficiary
5 who has not incurred costs, as deter-
6 mined in accordance with section
7 1860D–2(b)(4)(C), for covered part D
8 drugs in the year that are equal to or
9 exceed the annual out-of-pocket
10 threshold specified in section 1860D–
11 2(b)(4)(B)(i) for the year—

12 “(aa) for 2025, 99 percent;
13 “(bb) for 2026, 98 percent;
14 “(cc) for 2027, 95 percent;
15 “(dd) for 2028, 92 percent;

16 and

17 “(ee) for 2029 and each
18 subsequent year, 90 percent; and

19 “(II) for an applicable drug dis-
20 pensed for an applicable beneficiary
21 who has incurred costs, as determined
22 in accordance with section 1860D–
23 2(b)(4)(C), for covered part D drugs
24 in the year that are equal to or exceed
25 the annual out-of-pocket threshold

1 specified in section 1860D–
2 2(b)(4)(B)(i) for the year—
3 “(aa) for 2025, 99 percent;
4 “(bb) for 2026, 98 percent;
5 “(cc) for 2027, 95 percent;
6 “(dd) for 2028, 92 percent;
7 “(ee) for 2029, 90 percent;
8 “(ff) for 2030, 85 percent;
9 and
10 “(gg) for 2031 and each
11 subsequent year, 80 percent.

12 “(D) TOTAL EXPENDITURES.—For pur-
13 poses of this paragraph, the term ‘total expend-
14 itures’ includes, in the case of expenditures with
15 respect to part D, the total gross covered pre-
16 scription drug costs as defined in section
17 1860D–15(b)(3). The term ‘total expenditures’
18 excludes, in the case of expenditures with re-
19 spect to part B, expenditures for a drug or bio-
20 logical that are bundled or packaged into the
21 payment for another service.

22 “(E) SPECIAL CASE FOR CERTAIN
23 CLAIMS.—

24 “(i) CLAIMS SPANNING DEDUCT-
25 IBLE.—In the case where the entire

1 amount of the negotiated price of an indi-
2 vidual claim for an applicable drug with re-
3 spect to an applicable beneficiary does not
4 fall above the annual deductible specified
5 in section 1860D–2(b)(1) for the year, the
6 manufacturer of the applicable drug shall
7 provide the discounted price under this
8 section on only the portion of the nego-
9 tiated price of the applicable drug that
10 falls above such annual deductible.

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

22 “(I) in accordance with subpara-
23 graph (A)(i) on the portion of the ne-
24 gotiated price of the applicable drug
25 that falls below such threshold; and

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

5 “(5) MANUFACTURER.—The term ‘manufac-
6 turer’ means any entity which is engaged in the pro-
7 duction, preparation, propagation, compounding,
8 conversion, or processing of prescription drug prod-
9 ucts, either directly or indirectly by extraction from
10 substances of natural origin, or independently by
11 means of chemical synthesis, or by a combination of
12 extraction and chemical synthesis. Such term does
13 not include a wholesale distributor of drugs or a re-
14 tail pharmacy licensed under State law.

15 “(6) NEGOTIATED PRICE.—The term ‘nego-
16 tiated price’ has the meaning given such term for
17 purposes of section 1860D–2(d)(1)(B), and, with re-
18 spect to an applicable drug, such negotiated price
19 shall include any dispensing fee and, if applicable,
20 any vaccine administration fee for the applicable
21 drug.

22 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
23 PLAN.—The term ‘qualified retiree prescription drug
24 plan’ has the meaning given such term in section
25 1860D–22(a)(2).

1 **“SEC. 1860D–14D. SELECTED DRUG SUBSIDY PROGRAM.**

2 “With respect to covered part D drugs that would
3 be applicable drugs (as defined in section 1860D–
4 14C(g)(2)) but for the application of subparagraph (B)
5 of such section, the Secretary shall provide a process
6 whereby, in the case of an applicable beneficiary (as de-
7 fined in section 1860D–14C(g)(1)) who, with respect to
8 a year, is enrolled in a prescription drug plan or is enrolled
9 in an MA–PD plan, has not incurred costs that are equal
10 to or exceed the annual out-of-pocket threshold specified
11 in section 1860D–2(b)(4)(B)(i), and is dispensed such a
12 drug, the Secretary (periodically and on a timely basis)
13 provides the PDP sponsor or the MA organization offering
14 the plan, a subsidy with respect to such drug that is equal
15 to 10 percent of the negotiated price (as defined in section
16 1860D–14C(g)(6)) of such drug.”.

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

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

24 (B) by adding at the end the following new
25 subsection:

26 “(h) SUNSET OF PROGRAM.—

1 “(1) IN GENERAL.—The program shall not
2 apply with respect to applicable drugs dispensed on
3 or after January 1, 2025, and, subject to paragraph
4 (2), agreements under this section shall be termi-
5 nated as of such date.

6 “(2) CONTINUED APPLICATION FOR APPLICA-
7 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
8 provisions of this section (including all responsibil-
9 ities and duties) shall continue to apply on and after
10 January 1, 2025, with respect to applicable drugs
11 dispensed prior to such date.”.

12 (3) SELECTED DRUG SUBSIDY PAYMENTS FROM
13 MEDICARE PRESCRIPTION DRUG ACCOUNT.—Section
14 1860D–16(b)(1) of the Social Security Act (42
15 U.S.C. 1395w–116(b)(1)) is amended—

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

18 (B) in subparagraph (D), by striking the
19 period at the end and inserting “; and”; and

20 (C) by adding at the end the following new
21 subparagraph:

22 “(E) payments under section 1860D–14D
23 (relating to selected drug subsidy payments).”.

24 (d) MEDICARE PART D PREMIUM STABILIZATION.—

1 (1) 2024 THROUGH 2029.—Section 1860D–13
2 of the Social Security Act (42 U.S.C. 1395w–113)
3 is amended—

4 (A) in subsection (a)—

5 (i) in paragraph (1)(A), by inserting
6 “or (8) (as applicable)” after “paragraph
7 (2)”;

8 (ii) in paragraph (2), in the matter
9 preceding subparagraph (A), by striking
10 “The base” and inserting “Subject to
11 paragraph (8), the base”;

12 (iii) in paragraph (7)—

13 (I) in subparagraph (B)(ii), by
14 inserting “or (8) (as applicable)” after
15 “paragraph (2)”; and

16 (II) in subparagraph (E)(i), by
17 inserting “or (8) (as applicable)” after
18 “paragraph (2)”; and

19 (iv) by adding at the end the following
20 new paragraph:

21 “(8) PREMIUM STABILIZATION.—

22 “(A) IN GENERAL.—The base beneficiary
23 premium under this paragraph for a prescrip-
24 tion drug plan for a month in 2024 through
25 2029 shall be computed as follows:

1 “(i) 2024.—The base beneficiary pre-
2 mium for a month in 2024 shall be equal
3 to the lesser of—

4 “**(I)** the base beneficiary pre-
5 mium computed under paragraph (2)
6 for a month in 2023 increased by 6
7 percent; or

8 “**(II)** the base beneficiary pre-
9 mium computed under paragraph (2)
10 for a month in 2024 that would have
11 applied if this paragraph had not been
12 enacted.

13 “(ii) 2025.—The base beneficiary pre-
14 mium for a month in 2025 shall be equal
15 to the lesser of—

16 “**(I)** the base beneficiary pre-
17 mium computed under clause (i) for a
18 month in 2024 increased by 6 per-
19 cent; or

20 “**(II)** the base beneficiary pre-
21 mium computed under paragraph (2)
22 for a month in 2025 that would have
23 applied if this paragraph had not been
24 enacted.

1 “(iii) 2026.—The base beneficiary
2 premium for a month in 2026 shall be
3 equal to the lesser of—

4 “(I) the base beneficiary pre-
5 mium computed under clause (ii) for
6 a month in 2025 increased by 6 per-
7 cent; or

8 “(II) the base beneficiary pre-
9 mium computed under paragraph (2)
10 for a month in 2026 that would have
11 applied if this paragraph had not been
12 enacted.

13 “(iv) 2027.—The base beneficiary
14 premium for a month in 2027 shall be
15 equal to the lesser of—

16 “(I) the base beneficiary pre-
17 mium computed under clause (iii) for
18 a month in 2026 increased by 6 per-
19 cent; or

20 “(II) the base beneficiary pre-
21 mium computed under paragraph (2)
22 for a month in 2027 that would have
23 applied if this paragraph had not been
24 enacted.

1 “(v) 2028.—The base beneficiary pre-
2 mium for a month in 2028 shall be equal
3 to the lesser of—

4 “(I) the base beneficiary pre-
5 mium computed under clause (iv) for
6 a month in 2027 increased by 6 per-
7 cent; or

8 “(II) the base beneficiary pre-
9 mium computed under paragraph (2)
10 for a month in 2028 that would have
11 applied if this paragraph had not been
12 enacted.

13 “(vi) 2029.—The base beneficiary
14 premium for a month in 2029 shall be
15 equal to the lesser of—

16 “(I) the base beneficiary pre-
17 mium computed under clause (v) for a
18 month in 2028 increased by 6 per-
19 cent; or

20 “(II) the base beneficiary pre-
21 mium computed under paragraph (2)
22 for a month in 2029 that would have
23 applied if this paragraph had not been
24 enacted.

1 “(B) CLARIFICATION REGARDING 2030 AND
2 SUBSEQUENT YEARS.—The base beneficiary
3 premium for a month in 2030 or a subsequent
4 year shall be computed under paragraph (2)
5 without regard to this paragraph.”; and

6 (B) in subsection (b)(3)(A)(ii), by striking
7 “subsection (a)(2)” and inserting “paragraph
8 (2) or (8) of subsection (a) (as applicable)”.

9 (2) ADJUSTMENT TO BENEFICIARY PREMIUM
10 PERCENTAGE FOR 2030 AND SUBSEQUENT YEARS.—
11 Section 1860D–13(a) of the Social Security Act (42
12 U.S.C. 1395w–113(a)), as amended by paragraph
13 (1), is amended—

14 (A) in paragraph (3)(A), by inserting “(or,
15 for 2030 and each subsequent year, the percent
16 specified under paragraph (9))” after “25.5
17 percent”; and

18 (B) by adding at the end the following new
19 paragraph:

20 “(9) PERCENT SPECIFIED.—

21 “(A) IN GENERAL.—Subject to subpara-
22 graph (B), for purposes of paragraph (3)(A),
23 the percent specified under this paragraph for
24 2030 and each subsequent year is the percent
25 that the Secretary determines is necessary to

1 ensure that the base beneficiary premium com-
2 puted under paragraph (2) for a month in 2030
3 is equal to the lesser of—

4 “(i) the base beneficiary premium
5 computed under paragraph (8)(A)(vi) for a
6 month in 2029 increased by 6 percent; or

7 “(ii) the base beneficiary premium
8 computed under paragraph (2) for a
9 month in 2030 that would have applied if
10 this paragraph had not been enacted.

11 “(B) FLOOR.—The percent specified under
12 subparagraph (A) may not be less than 20 per-
13 cent.”.

14 (3) CONFORMING AMENDMENTS.—

15 (A) Section 1854(b)(2)(B) of the Social
16 Security Act 42 U.S.C. 1395w–24(b)(2)(B)) is
17 amended by striking “section 1860D–13(a)(2)”
18 and inserting “paragraph (2) or (8) (as applica-
19 ble) of section 1860D–13(a)”.

20 (B) Section 1860D–11(g)(6) of the Social
21 Security Act (42 U.S.C. 1395w–111(g)(6)) is
22 amended by inserting “(or, for 2030 and each
23 subsequent year, the percent specified under
24 section 1860D–13(a)(9))” after “25.5 percent”.

1 (C) Section 1860D–13(a)(7)(B)(i) of the
2 Social Security Act (42 U.S.C. 1395w–
3 113(a)(7)(B)(i)) is amended—

4 (i) in subclause (I), by inserting “(or,
5 for 2030 and each subsequent year, the
6 percent specified under paragraph (9))”
7 after “25.5 percent”; and

8 (ii) in subclause (II), by inserting
9 “(or, for 2030 and each subsequent year,
10 the percent specified under paragraph
11 (9))” after “25.5 percent”.

12 (D) Section 1860D–15(a) of the Social Se-
13 curity Act (42 U.S.C. 1395w–115(a)) is amend-
14 ed—

15 (i) in the matter preceding paragraph
16 (1), by inserting “(or, for each of 2024
17 through 2029, the percent applicable as a
18 result of the application of section 1860D–
19 13(a)(8), or, for 2030 and each subsequent
20 year, 100 percent minus the percent speci-
21 fied under section 1860D–13(a)(9))” after
22 “74.5 percent”; and

23 (ii) in paragraph (1)(B), by striking
24 “paragraph (2) of section 1860D–13(a)”

1 and inserting “paragraph (2) or (8) of sec-
2 tion 1860D–13(a) (as applicable)”.

3 (e) CONFORMING AMENDMENTS.—

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

6 (A) in subsection (a)(2)(A)(i)(I), by striking
7 “, or an increase in the initial” and inserting
8 “or, for a year preceding 2025, an increase in
9 the initial”;

10 (B) in subsection (c)(1)(C)—

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

14 (ii) by inserting “for a year preceding
15 2025 or the annual out-of-pocket threshold
16 specified in subsection (b)(4)(B) for the
17 year for 2025 and each subsequent year”
18 after “subsection (b)(3) for the year” each
19 place it appears; and

20 (C) in subsection (d)(1)(A), by striking “or
21 an initial” and inserting “or, for a year pre-
22 ceding 2025, an initial”.

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

1 amended by striking “the initial” and inserting “for
2 a year preceding 2025, the initial”.

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

5 (A) in paragraph (1)—

6 (i) in subparagraph (C), by striking
7 “The continuation” and inserting “For a
8 year preceding 2025, the continuation”;

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

12 (iii) in subparagraph (E), by striking
13 “The elimination” and inserting “For a
14 year preceding 2024, the elimination”; and

15 (B) in paragraph (2)—

16 (i) in subparagraph (C), by striking
17 “The continuation” and inserting “For a
18 year preceding 2025, the continuation”;

19 and

20 (ii) in subparagraph (E), by striking
21 “1860D–2(b)(4)(A)(i)(I)” and inserting
22 “1860D–2(b)(4)(A)(i)(I)(aa) (for a year
23 preceding 2024)”.

24 (4) Section 1860D–21(d)(7) of the Social Secu-
25 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended

1 by striking “section 1860D–2(b)(4)(B)(i)” and in-
2 sserting “section 1860D–2(b)(4)(C)(i)”.

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

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

8 “(i) for years prior to 2025, any dis-
9 count”;

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

13 (C) by adding at the end the following new
14 clause:

15 “(ii) for 2025 and each subsequent
16 year, any discount provided pursuant to
17 section 1860D–14C.”.

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

20 (A) by inserting “for a year before 2025”
21 after “1860D–2(b)(3)”; and

22 (B) by inserting “for such year” before the
23 period.

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

1 (A) in subsection (a)—

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

4 “(1) participate in—

5 “(A) for 2011 through 2024, the Medicare
6 coverage gap discount program under section
7 1860D–14A; and

8 “(B) for 2025 and each subsequent year,
9 the manufacturer discount program under sec-
10 tion 1860D–14C;”;

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

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

14 “(A) for 2011 through 2024, an agreement
15 described in subsection (b) of section 1860D–
16 14A with the Secretary; and

17 “(B) for 2025 and each subsequent year,
18 an agreement described in subsection (b) of sec-
19 tion 1860D–14C with the Secretary; and”;

20 (iii) in paragraph (3), by striking
21 “such section” and inserting “section
22 1860D–14A”; and

23 (B) by striking subsection (b) and insert-
24 ing the following:

1 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),
2 and (3) of subsection (a) shall apply to covered part D
3 drugs dispensed under this part on or after January 1,
4 2011, and before January 1, 2025, and paragraphs (1)(B)
5 and (2)(B) of such subsection shall apply to covered part
6 D drugs dispensed under this part on or after January
7 1, 2025.”.

8 (8) Section 1927 of the Social Security Act (42
9 U.S.C. 1396r–8) is amended—

10 (A) in subsection (c)(1)(C)(i)(VI), by in-
11 serting before the period at the end the fol-
12 lowing: “or under the manufacturer discount
13 program under section 1860D–14C”; and

14 (B) in subsection (k)(1)(B)(i)(V), by in-
15 serting before the period at the end the fol-
16 lowing: “or under section 1860D–14C”.

17 (f) IMPLEMENTATION FOR 2024 THROUGH 2026.—
18 The Secretary shall implement this section, including the
19 amendments made by this section, for 2024, 2025, and
20 2026 by program instruction or other forms of program
21 guidance.

22 (g) FUNDING.—In addition to amounts otherwise
23 available, there are appropriated to the Centers for Medi-
24 care & Medicaid Services, out of any money in the Treas-
25 ury not otherwise appropriated, \$341,000,000 for fiscal

1 year 2022, including \$20,000,000 and \$65,000,000 to
2 carry out the provisions of, including the amendments
3 made by, this section in fiscal years 2022 and 2023, re-
4 spectively, and \$32,000,000 to carry out the provisions of,
5 including the amendments made by, this section in each
6 of fiscal years 2024 through 2031, to remain available
7 until expended.

8 **SEC. 129202. MAXIMUM MONTHLY CAP ON COST-SHARING**
9 **PAYMENTS UNDER PRESCRIPTION DRUG**
10 **PLANS AND MA-PD PLANS.**

11 (a) IN GENERAL.—Section 1860D–2(b) of the Social
12 Security Act (42 U.S.C. 1395w–102(b)) is amended—

13 (1) in paragraph (2)—

14 (A) in subparagraph (A), by striking “and
15 (D)” and inserting “, (D), and (E)”; and

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

18 “(E) MAXIMUM MONTHLY CAP ON COST-
19 SHARING PAYMENTS.—

20 “(i) IN GENERAL.—For plan years be-
21 ginning on or after January 1, 2025, each
22 PDP sponsor offering a prescription drug
23 plan and each MA organization offering an
24 MA–PD plan shall provide to any enrollee
25 of such plan, including an enrollee who is

1 a subsidy eligible individual (as defined in
2 paragraph (3) of section 1860D–14(a)),
3 the option to elect with respect to a plan
4 year to pay cost-sharing under the plan in
5 monthly amounts that are capped in ac-
6 cordance with this subparagraph.

7 “(ii) DETERMINATION OF MAXIMUM
8 MONTHLY CAP.—For each month in the
9 plan year for which an enrollee in a pre-
10 scription drug plan or an MA–PD plan has
11 made an election pursuant to clause (i),
12 the PDP sponsor or MA organization shall
13 determine a maximum monthly cap (as de-
14 fined in clause (iv)) for such enrollee.

15 “(iii) BENEFICIARY MONTHLY PAY-
16 MENTS.—With respect to an enrollee who
17 has made an election pursuant to clause
18 (i), for each month described in clause (ii),
19 the PDP sponsor or MA organization shall
20 bill such enrollee an amount (not to exceed
21 the maximum monthly cap) for the out-of-
22 pocket costs of such enrollee in such
23 month.

24 “(iv) MAXIMUM MONTHLY CAP DE-
25 FINED.—In this subparagraph, the term

1 ‘maximum monthly cap’ means, with re-
2 spect to an enrollee—

3 “(I) for the first month for which
4 the enrollee has made an election pur-
5 suant to clause (i), an amount deter-
6 mined by calculating—

7 “(aa) the annual out-of-
8 pocket threshold specified in
9 paragraph (4)(B) minus the in-
10 curred costs of the enrollee as de-
11 scribed in paragraph (4)(C); di-
12 vided by

13 “(bb) the number of months
14 remaining in the plan year; and

15 “(II) for a subsequent month, an
16 amount determined by calculating—

17 “(aa) the sum of any re-
18 maining out-of-pocket costs owed
19 by the enrollee from a previous
20 month that have not yet been
21 billed to the enrollee and any ad-
22 ditional out-of-pocket costs in-
23 curred by the enrollee; divided by

24 “(bb) the number of months
25 remaining in the plan year.

1 “(v) ADDITIONAL REQUIREMENTS.—

2 The following requirements shall apply
3 with respect to the option to make an elec-
4 tion pursuant to clause (i) under this sub-
5 paragraph:

6 “(I) SECRETARIAL RESPONSIBIL-
7 ITIES.—The Secretary shall provide
8 information to part D eligible individ-
9 uals on the option to make such elec-
10 tion through educational materials, in-
11 cluding through the notices provided
12 under section 1804(a).

13 “(II) TIMING OF ELECTION.—An
14 enrollee in a prescription drug plan or
15 an MA–PD plan may make such an
16 election—

17 “(aa) prior to the beginning
18 of the plan year; or

19 “(bb) in any month during
20 the plan year.

21 “(III) PDP SPONSOR AND MA OR-
22 GANIZATION RESPONSIBILITIES.—
23 Each PDP sponsor offering a pre-
24 scription drug plan or MA organiza-
25 tion offering an MA–PD plan—

1 “(aa) may not limit the op-
2 tion for an enrollee to make such
3 an election to certain covered
4 part D drugs;

5 “(bb) shall, prior to the plan
6 year, notify prospective enrollees
7 of the option to make such an
8 election in promotional materials;

9 “(cc) shall include informa-
10 tion on such option in enrollee
11 educational materials;

12 “(dd) shall have in place a
13 mechanism to notify a pharmacy
14 during the plan year when an en-
15 rollee incurs out-of-pocket costs
16 with respect to covered part D
17 drugs that make it likely the en-
18 rollee may benefit from making
19 such an election;

20 “(ee) shall provide that a
21 pharmacy, after receiving a noti-
22 fication described in item (dd)
23 with respect to an enrollee, in-
24 forms the enrollee of such notifi-
25 cation;

1 “(ff) shall ensure that such
2 an election by an enrollee has no
3 effect on the amount paid to
4 pharmacies (or the timing of
5 such payments) with respect to
6 covered part D drugs dispensed
7 to the enrollee; and

8 “(gg) shall have in place a
9 financial reconciliation process to
10 correct inaccuracies in payments
11 made by an enrollee under this
12 subparagraph with respect to
13 covered part D drugs during the
14 plan year.

15 “(IV) FAILURE TO PAY AMOUNT
16 BILLED.—If an enrollee fails to pay
17 the amount billed for a month as re-
18 quired under this subparagraph—

19 “(aa) the election of the en-
20 rollee pursuant to clause (i) shall
21 be terminated and the enrollee
22 shall pay the cost-sharing other-
23 wise applicable for any covered
24 part D drugs subsequently dis-
25 pensed to the enrollee up to the

1 annual out-of-pocket threshold
2 specified in paragraph (4)(B);
3 and

4 “(bb) the PDP sponsor or
5 MA organization may preclude
6 the enrollee from making an elec-
7 tion pursuant to clause (i) in a
8 subsequent plan year.

9 “(V) CLARIFICATION REGARDING
10 PAST DUE AMOUNTS.—Nothing in this
11 subparagraph shall be construed as
12 prohibiting a PDP sponsor or an MA
13 organization from billing an enrollee
14 for an amount owed under this sub-
15 paragraph.

16 “(VI) TREATMENT OF UNSET-
17 TLED BALANCES.—Any unsettled bal-
18 ances with respect to amounts owed
19 under this subparagraph shall be
20 treated as plan losses and the Sec-
21 retary shall not be liable for any such
22 balances outside of those assumed as
23 losses estimated in plan bids.”; and

24 (2) in paragraph (4)—

1 (A) in subparagraph (C), by striking “sub-
2 paragraph (E)” and inserting “subparagraph
3 (E) or subparagraph (F)”; and

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

6 “(F) INCLUSION OF COSTS PAID UNDER
7 MAXIMUM MONTHLY CAP OPTION.—In applying
8 subparagraph (A), with respect to an enrollee
9 who has made an election pursuant to clause (i)
10 of paragraph (2)(E), costs shall be treated as
11 incurred if such costs are paid by a PDP spon-
12 sor or an MA organization under the option
13 provided under such paragraph.”.

14 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
15 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
16 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
17 ing at the end the following new paragraph:

18 “(4) SAME MAXIMUM MONTHLY CAP ON COST-
19 SHARING.—The maximum monthly cap on cost-shar-
20 ing payments shall apply to coverage with respect to
21 an enrollee who has made an election pursuant to
22 clause (i) of subsection (b)(2)(E) under the option
23 provided under such subsection.”.

24 (c) IMPLEMENTATION FOR 2025.—The Secretary
25 shall implement this section, including the amendments

1 made by this section, for 2025 by program instruction or
2 other forms of program guidance.

3 (d) FUNDING.—In addition to amounts otherwise
4 available, there are appropriated to the Centers for Medi-
5 care & Medicaid Services, out of any money in the Treas-
6 ury not otherwise appropriated, \$10,000,000 for fiscal
7 year 2023, to remain available until expended, to carry
8 out the provisions of, including the amendments made by,
9 this section.

10 **PART 4—REPEAL OF PRESCRIPTION DRUG**

11 **REBATE RULE**

12 **SEC. 129301. PROHIBITING IMPLEMENTATION OF RULE RE-**
13 **LATING TO ELIMINATING THE ANTI-KICK-**
14 **BACK STATUTE SAFE HARBOR PROTECTION**
15 **FOR PRESCRIPTION DRUG REBATES.**

16 Section 90006 of division I of the Infrastructure In-
17 vestment and Jobs Act (42 U.S.C. 1320a–7b note), as
18 amended by section 13101 of division A of the Bipartisan
19 Safer Communities Act, is amended by striking “, prior
20 to January 1, 2027,”.

1 **PART 5—MISCELLANEOUS**
2 **SEC. 129401. COVERAGE OF ADULT VACCINES REC-**
3 **COMMENDED BY THE ADVISORY COMMITTEE**
4 **ON IMMUNIZATION PRACTICES UNDER MEDI-**
5 **CARE PART D.**

6 (a) ENSURING TREATMENT OF COST-SHARING AND
7 DEDUCTIBLE IS CONSISTENT WITH TREATMENT OF VAC-
8 CINES UNDER MEDICARE PART B.—Section 1860D–2 of
9 the Social Security Act (42 U.S.C. 1395w–102), as
10 amended by sections 129201 and 129202, is amended—

11 (1) in subsection (b)—

12 (A) in paragraph (1)(A), by striking “The
13 coverage” and inserting “Subject to paragraph
14 (8), the coverage”;

15 (B) in paragraph (2)—

16 (i) in subparagraph (A), by inserting
17 “and paragraph (8)” after “and (E)”;

18 (ii) in subparagraph (C)(i), in the
19 matter preceding subclause (I), by striking
20 “paragraph (4)” and inserting “para-
21 graphs (4) and (8)”;

22 (iii) in subparagraph (D)(i), in the
23 matter preceding subclause (I), by striking
24 “paragraph (4)” and inserting “para-
25 graphs (4) and (8)”;

1 (C) in paragraph (4)(A)(i), by striking
2 “The coverage” and inserting “Subject to para-
3 graph (8), the coverage”; and

4 (D) by adding at the end the following new
5 paragraph:

6 “(8) TREATMENT OF COST-SHARING FOR
7 ADULT VACCINES RECOMMENDED BY THE ADVISORY
8 COMMITTEE ON IMMUNIZATION PRACTICES CON-
9 SISTENT WITH TREATMENT OF VACCINES UNDER
10 PART B.—

11 “(A) IN GENERAL.—For plan years begin-
12 ning on or after January 1, 2023, with respect
13 to an adult vaccine recommended by the Advi-
14 sory Committee on Immunization Practices (as
15 defined in subparagraph (B))—

16 “(i) the deductible under paragraph
17 (1) shall not apply; and

18 “(ii) there shall be no coinsurance or
19 other cost-sharing under this part with re-
20 spect to such vaccine.

21 “(B) ADULT VACCINES RECOMMENDED BY
22 THE ADVISORY COMMITTEE ON IMMUNIZATION
23 PRACTICES.—For purposes of this paragraph,
24 the term ‘adult vaccine recommended by the
25 Advisory Committee on Immunization Prac-

1 tices’ means a covered part D drug that is a
2 vaccine licensed under section 351 of the Public
3 Health Service Act for use by adult populations
4 and administered in accordance with rec-
5 ommendations of the Advisory Committee on
6 Immunization Practices of the Centers for Dis-
7 ease Control and Prevention.”; and

8 (2) in subsection (c), by adding at the end the
9 following new paragraph:

10 “(5) TREATMENT OF COST-SHARING FOR
11 ADULT VACCINES RECOMMENDED BY THE ADVISORY
12 COMMITTEE ON IMMUNIZATION PRACTICES.—The
13 coverage is in accordance with subsection (b)(8).”.

14 (b) CONFORMING AMENDMENTS TO COST-SHARING
15 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
16 of the Social Security Act (42 U.S.C. 1395w–114(a)), as
17 amended by section 129201, is amended—

18 (1) in paragraph (1)(D), in each of clauses (ii)
19 and (iii), by striking “In the case” and inserting
20 “Subject to paragraph (6), in the case”;

21 (2) in paragraph (2)—

22 (A) in subparagraph (B), by striking “A
23 reduction” and inserting “Subject to section
24 1860D–2(b)(8), a reduction”;

1 (B) in subparagraph (D), by striking “The
2 substitution” and inserting “Subject to para-
3 graph (6), the substitution”; and

4 (C) in subparagraph (E), by striking “and
5 subsection (c)” and inserting “, paragraph (6)
6 of this subsection, and subsection (c)”; and

7 (3) by adding at the end the following new
8 paragraph:

9 “(6) NO APPLICATION OF COST-SHARING OR
10 DEDUCTIBLE FOR ADULT VACCINES RECOMMENDED
11 BY THE ADVISORY COMMITTEE ON IMMUNIZATION
12 PRACTICES.—For plan years beginning on or after
13 January 1, 2023, with respect to an adult vaccine
14 recommended by the Advisory Committee on Immu-
15 nization Practices (as defined in section 1860D-
16 2(b)(8)(B))—

17 “(A) the deductible under section 1860D-
18 2(b)(1) shall not apply; and

19 “(B) there shall be no cost-sharing under
20 this section with respect to such vaccine.”.

21 (c) TEMPORARY RETROSPECTIVE SUBSIDY.—Section
22 1860D-15 of the Social Security Act (42 U.S.C. 1395w-
23 115) is amended by adding at the end the following new
24 subsection:

1 “(h) TEMPORARY RETROSPECTIVE SUBSIDY FOR RE-
2 DUCTION IN COST-SHARING FOR ADULT VACCINES REC-
3 COMMENDED BY THE ADVISORY COMMITTEE ON IMMUNI-
4 ZATION PRACTICES DURING 2023.—

5 “(1) IN GENERAL.—In addition to amounts
6 otherwise payable under this section to a PDP spon-
7 sor of a prescription drug plan or an MA organiza-
8 tion offering an MA–PD plan, for plan year 2023,
9 the Secretary shall provide the PDP sponsor or MA
10 organization offering the plan subsidies in an
11 amount equal to the aggregate reduction in cost-
12 sharing by reason of the application of section
13 1860D–2(b)(8) for individuals under the plan during
14 the year.

15 “(2) TIMING.—The Secretary shall provide a
16 subsidy under paragraph (1), as applicable, not later
17 than 18 months following the end of the applicable
18 plan year.”.

19 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
20 tion shall be construed as limiting coverage under part D
21 of title XVIII of the Social Security Act for vaccines that
22 are not recommended by the Advisory Committee on Im-
23 munization Practices.

24 “(e) IMPLEMENTATION FOR 2023 THROUGH 2025.—
25 The Secretary shall implement this section, including the

1 amendments made by this section, for 2023, 2024, and
2 2025, by program instruction or other forms of program
3 guidance.

4 **SEC. 129402. PAYMENT FOR BIOSIMILAR BIOLOGICAL**
5 **PRODUCTS DURING INITIAL PERIOD.**

6 Section 1847A(c)(4) of the Social Security Act (42
7 U.S.C. 1395w-3a(c)(4)) is amended—

8 (1) in each of subparagraphs (A) and (B), by
9 redesignating clauses (i) and (ii) as subclauses (I)
10 and (II), respectively, and moving such subclauses 2
11 ems to the right;

12 (2) by redesignating subparagraphs (A) and
13 (B) as clauses (i) and (ii) and moving such clauses
14 2 ems to the right;

15 (3) by striking “UNAVAILABLE.—In the case”
16 and inserting “UNAVAILABLE.—

17 “(A) IN GENERAL.—Subject to subpara-
18 graph (B), in the case”; and

19 (4) by adding at the end the following new sub-
20 paragraph:

21 “(B) LIMITATION ON PAYMENT AMOUNT
22 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
23 ING INITIAL PERIOD.—In the case of a bio-
24 similar biological product furnished on or after
25 July 1, 2024, during the initial period described

1 in subparagraph (A) with respect to the bio-
2 similar biological product, the amount payable
3 under this section for the biosimilar biological
4 product is the lesser of the following:

5 “(i) The amount determined under
6 clause (ii) of such subparagraph for the
7 biosimilar biological product.

8 “(ii) The amount determined under
9 subsection (b)(1)(B) for the reference bio-
10 logical product.”.

11 **SEC. 129403. TEMPORARY INCREASE IN MEDICARE PART B**
12 **PAYMENT FOR CERTAIN BIOSIMILAR BIO-**
13 **LOGICAL PRODUCTS.**

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

16 (1) by redesignating subparagraphs (A) and
17 (B) as clauses (i) and (ii), respectively, and moving
18 the margin of each such redesignated clause 2 ems
19 to the right;

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

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

24 (3) by adding at the end the following new sub-
25 paragraph:

1 “(B) TEMPORARY PAYMENT INCREASE.—

2 “(i) IN GENERAL.—In the case of a
3 qualifying biosimilar biological product
4 that is furnished during the applicable 5-
5 year period for such product, the amount
6 specified in this paragraph for such prod-
7 uct with respect to such period is the sum
8 determined under subparagraph (A), ex-
9 cept that clause (ii) of such subparagraph
10 shall be applied by substituting ‘8 percent’
11 for ‘6 percent’.

12 “(ii) APPLICABLE 5-YEAR PERIOD.—
13 For purposes of clause (i), the applicable
14 5-year period for a qualifying biosimilar bi-
15 ological product is—

16 “(I) in the case of such a product
17 for which payment was made under
18 this paragraph as of September 30,
19 2022, the 5-year period beginning on
20 October 1, 2022; and

21 “(II) in the case of such a prod-
22 uct for which payment is first made
23 under this paragraph during a cal-
24 endar quarter during the period be-
25 ginning October 1, 2022, and ending

1 December 31, 2027, the 5-year period
2 beginning on the first day of such cal-
3 endar quarter during which such pay-
4 ment is first made.

5 “(iii) QUALIFYING BIOSIMILAR BIO-
6 LOGICAL PRODUCT DEFINED.—For pur-
7 poses of this subparagraph, the term
8 ‘qualifying biosimilar biological product’
9 means a biosimilar biological product de-
10 scribed in paragraph (1)(C) with respect to
11 which—

12 “(I) in the case of a product de-
13 scribed in clause (ii)(I), the average
14 sales price under paragraph (8)(A)(i)
15 for a calendar quarter during the 5-
16 year period described in such clause is
17 not more than the average sales price
18 under paragraph (4)(A) for such
19 quarter for the reference biological
20 product; and

21 “(II) in the case of a product de-
22 scribed in clause (ii)(II), the average
23 sales price under paragraph (8)(A)(i)
24 for a calendar quarter during the 5-
25 year period described in such clause is

1 not more than the average sales price
2 under paragraph (4)(A) for such
3 quarter for the reference biological
4 product.”.

5 **SEC. 129404. EXPANDING ELIGIBILITY FOR LOW-INCOME**
6 **SUBSIDIES UNDER PART D OF THE MEDI-**
7 **CARE PROGRAM.**

8 Section 1860D–14(a) of the Social Security Act (42
9 U.S.C. 1395w–114(a)), as amended by section 129201, is
10 amended—

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

14 (2) in paragraph (1)—

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

18 (B) in the matter preceding subparagraph
19 (A), by inserting “(or, with respect to a plan
20 year beginning on or after January 1, 2024,
21 150 percent)” after “135 percent”; and

22 (3) in paragraph (2)—

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

1 (B) in the matter preceding subparagraph
2 (A), by striking “In the case of a subsidy” and
3 inserting “With respect to a plan year begin-
4 ning before January 1, 2024, in the case of a
5 subsidy”.

6 **SEC. 129405. IMPROVING ACCESS TO ADULT VACCINES**
7 **UNDER MEDICAID AND CHIP.**

8 (a) MEDICAID.—

9 (1) REQUIRING COVERAGE OF ADULT VACCINA-
10 TIONS.—

11 (A) IN GENERAL.—Section 1902(a)(10)(A)
12 of the Social Security Act (42 U.S.C.
13 1396a(a)(10)(A)) is amended in the matter pre-
14 ceeding clause (i) by inserting “(13)(B),” after
15 “(5),”.

16 (B) MEDICALLY NEEDED.—Section
17 1902(a)(10)(C)(iv) of such Act (42 U.S.C.
18 1396a(a)(10)(C)(iv)) is amended by inserting “,
19 (13)(B),” after “(5)”.

20 (2) NO COST SHARING FOR VACCINATIONS.—

21 (A) GENERAL COST-SHARING LIMITA-
22 TIONS.—Section 1916 of the Social Security
23 Act (42 U.S.C. 1396o) is amended—

24 (i) in subsection (a)(2)—

1 (I) in subparagraph (G), by in-
2 serting a comma after “State plan”;

3 (II) in subparagraph (H), by
4 striking “; or” and inserting a
5 comma;

6 (III) in subparagraph (I), by
7 striking “; and” and inserting “, or”;
8 and

9 (IV) by adding at the end the fol-
10 lowing new subparagraph:

11 “(J) vaccines described in section
12 1905(a)(13)(B) and the administration of such
13 vaccines; and”;

14 (ii) in subsection (b)(2)—

15 (I) in subparagraph (G), by in-
16 serting a comma after “State plan”;

17 (II) in subparagraph (H), by
18 striking “; or” and inserting a
19 comma;

20 (III) in subparagraph (I), by
21 striking “; and” and inserting “, or”;
22 and

23 (IV) by adding at the end the fol-
24 lowing new subparagraph:

1 “(J) vaccines described in section
2 1905(a)(13)(B) and the administration of such
3 vaccines; and”.

4 (B) APPLICATION TO ALTERNATIVE COST
5 SHARING.—Section 1916A(b)(3)(B) of the So-
6 cial Security Act (42 U.S.C. 1396o–1(b)(3)(B))
7 is amended by adding at the end the following
8 new clause:

9 “(xiv) Vaccines described in section
10 1905(a)(13)(B) and the administration of
11 such vaccines.”.

12 (3) INCREASED FMAP FOR ADULT VACCINES
13 AND THEIR ADMINISTRATION.—Section 1905(b) of
14 the Social Security Act (42 U.S.C. 1396d(b)) is
15 amended—

16 (A) by striking “and (5)” and inserting
17 “(5)”;

18 (B) by striking “services and vaccines de-
19 scribed in subparagraphs (A) and (B) of sub-
20 section (a)(13), and prohibits cost-sharing for
21 such services and vaccines” and inserting “serv-
22 ices described in subsection (a)(13)(A), and
23 prohibits cost-sharing for such services”;

1 (C) by striking “medical assistance for
2 such services and vaccines” and inserting “med-
3 ical assistance for such services”; and

4 (D) by inserting “, and (6) during the first
5 8 fiscal quarters beginning on or after the effec-
6 tive date of this clause, in the case of a State
7 which, as of the date of enactment of the Act
8 titled ‘An Act to provide for reconciliation pur-
9 suant to title II of S. Con. Res. 14’, provides
10 medical assistance for vaccines described in
11 subsection (a)(13)(B) and their administration
12 and prohibits cost-sharing for such vaccines, the
13 Federal medical assistance percentage, as deter-
14 mined under this subsection and subsection (y),
15 shall be increased by 1 percentage point with
16 respect to medical assistance for such vaccines
17 and their administration” before the first pe-
18 riod.

19 (b) CHIP.—

20 (1) REQUIRING COVERAGE OF ADULT VACCINA-
21 TIONS.—Section 2103(c) of the Social Security Act
22 (42 U.S.C. 1397cc(c)) is amended by adding at the
23 end the following paragraph:

24 “(12) REQUIRED COVERAGE OF APPROVED,
25 RECOMMENDED ADULT VACCINES AND THEIR AD-

1 MINISTRATION.—Regardless of the type of coverage
2 elected by a State under subsection (a), if the State
3 child health plan or a waiver of such plan provides
4 child health assistance or pregnancy-related assist-
5 ance (as defined in section 2112) to an individual
6 who is 19 years of age or older, such assistance shall
7 include coverage of vaccines described in section
8 1905(a)(13)(B) and their administration.”.

9 (2) NO COST-SHARING FOR VACCINATIONS.—
10 Section 2103(e)(2) of such Act (42 U.S.C.
11 1397cc(e)(2)) is amended by inserting “vaccines de-
12 scribed in subsection (c)(12) (and the administration
13 of such vaccines),” after “in vitro diagnostic prod-
14 ucts described in subsection (c)(10) (and administra-
15 tion of such products),”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 this section take effect on the 1st day of the 1st fiscal
18 quarter that begins on or after the date that is 1 year
19 after the date of enactment of this Act and shall apply
20 to expenditures made under a State plan or waiver of such
21 plan under title XIX of the Social Security Act (42 U.S.C.
22 1396 through 1396w–6) or under a State child health plan
23 or waiver of such plan under title XXI of such Act (42
24 U.S.C. 1397aa through 1397mm) on or after such effec-
25 tive date.