

1 ness by reason of such requirements before final ac-
2 tion on such application.

3 **SEC. 138521. TERMINATION OF EMPLOYER CREDIT FOR**
4 **PAID FAMILY AND MEDICAL LEAVE.**

5 Section 45S(i) is amended by striking “December 31,
6 2025” and inserting “December 31, 2023”.

7 **Subtitle I—Drug Pricing**

8 **PART 1—LOWERING PRICES THROUGH DRUG**
9 **PRICE NEGOTIATION**

10 **SEC. 139001. PROVIDING FOR LOWER PRICES FOR CERTAIN**
11 **HIGH-PRICED SINGLE SOURCE DRUGS.**

12 (a) PROGRAM TO LOWER PRICES FOR CERTAIN
13 HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
14 Social Security Act is amended by adding after section
15 1184 (42 U.S.C. 1320e–3) the following new part:

16 **“PART E—PRICE NEGOTIATION PROGRAM TO**
17 **LOWER PRICES FOR CERTAIN HIGH-PRICED**
18 **SINGLE SOURCE DRUGS**

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

20 “(a) IN GENERAL.—The Secretary shall establish a
21 Drug Price Negotiation Program (in this part referred to
22 as the ‘program’). Under the program, with respect to
23 each price applicability period, the Secretary shall—

24 “(1) publish a list of negotiation-eligible drugs
25 and selected drugs in accordance with section 1192;

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

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

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

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

11 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
12 term ‘initial price applicability year’ means a year
13 (beginning with 2025).

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

21 “(3) SELECTED DRUG PUBLICATION DATE.—
22 The term ‘selected drug publication date’ means,
23 with respect to each initial price applicability year,
24 February 1 of the year that begins 2 years prior to
25 such year.

1 “(4) NEGOTIATION PERIOD.—The term ‘nego-
2 tiation period’ means, with respect to an initial price
3 applicability year with respect to a selected drug, the
4 period—

5 “(A) beginning on the sooner of—

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

10 “(ii) February 28 following the se-
11 lected drug publication date with respect to
12 such selected drug; and

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

16 “(c) OTHER DEFINITIONS.—For purposes of this
17 part:

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

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

1 under part C of such title if coverage is pro-
2 vided under such plan for such selected drug;
3 and

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

12 “(2) MAXIMUM FAIR PRICE.—The term ‘max-
13 imum fair price’ means, with respect to a year dur-
14 ing a price applicability period and with respect to
15 a selected drug (as defined in section 1192(c)) with
16 respect to such period, the price published pursuant
17 to section 1195 in the Federal Register for such
18 drug and year.

19 “(3) UNIT.—The term ‘unit’ means, with re-
20 spect to a drug or biological, the lowest identifiable
21 amount (such as a capsule or tablet, milligram of
22 molecules, or grams) of the drug or biological that
23 is dispensed or furnished. The determination of a
24 unit, with respect to a drug or biological, pursuant

1 to this paragraph shall not be subject to administra-
2 tive or judicial review.

3 “(4) TOTAL EXPENDITURES.—The term ‘total
4 expenditures’ includes, in the case of expenditures
5 with respect to part D of title XVIII, ingredient
6 costs, dispensing fees, sales tax, and if applicable,
7 vaccine administration fees. The term ‘total expendi-
8 tures’ excludes, in the case of expenditures with re-
9 spect to part B of such title, expenditures for a drug
10 or biological that are bundled or packaged into the
11 payment for another service.

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

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

19 “(1)(A) with respect to the initial price applica-
20 bility year 2025, not more than 10 negotiation-eli-
21 ble drugs described in subparagraph (A)(i) of sub-
22 section (d)(1), but not subparagraph (B) of such
23 subsection, with respect to such year;

24 “(B) with respect to the initial price applica-
25 bility year 2026, not more than 15 negotiation-eli-

1 ble drugs described in subparagraph (A)(i) of sub-
2 section (d)(1), but not subparagraph (B) of such
3 subsection, with respect to such year;

4 “(C) with respect to the initial price applica-
5 bility year 2027, not more than 15 negotiation-eligible
6 ble drugs described in subparagraph (A) of sub-
7 section (d)(1), but not subparagraph (B) of such
8 subsection, with respect to such year; and

9 “(D) with respect to the initial price applica-
10 bility year 2028 or a subsequent year, not more than
11 20 negotiation-eligible drugs described in subpara-
12 graph (A) of subsection (d)(1), but not subpara-
13 graph (B) of such subsection, with respect to such
14 year; and

15 “(2) all negotiation-eligible drugs described in
16 subparagraph (B) of such subsection with respect to
17 such year.

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—

4 “(A) rank a combined list of negotiation-el-
5 igible drugs described in subsection (d)(1)(A)
6 according to the total expenditures for such
7 drugs under parts B and D of title XVIII, as
8 determined by the Secretary, during the most
9 recent period of 12 months prior to the selected
10 drug publication date (but ending not later
11 than October 31 of the year prior to the year
12 of such drug publication date), with respect to
13 such year, for which data are available, with the
14 negotiation-eligible drugs with the highest total
15 expenditures being ranked the highest; and

16 “(B) select from such ranked combined list
17 for inclusion on the published list described in
18 subsection (a) with respect to such year the ne-
19 gotiation-eligible drugs with the highest such
20 rankings.

21 “(2) HIGH SPEND PART D DRUGS FOR 2025 AND
22 2026.—With respect to the initial price applicability
23 year 2025 and with respect to the initial price appli-
24 cability year 2026, the Secretary shall apply para-
25 graph (1) as if the reference to ‘negotiation-eligible

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

7 “(c) SELECTED DRUG.—

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

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

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

23 “(ii) under section 351(k) of the Pub-
24 lic Health Service Act using such drug as
25 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 ble 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 2025 or 2026, that
3 is described in subparagraph (A)(i) or (B)):

4 “(A) HIGH SPEND DRUGS.—The qualifying
5 single source drug is, determined in accordance
6 with subsection (e)(2)—

7 “(i) among the 50 qualifying single
8 source drugs with the highest total expend-
9 itures under part D of title XVIII, as de-
10 termined by the Secretary in accordance
11 with paragraph (3), during the most recent
12 period for which data are available of at
13 least 12 months prior to the selected drug
14 publication date (but ending no later than
15 October 31 of the year prior to the year of
16 such drug publication date), with respect
17 to such year; or

18 “(ii) among the 50 qualifying single
19 source drugs with the highest total expend-
20 itures under part B of title XVIII, as de-
21 termined by the Secretary in accordance
22 with paragraph (3), during such most re-
23 cent period, as described in clause (i).

24 “(B) INSULIN.—The qualifying single
25 source drug is described in subsection (e)(1)(C).

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

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (C), the term ‘negotiation-eligible drug’
5 shall not include, with respect to the initial
6 price applicability years 2025, 2026, and 2027,
7 a qualifying single source drug that meets ei-
8 ther of the following:

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

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

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

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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), 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 qualifying sin-
2 gle source drug described in subparagraph
3 (A) shall not include a qualifying single
4 source drug of a manufacturer if such
5 manufacturer is acquired after 2021 by
6 another manufacturer that does not meet
7 the 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 2024,
12 effective January 1, 2024.

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 “(iii) A qualifying single source drug
25 described in subsection (e)(1)(C).

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1 “(3) CLARIFICATIONS AND DETERMINATIONS.—

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

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

8 “(ii) for initial price applicability
9 years 2025, 2026, and 2027, qualifying
10 single source drugs described in paragraph
11 (2)(A).

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

21 “(4) PUBLICATION.—Not later than the se-
22 lected drug publication date with respect to an ini-
23 tial price applicability year, the Secretary shall pub-
24 lish in the Federal Register a list of negotiation-eli-

1 gible drugs with respect to such selected drug publi-
2 cation date.

3 “(e) QUALIFYING SINGLE SOURCE DRUG.—

4 “(1) IN GENERAL.—For purposes of this part,
5 the term ‘qualifying single source drug’ means, with
6 respect to an initial price applicability year, subject
7 to paragraphs (2) and (3), a covered part D drug
8 (as defined in section 1860D–2(e)) that is described
9 in any of the following or a drug or biological prod-
10 uct covered under part B of title XVIII that is de-
11 scribed in any of the following:

12 “(A) DRUG PRODUCTS.—A drug—

13 “(i) that is approved under section
14 505(c) of the Federal Food, Drug, and
15 Cosmetic Act and is marketed pursuant to
16 such approval;

17 “(ii) for which, as of the selected drug
18 publication date with respect to such initial
19 price applicability year, at least 7 years
20 will have elapsed since the date of such ap-
21 proval; and

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

1 “(B) BIOLOGICAL PRODUCTS.—A biologi-
2 cal product—

3 “(i) that is licensed under section
4 351(a) of the Public Health Service Act
5 and is marketed under section 351 of such
6 Act;

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

12 “(iii) that is not the reference product
13 for any biological product that is licensed
14 and marketed under section 351(k) of such
15 Act.

16 “(C) INSULIN PRODUCT.—Any insulin
17 product that is approved under section 505 of
18 the Federal Food, Drug, and Cosmetic Act or
19 licensed under section 351 of the Public Health
20 Service Act and marketed pursuant to such ap-
21 proval or licensure, including any insulin prod-
22 uct that has been deemed to be licensed under
23 section 351 of the Public Health Service Act
24 pursuant to section 7002(e)(4) of the Biologics
25 Price Competition and Innovation Act of 2009

1 and is marketed pursuant to such section, re-
2 gardless of whether such insulin product would
3 be described in subparagraph (A) or (B).

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

6 “(A) IN GENERAL.—In the case of a quali-
7 fying single source drug described in subpara-
8 graph (A) or (B) of paragraph (1) that is the
9 listed drug (as such term is used in section
10 505(j) of the Federal Food, Drug, and Cos-
11 metic Act) or the reference product (as defined
12 in section 351(i) of the Public Health Service
13 Act), with respect to an authorized generic
14 drug, in applying the provisions of this part,
15 such authorized generic drug and such listed
16 drug or reference product shall be treated as
17 the same qualifying single source drug.

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

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

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1 “(ii) in the case of a biological prod-
2 uct, a reference product (as such term is
3 defined in section 351(i) of the Public
4 Health Service Act) 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.

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

12 “(i) with respect to 2021,
13 \$200,000,000; or

14 “(ii) with respect to a subsequent
15 year, the dollar amount specified in this
16 subparagraph for the previous year in-
17 creased by the annual percentage increase
18 in the consumer price index (all items;
19 U.S. city average) as of December of such
20 previous year.

21 “(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW OF
22 DETERMINATIONS AND SELECTIONS.—The determination
23 of negotiation-eligible drugs under subsection (d) and the
24 selection of drugs under this section are not subject to
25 administrative or judicial review.

1 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

2 “(a) IN GENERAL.—For purposes of section
3 1191(a)(2), the Secretary shall enter into agreements with
4 manufacturers of selected drugs with respect to a price
5 applicability period, by not later than February 28 fol-
6 lowing the selected drug publication date with respect to
7 such selected drug, under which—

8 “(1) during the negotiation period for the initial
9 price applicability year for the selected drug, the
10 Secretary and manufacturer, in accordance with sec-
11 tion 1194, negotiate to determine (and, by not later
12 than the last date of such period, agree to) a max-
13 imum fair price for such selected drug of the manu-
14 facturer in order for the manufacturer to provide ac-
15 cess to such price—

16 “(A) to maximum fair price eligible indi-
17 viduals who with respect to such drug are de-
18 scribed in subparagraph (A) of section
19 1191(c)(1) and are dispensed such drug (and to
20 pharmacies, mail order services, and other dis-
21 pensers, with respect to such maximum fair
22 price eligible individuals who are dispensed such
23 drugs) during, subject to subparagraph (2), the
24 price applicability period; and

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

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1 to maximum fair price eligible individuals who
2 with respect to such drug are described in sub-
3 paragraph (B) of such section and are fur-
4 nished or administered such drug during, sub-
5 ject to subparagraph (2), the price applicability
6 period;

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

13 “(A) to maximum fair price eligible indi-
14 viduals who with respect to such drug are de-
15 scribed in subparagraph (A) of section
16 1191(c)(1) and are dispensed such drug (and to
17 pharmacies, mail order services, and other dis-
18 pensers, with respect to such maximum fair
19 price eligible individuals who are dispensed such
20 drugs) during any year during the price appli-
21 cability period (beginning after such renegoti-
22 ation) with respect to such selected drug; and

23 “(B) to hospitals, physicians, and other
24 providers of services and suppliers with respect
25 to maximum fair price eligible individuals who

1 with respect to such drug are described in sub-
2 paragraph (B) of such section and are fur-
3 nished or administered such drug during any
4 year described in subparagraph (A);

5 “(3) access to the maximum fair price (includ-
6 ing as renegotiated pursuant to paragraph (2)), with
7 respect to such a selected drug, shall be provided by
8 the manufacturer to—

9 “(A) maximum fair price eligible individ-
10 uals, who with respect to such drug are de-
11 scribed in subparagraph (A) of section
12 1191(c)(1), at the pharmacy, mail order service,
13 or other dispenser at the point-of-sale of such
14 drug (and shall be provided by the manufac-
15 turer to the pharmacy, mail order service, or
16 other dispenser, with respect to such maximum
17 fair price eligible individuals who are dispensed
18 such drugs), as described in paragraph (1)(A)
19 or (2)(A), as applicable; and

20 “(B) hospitals, physicians, and other pro-
21 viders of services and suppliers with respect to
22 maximum fair price eligible individuals who
23 with respect to such drug are described in sub-
24 paragraph (B) of such section and are fur-

1 nished or administered such drug, as described
2 in paragraph (1)(B) or (2)(B), as applicable;

3 “(4) the manufacturer, subject to subsection
4 (d), submits to the Secretary, through an online por-
5 tal established by the Secretary or other form and
6 manner specified by the Secretary, for the negotia-
7 tion period for the price applicability period (and, if
8 applicable, before any period of renegotiation pursu-
9 ant to section 1194(f)) with respect to such drug—

10 “(A) information on the non-Federal aver-
11 age manufacturer price for the drug for the ap-
12 plicable year or period; and

13 “(B) all other information that the Sec-
14 retary requires to carry out the negotiation (or
15 renegotiation process) under this part, including
16 information described in section 1194(e)(1);
17 and

18 “(5) the manufacturer complies with require-
19 ments imposed by the Secretary for purposes of ad-
20 ministering the program, including with respect to
21 the duties described in section 1196.

22 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO
23 LONGER A SELECTED DRUG.—An agreement entered into
24 under this section shall be effective, with respect to a se-

1 lected drug, until such drug is no longer considered a se-
2 lected drug under section 1192(c).

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

11 “(d) IMPLEMENTATION FOR 2025 AND 2026.—Not-
12 withstanding any other provision of this part, the Sec-
13 retary shall implement this section for 2025 and 2026 by
14 program instruction or otherwise.

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

16 “(a) IN GENERAL.—For purposes of this part, under
17 an agreement under section 1193 between the Secretary
18 and a manufacturer of a selected drug, with respect to
19 the period for which such agreement is in effect and in
20 accordance with subsections (b), (c), and (d), the Sec-
21 retary and the manufacturer—

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

1 “(2) renegotiate, in accordance with the process
2 specified pursuant to subsection (f), such maximum
3 fair price for such drug if such drug is a renegoti-
4 ation-eligible drug under such subsection.

5 “(b) NEGOTIATION PROCESS REQUIREMENTS.—

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

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

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

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1 “(B) INITIAL OFFER BY SECRETARY.—Not
2 later than the June 1 following the selected
3 drug publication date, the Secretary shall pro-
4 vide the manufacturer of a selected drug with
5 a written initial offer that contains the Sec-
6 retary’s proposal for the maximum fair price of
7 the drug and a list of the considerations de-
8 scribed in section 1194(e) that were used in de-
9 veloping such offer.

10 “(C) RESPONSE TO INITIAL OFFER.—

11 “(i) IN GENERAL.—Not later than 30
12 days after the date of receipt of an initial
13 offer under subparagraph (B), the manu-
14 facturer shall either accept such offer or
15 propose a counteroffer to such offer.

16 “(ii) COUNTEROFFER REQUIRE-
17 MENTS.—If a manufacturer proposes a
18 counteroffer, such counteroffer—

19 “(I) shall be in writing; and

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

22 “(D) RESPONSE TO COUNTEROFFER.—
23 After receiving a counteroffer under subpara-
24 graph (C), the Secretary shall respond in writ-
25 ing to such counteroffer.

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1 “(E) DEADLINE.—All negotiations shall
2 end prior to the first day of November following
3 the selected drug publication date, with respect
4 to the initial price applicability year.

5 “(F) LIMITATIONS ON OFFER AMOUNT.—
6 In negotiating the maximum fair price of a se-
7 lected drug, with respect to an initial price ap-
8 plicability year for the selected drug, and, as
9 applicable, in renegotiating the maximum fair
10 price for such drug, with respect to a subse-
11 quent year during the price applicability period
12 for such drug, the Secretary shall not offer (or
13 agree to a counteroffer for) a maximum fair
14 price for the selected drug that—

15 “(i) exceeds the ceiling determined
16 under subsection (c) for the selected drug
17 and year; or

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

21 “(G) TREATMENT OF DETERMINATION.—
22 The establishment of a maximum fair price
23 under this section is not subject to administra-
24 tive or judicial review.

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

1 “(1) IN GENERAL.—The maximum fair price
2 negotiated under this section for a selected drug,
3 with respect to the first year of the price applica-
4 bility period with respect to such drug, shall not ex-
5 ceed the applicable percent described in paragraph
6 (2), with respect to such drug, of the following:

7 “(A) INITIAL PRICE APPLICABILITY YEAR
8 2025.—In the case of a selected drug with re-
9 spect to which such initial price applicability
10 year is 2025, the non-Federal average manufac-
11 turer price for such drug for 2020 (or, in the
12 case that there is not a non-Federal average
13 manufacturer price available for such drug for
14 2020, for the first full year following the mar-
15 ket entry for such drug), increased by the per-
16 centage increase in the consumer price index for
17 all urban consumers (all items; United States
18 city average) from 2020 (or such first full year
19 following the market entry), as applicable, to
20 the year prior to the selected drug publication
21 date with respect to such initial price applica-
22 bility year.

23 “(B) INITIAL PRICE APPLICABILITY YEAR
24 2026 AND SUBSEQUENT YEARS.—In the case of
25 a selected drug with respect to which such ini-

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1 tial price applicability year is 2026 or a subse-
2 quent year, the lower of—

3 “(i) the non-Federal average manufac-
4 turer price for such drug for 2020 (or, in
5 the case that there is not a non-Federal
6 average manufacturer price available for
7 such drug for 2020, for the first full year
8 following the market entry for such drug),
9 increased by the percentage increase in the
10 consumer price index for all urban con-
11 sumers (all items; United States city aver-
12 age) from 2020 (or such first full year fol-
13 lowing the market entry), as applicable, to
14 the year prior to the selected drug publica-
15 tion date with respect to such initial price
16 applicability year; or

17 “(ii) the non-Federal average manu-
18 facturer price for such drug for the year
19 prior to the selected drug publication date
20 with respect to such initial price applica-
21 bility year.

22 “(2) APPLICABLE PERCENT DESCRIBED.—For
23 purposes of paragraph (1), the applicable percent
24 described in this paragraph is the following:

1 “(A) SHORT-MONOPOLY DRUGS.—With re-
2 spect to a selected drug (other than a post-ex-
3 clusivity drug and a long-monopoly drug), 75
4 percent.

5 “(B) POST-EXCLUSIVITY DRUGS.—With re-
6 spect to a post-exclusivity drug, 65 percent.

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

9 “(3) POST-EXCLUSIVITY DRUG DEFINED.—

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

20 “(B) EXCLUSIONS.—The term ‘post-exclu-
21 sivity drug’ shall not include any of the fol-
22 lowing:

23 “(i) A vaccine that is licensed under
24 section 351 of the Public Health Service

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

3 “(ii) A selected drug that had an
4 agreement under this part with the Sec-
5 retary prior to the initial price applicability
6 year 2030.

7 “(C) CLARIFICATION.—Nothing in sub-
8 paragraph (B)(ii) shall limit the transition of a
9 selected drug described in paragraph (2)(A) to
10 a long-monopoly drug if the selected drug meets
11 the definition of a long-monopoly drug.

12 “(4) LONG-MONOPOLY DRUG DEFINED.—

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

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

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

3 “(5) NON-FEDERAL AVERAGE MANUFACTURER
4 PRICE.—In this part, the term ‘non-Federal average
5 manufacturer price’ has the meaning given such
6 term in section 8126(h)(5) of title 38, United States
7 Code.

8 “(d) TEMPORARY FLOOR FOR SMALL BIOTECH
9 DRUGS.—In the case of a selected drug that is a quali-
10 fying single source drug described in section 1192(d)(2)
11 and with respect to which the first initial price applica-
12 bility year of the price applicability period with respect to
13 such drug is 2028 or 2029, the maximum fair price nego-
14 tiated under this section for such drug for such initial
15 price applicability year may not be less than 66 percent
16 of the non-Federal average manufacturer price for such
17 drug (as defined and applied in subsection (c)(4)) for
18 2020 (or, in the case that there is not a non-Federal aver-
19 age manufacturer price available for such drug for 2020,
20 for the first full year following the market entry for such
21 drug), increased by the percentage increase in the con-
22 sumer price index for all urban consumers (all items;
23 United States city average) from 2020 (or such first full
24 year following the market entry), as applicable, to the year

1 prior to the selected drug publication date with respect
2 to the initial price applicability year.

3 “(e) CONSIDERATIONS.—For purposes of negotiating
4 the maximum fair price of a selected drug under this part
5 with the manufacturer of the drug, the Secretary shall
6 consider the following factors (and, with respect to post-
7 exclusivity drugs and long-monopoly drugs, shall not con-
8 sider factors other than those described in subparagraphs
9 (B) and (C) of paragraph (1)):

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

14 “(A) Research and development costs of
15 the manufacturer for the drug and the extent to
16 which the manufacturer has recouped research
17 and development costs.

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

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

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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 UNMET MEDICAL NEEDS
10 AND ALTERNATIVE TREATMENTS.—The following in-
11 formation, with respect to such selected drug:

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

17 “(B) Information on approval by the Food
18 and Drug Administration of alternative drug
19 products or biological products.

20 “(C) Information on comparative effective-
21 ness analysis for such products, taking into
22 consideration the effects of such products on
23 specific populations, such as individuals with
24 disabilities, the elderly, the terminally ill, chil-
25 dren, and other patient populations.

1 “(D) The extent to which the drug ad-
2 dresses unmet medical needs for a condition for
3 which treatment or diagnosis is not addressed
4 adequately by available therapy.

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

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

17 “(f) RENEGOTIATION PROCESS.—

18 “(1) IN GENERAL.—In the case of a renegoti-
19 ation-eligible drug (as defined in paragraph (2)) that
20 is selected under paragraph (3), the Secretary shall
21 provide for a process of renegotiation (for years (be-
22 ginning with 2027) during the price applicability pe-
23 riod, with respect to such drug) of the maximum fair
24 price for such drug consistent with paragraph (4).

1 “(2) RENEGOTIATION-ELIGIBLE DRUG DE-
2 FINED.—In this section, the term ‘renegotiation-eli-
3 gible drug’ means a selected drug that is any of the
4 following:

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

8 “(B) CHANGE OF STATUS TO A POST-EX-
9 CLUSIVITY DRUG.—A selected drug that is de-
10 scribed in section 1192(d)(1)(A) that—

11 “(i) is not a post-exclusivity drug or a
12 long-monopoly drug; and

13 “(ii) for which there is a change in
14 status to that of a post-exclusivity drug.

15 “(C) CHANGE OF STATUS TO A LONG-MO-
16 NOPOLY DRUG.—A selected drug that is de-
17 scribed in section 1192(d)(1)(A) that—

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

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

21 “(D) MATERIAL CHANGES.—A selected
22 drug for which the Secretary determines there
23 has been a material change of factors described
24 in paragraph (1) or (2) of subsection (e).

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1 “(3) SELECTION OF DRUGS FOR RENEGOTI-
2 ATION.—Each year the Secretary shall select among
3 renegotiation-eligible drugs for renegotiation as fol-
4 lows:

5 “(A) ALL POST-EXCLUSIVITY NEGOTIA-
6 TION-ELIGIBLE DRUGS.—The Secretary shall
7 select all renegotiation-eligible drugs described
8 in paragraph (2)(B).

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

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

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

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

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

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

1 “(g) REQUEST FOR INFORMATION.—For purposes of
2 negotiating and, as applicable, renegotiating (including for
3 purposes of determining whether to renegotiate) the max-
4 imum fair price of a selected drug under this part with
5 the manufacturer of the drug, with respect to a price ap-
6 plicability period, and other relevant data for purposes of
7 this section—

8 “(1) the Secretary shall, not later than the se-
9 lected drug publication date with respect to the ini-
10 tial price applicability year of such period, request
11 drug pricing information from the manufacturer of
12 such selected drug, including information described
13 in subsection (e)(1); and

14 “(2) by not later than March 1 following the se-
15 lected drug publication date, the manufacturer of
16 such selected drug shall submit to the Secretary
17 such requested information in such form and man-
18 ner as the Secretary requires.

19 The Secretary shall request, from the manufacturer or
20 others, all additional information needed to carry out the
21 negotiation and renegotiation process under this section.

22 “(h) IMPLEMENTATION FOR 2025 AND 2026.—Not-
23 withstanding any other provision of this part, the Sec-
24 retary shall implement this section for 2025 and 2026 by
25 program instruction or otherwise.

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

2 “(a) IN GENERAL.—With respect to an initial price
3 applicability year and a selected drug with respect to such
4 year—

5 “(1) not later than November 15 of the year
6 that is 2 years prior to such initial price applicability
7 year, the Secretary shall publish on CMS.gov the
8 maximum fair price for such drug negotiated under
9 this part with the manufacturer of such drug;

10 “(2) not later than November 30 of the year
11 that is 2 years prior to such initial price applicability
12 year, the Secretary shall publish in the Federal Reg-
13 ister the maximum fair price for such drug described
14 in paragraph (1); and

15 “(3) not later than March 1 of the year prior
16 to such initial price applicability year, the Secretary
17 shall publish in the Federal Register, subject to sec-
18 tion 1193(c) and based on the considerations as de-
19 scribed in section 1194(e), the explanation for the
20 maximum fair price for such drug described in para-
21 graphs (1) and (2).

22 “(b) UPDATES.—

23 “(1) SUBSEQUENT YEAR MAXIMUM FAIR
24 PRICES.—For a selected drug, for each year subse-
25 quent to first initial price applicability year of the
26 price applicability period with respect to such drug,

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1 with respect to which an agreement for such drug is
2 in effect under section 1193, not later than Novem-
3 ber 30 of the year that is 2 years prior to such sub-
4 sequent year, the Secretary shall publish in the Fed-
5 eral Register the maximum fair price applicable to
6 such drug and year, which shall be—

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

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

18 “(2) PRICES NEGOTIATED AFTER DEADLINE.—

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

1 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
2 **VISIONS.**

3 “(a) ADMINISTRATIVE DUTIES.—

4 “(1) IN GENERAL.—For purposes of section
5 1191, the administrative duties described in this sec-
6 tion are the following:

7 “(A) The establishment of procedures to
8 ensure that the maximum fair price for a se-
9 lected drug is applied before—

10 “(i) any coverage or financial assist-
11 ance under other health benefit plans or
12 programs that provide coverage or finan-
13 cial assistance for the purchase or provi-
14 sion of prescription drug coverage on be-
15 half of maximum fair price eligible individ-
16 uals; and

17 “(ii) any other discounts.

18 “(B) The establishment of procedures to
19 compute and apply the maximum fair price
20 across different strengths and dosage forms of
21 a selected drug and not based on the specific
22 formulation or package size or package type of
23 the drug.

24 “(C) The establishment of procedures to
25 carry out the provisions of this part, as applica-
26 ble, with respect to—

1 “(i) maximum fair price eligible indi-
2 viduals who are enrolled under a prescrip-
3 tion drug plan under part D of title XVIII
4 or an MA–PD plan under part C of such
5 title; and

6 “(ii) maximum fair price eligible indi-
7 viduals who are enrolled under part B of
8 such title, including who are enrolled under
9 an MA plan under part C of such title.

10 “(D) The establishment of a negotiation
11 process and renegotiation process in accordance
12 with section 1194, including a process for ac-
13 quiring information described in subsection (e)
14 of such section.

15 “(E) The establishment of an online portal
16 which manufacturers shall be required to use to
17 submit information described in section
18 1194(b)(2)(A).

19 “(F) The sharing with the Secretary of the
20 Treasury of such information as is necessary to
21 determine the tax imposed by section 4192 of
22 the Internal Revenue Code of 1986 (relating to
23 enforcement of this part).

1 “(G) The establishment of an attestation
2 and verification process for purposes of apply-
3 ing section 1192(d)(2)(B).

4 “(2) MONITORING COMPLIANCE.—The Sec-
5 retary shall monitor compliance by a manufacturer
6 with the terms of an agreement under section 1193,
7 including by establishing a mechanism through
8 which violations of such terms shall be reported.

9 “(b) IMPLEMENTATION FOR 2025 AND 2026.—Not-
10 withstanding any other provision of this part, the Sec-
11 retary shall implement this section for 2025 and 2026 by
12 program instruction or otherwise.

13 **“SEC. 1197. CIVIL MONETARY PENALTY.**

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

21 “(1) to a maximum fair price eligible individual
22 who with respect to such drug is described in sub-
23 paragraph (A) of section 1191(c)(1) and who is dis-
24 pensed such drug during such year (and to phar-
25 macies, mail order services, and other dispensers,

1 with respect to such maximum fair price eligible in-
2 dividuals who are dispensed such drugs); or

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

10 shall be subject to a civil monetary penalty equal to ten
11 times the amount equal to the product of the number of
12 units of such drug so furnished, dispensed, or adminis-
13 tered during such year and the difference between the
14 price for such drug made available for such year by such
15 manufacturer with respect to such individual or hospital,
16 physician, provider of services, or supplier and the max-
17 imum fair price for such drug for such year.

18 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
19 MENT.—Any manufacturer of a selected drug that has en-
20 tered into an agreement under section 1193, with respect
21 to a year during the price applicability period with respect
22 to such drug, that is in violation of a requirement imposed
23 pursuant to section 1193(a)(5), including the requirement
24 to submit information pursuant to section 1193(a)(4),

1 shall be subject to a civil monetary penalty equal to
2 \$1,000,000 for each day of such violation.

3 “(c) FALSE INFORMATION.—Any manufacturer that
4 knowingly provides false information for the attestation
5 process or verification process established pursuant to sec-
6 tion 1196(a)(1)(H), shall be subject to a civil monetary
7 penalty equal to \$100,000,000 for each item of such false
8 information.

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

14 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
15 CONFORMING AMENDMENTS.—

16 (1) UNDER MEDICARE.—

17 (A) APPLICATION TO PAYMENTS UNDER
18 PART B.—Section 1847A(b)(1)(B) of the Social
19 Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is
20 amended by inserting “or in the case of such a
21 drug or biological that is a selected drug (as re-
22 ferred to in section 1192(c)), with respect to a
23 price applicability period (as defined in section
24 1191(b)(2)), 106 percent of the maximum fair
25 price (as defined in section 1191(c)(2)) applica-

1 ble for such drug and a year during such pe-
2 riod” after “paragraph (4)”.

3 (B) APPLICATION UNDER MA OF COST-
4 SHARING FOR PART B DRUGS BASED OFF OF
5 NEGOTIATED PRICE.—Section
6 1852(a)(1)(B)(iv) of the Social Security Act
7 (42 U.S.C. 1395w–22(a)(1)(B)(iv)) is amend-
8 ed—

9 (i) by redesignating subclause (VII) as
10 subclause (VIII); and

11 (ii) by inserting after subclause (VI)
12 the following subclause:

13 “(VII) A drug or biological that
14 is a selected drug (as referred to in
15 section 1192(c)).”.

16 (C) EXCEPTION TO PART D NON-INTER-
17 FERENCE.—Section 1860D–11(i) of the Social
18 Security Act (42 U.S.C. 1395w–111(i)) is
19 amended—

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

22 (ii) in paragraph (2), by striking “or
23 institute a price structure for the reim-
24 bursement of covered part D drugs” and

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1 inserting “for covered part D drugs; and”;

2 and

3 (iii) by adding at the end the fol-

4 lowing:

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

8 (D) APPLICATION AS NEGOTIATED PRICE
9 UNDER PART D.—Section 1860D–2(d)(1) of the
10 Social Security Act (42 U.S.C. 1395w–
11 102(d)(1)) is amended—

12 (i) in subparagraph (B), by inserting
13 “, subject to subparagraph (D),” after
14 “negotiated prices”; and

15 (ii) by adding at the end the following
16 new subparagraph:

17 “(D) APPLICATION OF MAXIMUM FAIR
18 PRICE FOR SELECTED DRUGS.—In applying this
19 section, in the case of a covered part D drug
20 that is a selected drug (as referred to in section
21 1192(c)), with respect to a price applicability
22 period (as defined in section 1191(b)(2)), the
23 negotiated prices used for payment (as de-
24 scribed in this subsection) shall be no greater
25 than the maximum fair price (as defined in sec-

1 tion 1191(c)(2)) for such drug and for each
2 year during such period plus any dispensing
3 fees for such drug.”.

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

9 “(I) REQUIRED INCLUSION OF SELECTED
10 DRUGS.—For 2025 and each subsequent year,
11 the PDP sponsor offering a prescription drug
12 plan shall include each covered part D drug
13 that is a selected drug under section 1192 for
14 which an agreement for such drug is in effect
15 under section 1193 with respect to the year.”.

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

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

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

1 a prescription drug plan offered by such sponsor
2 shall require the sponsor to provide information to
3 the Secretary as requested by the Secretary in ac-
4 cordance with section 1194(g).”.

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

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

13 (2) DRUG PRICE NEGOTIATION PROGRAM
14 PRICES INCLUDED IN BEST PRICE.—Section
15 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
16 1396r–8(c)(1)(C)) is amended—

17 (A) in clause (i)(VI), by striking “any
18 prices charged” and inserting “subject to clause
19 (ii)(V), any prices charged”; and

20 (B) in clause (ii)—

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

23 (ii) in subclause (IV), by striking at
24 the end the period and inserting “; and”;
25 and

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1 (iii) by adding at the end the fol-
2 lowing new subclause:

3 “(V) in the case of a rebate pe-
4 riod and a covered outpatient drug
5 that is a selected drug (as referred to
6 in section 1192(c)) during such rebate
7 period, shall be inclusive of the max-
8 imum fair price (as defined in section
9 1191(c)(2)) for such drug with re-
10 spect to such period.”.

11 **SEC. 139002. SELECTED DRUG MANUFACTURER EXCISE TAX**
12 **IMPOSED DURING NONCOMPLIANCE PERI-**
13 **ODS.**

14 (a) IN GENERAL.—Chapter 32 of the Internal Rev-
15 enue Code of 1986 is amended by adding at the end the
16 following new subchapter:

17 **“Subchapter E—Other Items**

“Sec. 4192. Selected drugs during noncompliance periods.

18 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
19 **PERIODS.**

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

1 “(1) such tax, divided by

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

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

7 “(1) The period beginning on the March 1st
8 immediately following the selected drug publication
9 date and ending on the first date during which the
10 manufacturer of the drug has in place an agreement
11 described in subsection (a) of section 1193 of the
12 Social Security Act with respect to such drug.

13 “(2) The period beginning on the November
14 2nd immediately following the March 1st described
15 in paragraph (1) and ending on the first date during
16 which the manufacturer of the drug and the Sec-
17 retary have agreed to a maximum fair price under
18 such agreement.

19 “(3) In the case of a selected drug with respect
20 to which the Secretary of Health and Human Serv-
21 ices has specified a renegotiation period under such
22 agreement, the period beginning on the first date
23 after the last date of such renegotiation period and
24 ending on the first date during which the manufac-

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1 turer of the drug has agreed to a renegotiated max-
2 imum fair price under such agreement.

3 “(4) With respect to information that is re-
4 quired to be submitted to the Secretary of Health
5 and Human Services under such agreement, the pe-
6 riod beginning on the date on which such Secretary
7 certifies that such information is overdue and ending
8 on the date that such information is so submitted.

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

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

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

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

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

23 “(d) SELECTED DRUG.—For purposes of this sec-
24 tion—

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1 “(1) IN GENERAL.—The term ‘selected drug’
2 means any selected drug (within the meaning of sec-
3 tion 1192 of the Social Security Act) which is manu-
4 factured or produced in the United States or entered
5 into the United States for consumption, use, or
6 warehousing.

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

10 “(3) COORDINATION WITH RULES FOR POSSES-
11 SIONS OF THE UNITED STATES.—Rules similar to
12 the rules of paragraphs (2) and (4) of section
13 4132(c) shall apply for purposes of this section.

14 “(e) OTHER DEFINITIONS.—For purposes of this
15 section, the terms ‘selected drug publication date’ and
16 ‘maximum fair price’ have the meaning given such terms
17 in section 1191 of the Social Security Act.

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

22 (b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—
23 Section 275(a)(6) of the Internal Revenue Code of 1986
24 is amended by inserting “or by section 4192” before the
25 period at the end.

1 (c) CERTAIN EXEMPTIONS FROM TAX NOT APPLICA-
2 BLE.—

3 (1) Section 4221(a) of the Internal Revenue
4 Code of 1986 is amended by adding at the end the
5 following: “In the case of the tax imposed by section
6 4192, paragraphs (3), (4), (5), and (6) shall not
7 apply.”.

8 (2) Section 6416(b)(2) of such Code is amend-
9 ed by adding at the end the following: “In the case
10 of the tax imposed by section 4192, subparagraphs
11 (B), (C), (D), and (E) shall not apply.”.

12 (d) CLERICAL AMENDMENT.—The table of sub-
13 chapters for chapter 32 of such Code is amended by add-
14 ing at the end the following new item:

“SUBCHAPTER E. OTHER ITEMS”.

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

18 **SEC. 139003. FUNDING.**

19 In addition to amounts otherwise available, there is
20 appropriated for fiscal year 2022, out of any money in
21 the Treasury not otherwise appropriated, to remain avail-
22 able until expended—

23 (1) \$300,000,000 to carry out the provisions of,
24 including the amendments made by, this part in fis-
25 cal year 2022;

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1 (2) \$300,000,000 to carry out the provisions of,
2 including the amendments made by, this part in fis-
3 cal year 2023;

4 (3) \$300,000,000 to carry out the provisions of,
5 including the amendments made by, this part in fis-
6 cal year 2024;

7 (4) \$300,000,000 to carry out the provisions of,
8 including the amendments made by, this part in fis-
9 cal year 2025;

10 (5) \$300,000,000 to carry out the provisions of,
11 including the amendments made by, this part in fis-
12 cal year 2026;

13 (6) \$300,000,000 to carry out the provisions of,
14 including the amendments made by, this part in fis-
15 cal year 2027;

16 (7) \$300,000,000 to carry out the provisions of,
17 including the amendments made by, this part in fis-
18 cal year 2028;

19 (8) \$300,000,000 to carry out the provisions of,
20 including the amendments made by, this part in fis-
21 cal year 2029;

22 (9) \$300,000,000 to carry out the provisions of,
23 including the amendments made by, this part in fis-
24 cal year 2030; and

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1 (10) \$300,000,000 to carry out the provisions
2 of, including the amendments made by, this part in
3 fiscal year 2031.

4 **PART 2—PRESCRIPTION DRUG INFLATION**

5 **REBATES**

6 **SEC. 139101. MEDICARE PART B REBATE BY MANUFACTUR-**
7 **ERS.**

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

10 (1) by redesignating subsection (h) as sub-
11 section (i) and by inserting after subsection (g) the
12 following subsection:

13 “(h) REBATE BY MANUFACTURERS FOR SINGLE
14 SOURCE DRUGS AND BIOLOGICALS WITH PRICES IN-
15 CREASING FASTER THAN INFLATION.—

16 “(1) REQUIREMENTS.—

17 “(A) SECRETARIAL PROVISION OF INFOR-
18 MATION.—Not later than 6 months after the
19 end of each calendar quarter beginning on or
20 after July 1, 2023, the Secretary shall, for each
21 part B rebatable drug, report to each manufac-
22 turer of such part B rebatable drug the fol-
23 lowing for such calendar quarter:

24 “(i) Information on the total number
25 of billing units of the billing and payment

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1 code described in subparagraph (A)(i) of
2 paragraph (3) with respect to such drug
3 and calendar quarter.

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

9 “(iii) The rebate amount specified
10 under such paragraph for such part B
11 rebatable drug and calendar quarter.

12 “(B) MANUFACTURER REQUIREMENT.—
13 For each calendar quarter beginning on or after
14 July 1, 2023, the manufacturer of a part B
15 rebatable drug shall, for such drug, not later
16 than 30 days after the date of receipt from the
17 Secretary of the information described in sub-
18 paragraph (A) for such calendar quarter, pro-
19 vide to the Secretary a rebate that is equal to
20 the amount specified in paragraph (3) for such
21 drug for such calendar quarter.

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

23 “(A) IN GENERAL.—In this subsection, the
24 term ‘part B rebatable drug’ means a single
25 source drug or biological (as defined in sub-

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1 paragraph (D) of subsection (c)(6)), including a
2 biosimilar biological product (as defined in sub-
3 paragraph (H) of such subsection) but exclud-
4 ing a qualifying biosimilar biological product
5 (as defined in subsection (b)(8)(B)(iii)), that
6 would be payable under this part if such drug
7 were furnished to an individual enrolled under
8 this part, except such term shall not include
9 such a drug or biological—

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

16 “(ii) that is a vaccine described in
17 subparagraph (A) or (B) of section
18 1861(s)(10).

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

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

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

3 “(ii) for a subsequent year, shall be
4 the dollar amount specified in this clause
5 (or clause (i)) for the previous year (with-
6 out application of subparagraph (C)), in-
7 creased by the percentage increase in the
8 consumer price index for all urban con-
9 sumers (United States city average) for
10 the 12-month period ending with June of
11 the previous year.

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

16 “(3) REBATE AMOUNT.—

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

24 “(i) the total number of billing units
25 determined under subparagraph (B) for

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1 the billing and payment code of such drug;

2 and

3 “(ii) the amount (if any) by which—

4 “(I) the amount equal to—

5 “(aa) in the case of a part B

6 rebatable drug described in para-

7 graph (1)(B) of section

8 1847A(b), 106 percent of the

9 amount determined under para-

10 graph (4) of such section for

11 such drug during the calendar

12 quarter; or

13 “(bb) in the case of a part B

14 rebatable drug described in para-

15 graph (1)(C) of such section, the

16 payment amount under such

17 paragraph for such drug during

18 the calendar quarter; exceeds

19 “(II) the inflation-adjusted pay-

20 ment amount determined under sub-

21 paragraph (C) for such part B

22 rebatable drug during the calendar

23 quarter.

24 “(B) TOTAL NUMBER OF BILLING

25 UNITS.—For purposes of subparagraph (A)(i),

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1 the total number of billing units with respect to
2 a part B rebatable drug is determined as fol-
3 lows:

4 “(i) Determine the total number of
5 units equal to—

6 “(I) the total number of units, as
7 reported under subsection (c)(1)(B)
8 for each National Drug Code of such
9 drug during the calendar quarter that
10 is two calendar quarters prior to the
11 calendar quarter as described in sub-
12 paragraph (A), minus

13 “(II) the total number of units
14 with respect to each National Drug
15 Code of such drug for which payment
16 was made under a State plan under
17 title XIX (or waiver of such plan), as
18 reported by States under section
19 1927(b)(2)(A) for the rebate period
20 that is the same calendar quarter as
21 described in subclause (I).

22 “(ii) Convert the units determined
23 under clause (i) to billing units for the bill-
24 ing and payment code of such drug, using
25 a methodology similar to the methodology

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1 used under this section, by dividing the
2 units determined under clause (i) for each
3 National Drug Code of such drug by the
4 billing unit for the billing and payment
5 code of such drug.

6 “(iii) Compute the sum of the billing
7 units for each National Drug Code of such
8 drug in clause (ii).

9 “(C) DETERMINATION OF INFLATION-AD-
10 JUSTED PAYMENT AMOUNT.—The inflation-ad-
11 justed payment amount determined under this
12 subparagraph for a part B rebatable drug for
13 a calendar quarter is—

14 “(i) the payment amount for the bill-
15 ing and payment code for such drug in the
16 payment amount benchmark quarter (as
17 defined in subparagraph (D)); increased by

18 “(ii) the percentage by which the re-
19 bate period CPI–U (as defined in subpara-
20 graph (F)) for the calendar quarter ex-
21 ceeds the benchmark period CPI–U (as de-
22 fined in subparagraph (E)).

23 “(D) PAYMENT AMOUNT BENCHMARK
24 QUARTER.—The term ‘payment amount bench-

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1 mark quarter’ means the calendar quarter be-
2 ginning October 1, 2021.

3 “(E) BENCHMARK PERIOD CPI–U.—The
4 term ‘benchmark period CPI–U’ means the con-
5 sumer price index for all urban consumers
6 (United States city average) for March 2021.

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

16 “(G) EXEMPTION FOR SHORTAGES AND
17 SEVERE SUPPLY CHAIN DISRUPTIONS.—The
18 Secretary shall reduce or waive the amount
19 under subparagraph (A) with respect to a part
20 B rebatable drug that is described as currently
21 in shortage on the shortage list in effect under
22 section 506E of the Federal Food, Drug, and
23 Cosmetic Act or in the case of a biosimilar bio-
24 logical product, when the Secretary determines
25 there are severe supply chain disruptions.

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

3 “(A) SUBSEQUENTLY APPROVED DRUGS.—

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

19 “(B) TIMELINE FOR PROVISION OF RE-
20 BATES FOR SUBSEQUENTLY APPROVED
21 DRUGS.—In the case of a part B rebatable drug
22 first approved or licensed by the Food and
23 Drug Administration after March 1, 2021,
24 paragraph (1)(B) shall be applied as if the ref-
25 erence to ‘July 1, 2023’ under such paragraph

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1 were a reference to the later of the 6th full cal-
2 endar quarter after the day on which the drug
3 was first marketed or July 1, 2023.

4 “(D) SELECTED DRUGS.—In the case of a
5 part B rebatable drug that is a selected drug
6 (as defined in section 1192(c)) for a price appli-
7 cability period (as defined in section
8 1191(b)(2)), in the case such drug is deter-
9 mined (pursuant to such section 1192(c)) to no
10 longer be a selected drug, beginning the first
11 calendar quarter after the price applicability pe-
12 riod with respect to such drug, clause (i) of
13 paragraph (3)(C) shall be applied as if the term
14 ‘payment amount benchmark quarter’ were de-
15 fined under paragraph (3)(D) as the calendar
16 quarter beginning January 1 of the last year
17 beginning during such price applicability period
18 with respect to such selected drug and clause
19 (ii) of paragraph (3)(C) shall be applied as if
20 the term ‘benchmark period CPI–U’ were de-
21 fined under paragraph (3)(E) as if the ref-
22 erence to ‘March 2021’ under such paragraph
23 were a reference to the March of the year pre-
24 ceding such last year.

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

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

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

23 “(6) REBATE DEPOSITS.—Amounts paid as re-
24 bates under paragraph (1)(B) shall be deposited into

1 the Federal Supplementary Medical Insurance Trust
2 Fund established under section 1841.

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

18 (2) in subsection (i), as redesignated by para-
19 graph (1)—

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

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

24 (C) by adding at the end the following new
25 paragraphs:

1 “(6) the determination of units under sub-
2 section (h);

3 “(7) the determination of whether a drug is a
4 part B rebatable drug under subsection (h);

5 “(8) the calculation of the rebate amount under
6 subsection (h); and

7 “(9) the computation of coinsurance under sub-
8 section (h)(5); and

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

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

14 (1) in subsection (a)(1)—

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

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

21 (C) by striking “and (DD)” and inserting
22 “(DD)”; and

23 (D) by inserting before the semicolon at
24 the end the following: “, and (EE) with respect
25 to a part B rebatable drug (as defined in para-

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1 graph (2) of section 1847A(h)) for which the
2 payment amount for a calendar quarter under
3 paragraph (3)(A)(ii)(I) of such section (or, in
4 the case of a part B rebatable drug that is a
5 selected drug (as defined in section 1192(c) for
6 which, the payment amount described in section
7 1847A(b)(1)(B)) for such drug for such quarter
8 exceeds the inflation-adjusted payment under
9 paragraph (3)(A)(ii)(II) of such section for
10 such quarter, the amounts paid shall be equal
11 to the percent of the payment amount under
12 paragraph (3)(A)(ii)(I) of such section or sec-
13 tion 1847A(b)(1)(B), as applicable, that equals
14 the difference between (i) 100 percent, and (ii)
15 the percent applied under section
16 1847A(h)(5)(B)”;

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

19 “(9) In the case of a part B rebatable drug (as de-
20 fined in paragraph (2) of section 1847A(h)) for which pay-
21 ment under this subsection is not packaged into a payment
22 for a service furnished on or after July 1, 2023, under
23 the revised payment system under this subsection, in lieu
24 of calculation of coinsurance and the amount of payment
25 otherwise applicable under this subsection, the provisions

1 of section 1847A(h)(5) and paragraph (1)(EE) of sub-
2 section (a), shall, as determined appropriate by the Sec-
3 retary, apply under this subsection in the same manner
4 as such provisions of section 1847A(h)(5) and subsection
5 (a) apply under such section and subsection.”; and

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

8 “(F) PART B REBATABLE DRUGS.—In the
9 case of a part B rebatable drug (as defined in
10 paragraph (2) of section 1847A(h), except if
11 such drug does not have a copayment amount
12 as a result of application of subparagraph (E))
13 for which payment under this part is not pack-
14 aged into a payment for a covered OPD service
15 (or group of services) furnished on or after July
16 1, 2023, and the payment for such drug under
17 this subsection is the same as the amount for
18 a calendar quarter under paragraph
19 (3)(A)(ii)(I) of section 1847A(h), under the sys-
20 tem under this subsection, in lieu of calculation
21 of the copayment amount and the amount of
22 payment otherwise applicable under this sub-
23 section (other than the application of the limita-
24 tion described in subparagraph (C)), the provi-
25 sions of section 1847A(h)(5) and paragraph

1 (1)(EE) of subsection (a), shall, as determined
2 appropriate by the Secretary, apply under this
3 subsection in the same manner as such provi-
4 sions of section 1847A(h)(5) and subsection (a)
5 apply under such section and subsection.”.

6 (c) CONFORMING AMENDMENTS.—

7 (1) TO PART B ASP CALCULATION.—Section
8 1847A(c)(3) of the Social Security Act (42 U.S.C.
9 1395w–3a(c)(3)) is amended by inserting “sub-
10 section (h) or” before “section 1927”.

11 (2) EXCLUDING PART B DRUG INFLATION RE-
12 BATE FROM BEST PRICE.—Section
13 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
14 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-
15 serting “or section 1847A(h)” after “this section”.

16 (3) COORDINATION WITH MEDICAID REBATE IN-
17 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
18 of the Social Security Act (42 U.S.C. 1396r–
19 8(b)(3)(D)(i)) is amended by inserting “and the re-
20 bate” after “the payment amount”.

21 (4) EXCLUDING PART B DRUG INFLATION RE-
22 BATES FROM AVERAGE MANUFACTURER PRICE.—
23 Section 1927(k)(1)(B)(i) of the Social Security Act
24 (42 U.S.C. 1396r–8(k)(1)(B)(i)), as previously
25 amended, is further amended—

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1 (A) in subclause (IV), by striking “and”;

2 (B) in subclause (V), by striking the period

3 at the end and inserting a semicolon; and

4 (C) by adding at the end the following new

5 subclause:

6 “(VI) rebates paid by manufac-

7 turers under section 1847A(h); and”.

8 (d) FUNDING.—In addition to amounts otherwise
9 available, there are appropriated to the Centers for Medi-
10 care & Medicaid Services, out of any money in the Treas-
11 ury not otherwise appropriated, \$12,500,000 for fiscal
12 year 2022 and \$7,500,000 for each of fiscal years 2023
13 through 2031, to remain available until expended, to carry
14 out the provisions of, including the amendments made by,
15 this section.

16 **SEC. 139102. MEDICARE PART D REBATE BY MANUFACTUR-**
17 **ERS.**

18 (a) IN GENERAL.—Part D of title XVIII of the Social
19 Security Act is amended by inserting after section 1860D–
20 14A (42 U.S.C. 1395w–114a) the following new section:

21 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
22 **DRUGS WITH PRICES INCREASING FASTER**
23 **THAN INFLATION.**

24 “(a) REQUIREMENTS.—

1 “(1) SECRETARIAL PROVISION OF INFORMA-
2 TION.—Not later than 9 months after the end of
3 each applicable year (as defined in subsection
4 (g)(7)), subject to paragraph (3), the Secretary
5 shall, for each part D rebatable drug, report to each
6 manufacturer of such part D rebatable drug the fol-
7 lowing for such year:

8 “(A) The amount (if any) of the excess an-
9 nual manufacturer price increase described in
10 subsection (b)(1)(A)(ii) for each dosage form
11 and strength with respect to such drug and
12 year.

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

16 “(2) MANUFACTURER REQUIREMENTS.—For
17 each applicable year, the manufacturer of a part D
18 rebatable drug, for each dosage form and strength
19 with respect to such drug, not later than 30 days
20 after the date of receipt from the Secretary of the
21 information described in paragraph (1) for such
22 year, shall provide to the Secretary a rebate that is
23 equal to the amount specified in subsection (b) for
24 such dosage form and strength with respect to such
25 drug for such year.

2014

1 “(3) TRANSITION RULE FOR REPORTING.—The
2 Secretary may, for each rebatable covered part D
3 drug, delay the timeframe for reporting the informa-
4 tion and rebate amount described in subparagraphs
5 (A) and (B) of such paragraph for the applicable
6 year of 2023 until not later than September 30,
7 2025.

8 “(b) REBATE AMOUNT.—

9 “(1) IN GENERAL.—

10 “(A) CALCULATION.—For purposes of this
11 section, the amount specified in this subsection
12 for a dosage form and strength with respect to
13 a part D rebatable drug and applicable year is,
14 subject to subparagraph (C), paragraph (5)(B),
15 and paragraph (6), the amount equal to the
16 product of—

17 “(i) subject to subparagraph (B) of
18 this paragraph, the total number of units
19 that are used to calculate the average man-
20 ufacturer price of such dosage form and
21 strength with respect to such part D
22 rebatable drug, as reported by the manu-
23 facturer of such drug under section 1927
24 for each month, with respect to such year;
25 and

2015

1 “(ii) the amount (if any) by which—

2 “(I) the annual manufacturer
3 price (as determined in paragraph
4 (2)) paid for such dosage form and
5 strength with respect to such part D
6 rebatable drug for the year; exceeds

7 “(II) the inflation-adjusted pay-
8 ment amount determined under para-
9 graph (3) for such dosage form and
10 strength with respect to such part D
11 rebatable drug for the year.

12 “(B) EXCLUDED UNITS.—For purposes of
13 subparagraph (A)(i), the Secretary shall exclude
14 from the total number of units for a dosage
15 form and strength with respect to a part D
16 rebatable drug, with respect to an applicable
17 year, the following:

18 “(i) Units of each dosage form and
19 strength of such part D rebatable drug for
20 which payment was made under a State
21 plan under title XIX (or waiver of such
22 plan), as reported by States under section
23 1927(b)(2)(A).

24 “(ii) Units of each dosage form and
25 strength of such part D rebatable drug for

2016

1 which a rebate is paid under section
2 1847A(h).

3 “(C) EXEMPTION FOR SHORTAGES AND
4 SEVERE SUPPLY CHAIN DISRUPTIONS.—The
5 Secretary shall reduce or waive the amount
6 under subparagraph (A) with respect to a part
7 D rebatable drug that is described as currently
8 in shortage on the shortage list in effect under
9 section 506E of the Federal Food, Drug, and
10 Cosmetic Act or in the case of a generic drug,
11 when the Secretary determines there are severe
12 supply chain disruptions.

13 “(2) DETERMINATION OF ANNUAL MANUFAC-
14 Turer price.—The annual manufacturer price de-
15 termined under this paragraph for a dosage form
16 and strength, with respect to a part D rebatable
17 drug and an applicable year, is the sum of the prod-
18 ucts of—

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

24 “(B) the ratio of—

2017

1 “(i) the total number of units of such
2 dosage form and strength reported under
3 section 1927 with respect to each such cal-
4 endar quarter of such year; to

5 “(ii) the total number of units of such
6 dosage form and strength reported under
7 section 1927 with respect to such year, as
8 determined by the Secretary.

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

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

19 “(B) the percentage by which the applica-
20 ble year CPI–U (as defined in subsection
21 (g)(5)) for the year exceeds the benchmark pe-
22 riod CPI–U (as defined in subsection (g)(4)).

23 “(4) DETERMINATION OF BENCHMARK YEAR
24 MANUFACTURER PRICE.—The benchmark year man-
25 ufacturer price determined under this paragraph for

2018

1 a dosage form and strength, with respect to a part
2 D rebatable drug and an applicable year, is the sum
3 of the products of—

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

10 “(B) the ratio of—

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

16 “(ii) the total number of units re-
17 ported under section 1927 of such dosage
18 form and strength with respect to such
19 payment amount benchmark year.

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

22 “(A) SUBSEQUENTLY APPROVED DRUGS.—
23 In the case of a part D rebatable drug first ap-
24 proved or licensed by the Food and Drug Ad-
25 ministration after October 1, 2021, subpara-

2019

1 graphs (A) and (B) of paragraph (4) shall be
2 applied as if the term ‘payment amount bench-
3 mark year’ were defined under subsection
4 (g)(3) as the first calendar year beginning after
5 the day on which the drug was first marketed
6 by any manufacturer and subparagraph (B) of
7 paragraph (3) shall be applied as if the term
8 ‘benchmark period CPI-U’ were defined under
9 subsection (g)(4) as if the reference to ‘October
10 2021’ under such subsection were a reference to
11 ‘January of the first year beginning after the
12 date on which the drug was first marketed by
13 any manufacturer’.

14 “(B) TREATMENT OF NEW FORMULA-
15 TIONS.—

16 “(i) IN GENERAL.—In the case of a
17 part D rebatable drug that is a line exten-
18 sion of a part D rebatable drug that is an
19 oral solid dosage form, the Secretary shall
20 establish a formula for determining the re-
21 bate amount under paragraph (1) and the
22 inflation adjusted payment amount under
23 paragraph (3) with respect to such part D
24 rebatable drug and an applicable year, con-
25 sistent with the formula applied under sub-

2020

1 section (c)(2)(C) of section 1927 for deter-
2 mining a rebate obligation for a rebate pe-
3 riod under such section.

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

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

2021

1 the last year beginning during such price appli-
2 cability period with respect to such selected
3 drug and subparagraph (B) of paragraph (3)
4 shall be applied as if the term ‘benchmark pe-
5 riod CPI-U’ were defined under subsection
6 (g)(4) as if the reference to ‘October 2021’
7 under such subsection were a reference to Jan-
8 uary of the last year beginning during such
9 price applicability period with respect to such
10 drug.

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

1 not later than 30 days after the date of receipt from
2 the Secretary of information on such underpayment.

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

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

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

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

2 There shall be no administrative or judicial review of the
3 following:

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

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

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

10 “(g) DEFINITIONS.—In this section:

11 “(1) PART D REBATABLE DRUG.—

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

2024

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

3 “(i) for 2024, shall be the dollar
4 amount specified under such subparagraph
5 for 2023, increased by the percentage in-
6 crease in the consumer price index for all
7 urban consumers (United States city aver-
8 age) for the 12-month period beginning
9 with January of 2023; and

10 “(ii) for a subsequent year, shall be
11 the dollar amount specified in this sub-
12 paragraph for the previous year, increased
13 by the percentage increase in the consumer
14 price index for all urban consumers
15 (United States city average) for the 12-
16 month period beginning with January of
17 the previous year.

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

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

1 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—

2 The term ‘payment amount benchmark year’ means
3 the year beginning October 1, 2021.

4 “(4) BENCHMARK PERIOD CPI–U.—The term
5 ‘benchmark period CPI–U’ means the consumer
6 price index for all urban consumers (United States
7 city average) for October 2021.

8 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-
9 plicable year CPI–U’ means, with respect to an ap-
10 plicable year, the consumer price index for all urban
11 consumers (United States city average) for January
12 of such year.

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

19 “(7) APPLICABLE YEAR.—The term ‘applicable
20 year’ means a calendar year beginning with 2023.

21 “(h) IMPLEMENTATION FOR 2023 AND 2024.—Not-
22 withstanding any other provision of this section, the Sec-
23 retary shall implement this section for 2023 and 2024 by
24 program instruction or otherwise.”.

25 (b) CONFORMING AMENDMENTS.—

1 (1) TO PART B ASP CALCULATION.—Section
2 1847A(c)(3) of the Social Security Act (42 U.S.C.
3 1395w–3a(c)(3)), as amended by section
4 139101(c)(1), is further amended by striking “sub-
5 section (h) or section 1927” and inserting “sub-
6 section (h), section 1927, or section 1860D–14B”.

7 (2) EXCLUDING PART D DRUG INFLATION RE-
8 BATE FROM BEST PRICE.—Section
9 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
10 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
11 tion 139101(c)(2), is further amended by striking
12 “or section 1847A(h)” and inserting “, section
13 1847A(h), or section 1860D–14B”.

14 (3) COORDINATION WITH MEDICAID REBATE IN-
15 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
16 of the Social Security Act (42 U.S.C. 1396r–
17 8(b)(3)(D)(i)), as amended by section 139101(c)(3),
18 is further amended by striking “or to carry out sec-
19 tion 1847B” and inserting “or to carry out section
20 1847B or section 1860D–14B”.

21 (4) EXCLUDING PART D DRUG INFLATION RE-
22 BATES FROM AVERAGE MANUFACTURER PRICE.—
23 Section 1927(k)(1)(B)(i) of the Social Security Act
24 (42 U.S.C. 1396r–8(k)(1)(B)(i)), as previously

1 amended, is further amended by adding at the end
2 the following new subclause:

3 “(VII) rebates paid by manufac-
4 turers under section 1860D-14B.”.

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

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

16 **SEC. 139201. MEDICARE PART D BENEFIT REDESIGN.**

17 (a) BENEFIT STRUCTURE REDESIGN.—Section
18 1860D-2(b) of the Social Security Act (42 U.S.C. 1395w-
19 102(b)) is amended—

20 (1) in paragraph (2)—

21 (A) in subparagraph (A), in the matter
22 preceding clause (i), by inserting “for a year
23 preceding 2024 and for costs above the annual
24 deductible specified in paragraph (1) and up to
25 the annual out-of-pocket threshold specified in

1 paragraph (4)(B) for 2024 and each subsequent
2 year” after “paragraph (3)”;

3 (B) in subparagraph (C)—

4 (i) in clause (i), in the matter pre-
5 ceding subclause (I), by inserting “for a
6 year preceding 2024,” after “paragraph
7 (4),”; and

8 (ii) in clause (ii)(III), by striking
9 “and each subsequent year” and inserting
10 “through 2023”; and

11 (C) in subparagraph (D)—

12 (i) in clause (i)—

13 (I) in the matter preceding sub-
14 clause (I), by inserting “for a year
15 preceding 2024,” after “paragraph
16 (4),”; and

17 (II) in subclause (I)(bb), by
18 striking “a year after 2018” and in-
19 serting “each of years 2019 through
20 2023”; and

21 (ii) in clause (ii)(V), by striking
22 “2019 and each subsequent year” and in-
23 serting “each of years 2019 through
24 2023”;

25 (2) in paragraph (3)(A)—

1 (A) in the matter preceding clause (i), by
2 inserting “for a year preceding 2024,” 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 2023”; 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

2030

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 2023”; and

2031

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 2024, 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)(i), by striking
17 “and for amounts” and inserting “and, for a
18 year preceding 2024, for amounts”; and

19 (D) in subparagraph (E), by striking “In
20 applying” and inserting “For each of years
21 2011 through 2023, in applying”.

22 (b) REINSURANCE PAYMENT AMOUNT.—Section
23 1860D–15(b) of the Social Security Act (42 U.S.C.
24 1395w–115(b)) is amended—

25 (1) in paragraph (1)—

2032

1 (A) by striking “equal to 80 percent” and
2 inserting “equal to—

3 “(A) for a year preceding 2024, 80 per-
4 cent”;

5 (B) in subparagraph (A), as added by sub-
6 paragraph (A), by striking the period at the
7 end and inserting “; and”; and

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

10 “(B) for 2024 and each subsequent year,
11 the sum of—

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

22 “(ii) an amount equal to 40 percent of
23 such allowable reinsurance costs attrib-
24 utable to that portion of gross prescription
25 drug costs as specified in paragraph (3) in-

1 curred in the coverage year after such indi-
2 vidual has incurred costs that exceed the
3 annual out-of-pocket threshold specified in
4 section 1860D–2(b)(4)(B) with respect to
5 covered part D drugs that are not applica-
6 ble drugs (as so defined).”;

7 (2) in paragraph (2)—

8 (A) by striking “COSTS.—For purposes”
9 and inserting “COSTS.—

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

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

14 “(B) INCLUSION OF MANUFACTURER DIS-
15 COUNTS ON APPLICABLE DRUGS.—For purposes
16 of applying subparagraph (A), the term ‘allow-
17 able reinsurance costs’ shall include the portion
18 of the negotiated price (as defined in section
19 1860D–14C(g)(6)) of an applicable drug (as
20 defined in section 1860D–14C(g)(2)) that was
21 paid by a manufacturer under the manufacturer
22 discount program under section 1860D–14C.”;
23 and

24 (3) in paragraph (3)—

2034

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

4 (B) in the second sentence, by inserting
5 “(or, with respect to 2024 and subsequent
6 years, in the case of an applicable drug, as de-
7 fined in section 1860D-14C(g)(2), by a manu-
8 facturer)” after “by the individual or under the
9 plan”.

10 (c) REDUCED COST-SHARING; BENEFICIARY PRE-
11 MIUM PERCENTAGE.—

12 (1) COST-SHARING.—

13 (A) IN GENERAL.—Section 1860D-
14 2(b)(2)(A) of the Social Security Act (42
15 U.S.C. 1395w-102(b)(2)(A)) is amended—

16 (i) in the subparagraph header, by
17 striking “25 PERCENT COINSURANCE” and
18 inserting “COINSURANCE”;

19 (ii) in clause (i), by inserting “(or, for
20 2024 and each subsequent year, 23 per-
21 cent)” after “25 percent”; and

22 (iii) in clause (ii), by inserting “(or,
23 for 2024 and each subsequent year, 23
24 percent)” after “25 percent”.

1 (B) CONFORMING AMENDMENT.—Section
2 1860D–14(a)(2)(D) of the Social Security Act
3 (42 U.S.C. 1395w–114(a)(2)(D)) is amended
4 by inserting “(or, for 2024 and each subsequent
5 year, instead of coinsurance of ‘23 percent’)”
6 after “instead of coinsurance of ‘25 percent’”.

7 (2) BENEFICIARY PREMIUM PERCENTAGE.—

8 (A) IN GENERAL.—Section 1860D–
9 13(a)(3)(A) of the Social Security Act (42
10 U.S.C. 1395w–113(a)(3)(A)) is amended by in-
11 serting “(or, for 2024 and each subsequent
12 year, 23.5 percent)” after “25.5 percent”.

13 (B) CONFORMING AMENDMENTS.—

14 (i) Section 1860D–11(g)(6) of the So-
15 cial Security Act (42 U.S.C. 1395w–
16 111(g)(6)) is amended by inserting “(or,
17 for 2024 and each subsequent year, 23.5
18 percent)” after “25.5 percent”.

19 (ii) Section 1860D–13(a)(7)(B)(i) of
20 the Social Security Act (42 U.S.C. 1395w–
21 113(a)(7)(B)(i)) is amended—

22 (I) in subclause (I), by inserting
23 “(or, for 2024 and each subsequent
24 year, 23.5 percent)” after “25.5 per-
25 cent”; and

1 (II) in subclause (II), by insert-
2 ing “(or, for 2024 and each subse-
3 quent year, 23.5 percent)” after “25.5
4 percent”.

5 (iii) Section 1860D–15(a) of the So-
6 cial Security Act (42 U.S.C. 1395w–
7 115(a)) is amended by inserting “(or, for
8 2024 and each subsequent year, 76.5 per-
9 cent)” after “74.5 percent”.

10 (d) MANUFACTURER DISCOUNT PROGRAM.—

11 (1) IN GENERAL.—Part D of title XVIII of the
12 Social Security Act (42 U.S.C. 1395w–101 through
13 42 U.S.C. 1395w–153), as amended by section
14 139102, is further amended by inserting after sec-
15 tion 1860D–14B the following new sections:

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

17 “(a) ESTABLISHMENT.—The Secretary shall estab-
18 lish a manufacturer discount program (in this section re-
19 ferred to as the ‘program’). Under the program, the Sec-
20 retary shall enter into agreements described in subsection
21 (b) with manufacturers and provide for the performance
22 of the duties described in subsection (c). The Secretary
23 shall establish a model agreement for use under the pro-
24 gram by not later than January 1, 2023, in consultation

1 with manufacturers, and allow for comment on such model
2 agreement.

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, 2024.

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

13 “(i) the application of a coinsurance
14 of 23 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 2024.—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, 2024, and ending on December 31,
3 2024, the manufacturer shall enter into
4 such agreement not later than 30 days
5 after the date of the establishment of a
6 model agreement under subsection (a).

7 “(ii) 2025 AND SUBSEQUENT
8 YEARS.—In order for an agreement with a
9 manufacturer to be in effect under this
10 section with respect to plan year 2025 or
11 a subsequent plan year, the manufacturer
12 shall enter into such agreement not later
13 than a calendar quarter or semi-annual
14 deadline established by the Secretary.

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

21 “(3) COMPLIANCE WITH REQUIREMENTS FOR
22 ADMINISTRATION OF PROGRAM.—Each manufac-
23 turer with an agreement in effect under this section
24 shall comply with requirements imposed by the Sec-
25 retary or a third party with a contract under sub-

1 section (d)(3), as applicable, for purposes of admin-
2 istering the program, including any determination
3 under subparagraph (A) of subsection (c)(1) or pro-
4 cedures established under such subsection (c)(1).

5 “(4) LENGTH OF AGREEMENT.—

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

12 “(B) TERMINATION.—

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

1 effective date to be repealed if the Sec-
2 retary determines appropriate.

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

8 “(I) if the termination occurs be-
9 fore January 31 of a plan year, as of
10 the day after the end of the plan year;
11 and

12 “(II) if the termination occurs on
13 or after January 31 of a plan year, as
14 of the day after the end of the suc-
15 ceeding plan year.

16 “(iii) EFFECTIVENESS OF TERMI-
17 NATION.—Any termination under this sub-
18 paragraph shall not affect discounts for
19 applicable drugs of the manufacturer that
20 are due under the agreement before the ef-
21 fective date of its termination.

22 “(iv) NOTICE TO THIRD PARTY.—The
23 Secretary shall provide notice of such ter-
24 mination to a third party with a contract
25 under subsection (d)(3) within not less

1 than 30 days before the effective date of
2 such termination.

3 “(c) DUTIES DESCRIBED.—The duties described in
4 this subsection are the following:

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

7 “(A) the determination of the amount of
8 the discounted price of an applicable drug of a
9 manufacturer;

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

17 “(i) the negotiated price of the appli-
18 cable drug; and

19 “(ii) the discounted price of the appli-
20 cable drug;

21 “(C) the establishment of procedures to
22 ensure that the discounted price for an applica-
23 ble drug under this section is applied before any
24 coverage or financial assistance under other
25 health benefit plans or programs that provide

1 coverage or financial assistance for the pur-
2 chase or provision of prescription drug coverage
3 on behalf of applicable beneficiaries as specified
4 by the Secretary; and

5 “(D) providing a reasonable dispute resolu-
6 tion mechanism to resolve disagreements be-
7 tween manufacturers, applicable beneficiaries,
8 and the third party with a contract under sub-
9 section (d)(3).

10 “(2) MONITORING COMPLIANCE.—

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

14 “(B) NOTIFICATION.—If a third party
15 with a contract under subsection (d)(3) deter-
16 mines that the manufacturer is not in compli-
17 ance with such agreement, the third party shall
18 notify the Secretary of such noncompliance for
19 appropriate enforcement under subsection (e).

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

1 “(d) ADMINISTRATION.—

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

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

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

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

21 “(B) receive, distribute, or facilitate the
22 distribution of funds of manufacturers to ap-
23 propriate individuals or entities in order to
24 meet the obligations of manufacturers under
25 agreements under this section;

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

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

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

17 “(5) IMPLEMENTATION.—The Secretary shall
18 implement the program under this section for 2024
19 and 2025 by program instruction or otherwise.

20 “(e) ENFORCEMENT.—

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

24 “(2) CIVIL MONEY PENALTY.—

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

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

14 “(ii) 25 percent of such amount.

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

21 “(f) CLARIFICATION REGARDING AVAILABILITY OF
22 OTHER COVERED PART D DRUGS.—Nothing in this sec-
23 tion shall prevent an applicable beneficiary from pur-
24 chasing a covered part D drug that is not an applicable
25 drug (including a generic drug or a drug that is not on

1 the formulary of the prescription drug plan or MA–PD
2 plan that the applicable beneficiary is enrolled in).

3 “(g) DEFINITIONS.—In this section:

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

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

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

11 “(C) has incurred costs, as determined in
12 accordance with section 1860D–2(b)(4)(C) as if
13 clause (iii) of such section included a reference
14 to costs reimbursed through insurance, a group
15 health plan, or certain other third-party pay-
16 ment arrangements, for covered part D drugs
17 in the year that exceed—

18 “(i) in the case of an individual not
19 described in clause (ii) or (iii), the annual
20 deductible for such year, as specified in
21 section 1860D–2(b)(1);

22 “(ii) in the case of a subsidy eligible
23 individual described in section 1860D-
24 14(a)(1), the annual deductible for such

1 year, as specified in subparagraph (B) of
2 such section; and

3 “(iii) in the case of a subsidy eligible
4 individual described in section 1860D–
5 14(a)(2), the annual deductible for such
6 year, as specified in subparagraph (B) of
7 such section.

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

10 “(A) means a covered part D drug—

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

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

24 “(II) if the PDP sponsor of the pre-
25 scription drug plan or the MA organization

1 offering the MA–PD plan does not use a
2 formulary, for which benefits are available
3 under the prescription drug plan or MA–
4 PD plan that the applicable beneficiary is
5 enrolled in; or

6 “(III) is provided through an excep-
7 tion or appeal; and

8 “(B) does not include a selected drug (as
9 referred to under section 1192(c)) during a
10 price applicability period (as defined in section
11 1191(b)(2)) with respect to such drug.

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

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

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

19 “(4) DISCOUNTED PRICE.—

20 “(A) IN GENERAL.—The term ‘discounted
21 price’ means, subject to subparagraphs (B) and
22 (C), with respect to an applicable drug of a
23 manufacturer dispensed during a year to an ap-
24 plicable beneficiary—

1 “(i) who has not incurred costs, as de-
2 termined in accordance with section
3 1860D–2(b)(4)(C), for covered part D
4 drugs in the year that are equal to or ex-
5 ceed the annual out-of-pocket threshold
6 specified in section 1860D–2(b)(4)(B)(i)
7 for the year, 90 percent of the negotiated
8 price of such drug; and

9 “(ii) who has incurred such costs, as
10 so determined, in the year that are equal
11 to or exceed such threshold for the year,
12 80 percent of the negotiated price of such
13 drug.

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

16 “(i) IN GENERAL.—In the case of an
17 applicable drug of a specified manufacturer
18 (as defined in clause (ii)) that is marketed
19 as of the date of enactment of this sub-
20 paragraph and dispensed for an applicable
21 beneficiary who is a subsidy eligible indi-
22 vidual (as defined in section 1860D–
23 14(a)(3)), the term ‘discounted price’
24 means the specified LIS percent (as de-

1 fined in clause (iii)) of the negotiated price
2 of the applicable drug of the manufacturer.

3 “(ii) SPECIFIED MANUFACTURER.—

4 “(I) IN GENERAL.—In this sub-
5 paragraph, subject to subclause (II),
6 the term ‘specified manufacturer’
7 means a manufacturer of an applica-
8 ble drug for which, in 2021—

9 “(aa) the manufacturer had
10 a coverage gap discount agree-
11 ment under section 1860D-14A;

12 “(bb) the total expenditures
13 for all of the specified drugs of
14 the manufacturer covered by
15 such agreement or agreements
16 for such year and covered under
17 this part during such year rep-
18 resented less than 1.0 percent of
19 the total expenditures under this
20 part for all covered Part D drugs
21 during such year; and

22 “(cc) the total expenditures
23 for all of the specified drugs of
24 the manufacturer that are single
25 source drugs and biological prod-

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1 ucts covered under part B during
2 such year represented less than
3 1.0 percent of the total expendi-
4 tures under part B for all drugs
5 or biological products covered
6 under such part during such
7 year.

8 “(II) SPECIFIED DRUGS.—

9 “(aa) IN GENERAL.—For
10 purposes of this clause, the term
11 ‘specified drug’ means, with re-
12 spect to a specified manufac-
13 turer, for 2021, an applicable
14 drug that is produced, prepared,
15 propagated, compounded, con-
16 verted, or processed by the man-
17 ufacturer.

18 “(bb) AGGREGATION
19 RULE.—All persons treated as a
20 single employer under subsection
21 (a) or (b) of section 52 of the In-
22 ternal Revenue Code of 1986
23 shall be treated as one manufac-
24 turer for purposes of this sub-
25 paragraph. For purposes of mak-

1 ing a determination pursuant to
2 the previous sentence, an agree-
3 ment under this section shall re-
4 quire that a manufacturer pro-
5 vide and attest to such informa-
6 tion as specified by the Secretary
7 as necessary.

8 “(III) LIMITATION.—The term
9 ‘specified manufacturer’ shall not in-
10 clude a manufacturer described in
11 subclause (I) if such manufacturer is
12 acquired after 2021 by another manu-
13 facturer that is not a specified manu-
14 facturer, effective at the beginning of
15 the plan year immediately following
16 such acquisition or, in the case of an
17 acquisition before 2024, effective Jan-
18 uary 1, 2024.

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

22 “(I) for an applicable drug dis-
23 pensed for an applicable beneficiary
24 described in clause (i) who has not in-
25 curred costs, as determined in accord-

1 ance with section 1860D–2(b)(4)(C),
2 for covered part D drugs in the year
3 that are equal to or exceed the annual
4 out-of-pocket threshold specified in
5 section 1860D–2(b)(4)(B)(i) for the
6 year—

7 “(aa) for 2024, 99 percent;
8 “(bb) for 2025, 98 percent;
9 “(cc) for 2026, 95 percent;
10 “(dd) for 2027, 92 percent;

11 and

12 “(ee) for 2028 and each
13 subsequent year, 90 percent; and

14 “(II) for an applicable drug dis-
15 pensed for an applicable beneficiary
16 described in clause (i) who has in-
17 curred costs, as determined in accord-
18 ance with section 1860D–2(b)(4)(C),
19 for covered part D drugs in the year
20 that are equal to or exceed the annual
21 out-of-pocket threshold specified in
22 section 1860D–2(b)(4)(B)(i) for the
23 year—

24 “(aa) for 2024, 99 percent;
25 “(bb) for 2025, 98 percent;

1 “(cc) for 2026, 95 percent;
2 “(dd) for 2027, 92 percent;
3 “(ee) for 2028, 90 percent;
4 “(ff) for 2029, 85 percent;
5 and
6 “(gg) for 2030 and each
7 subsequent year, 80 percent.

8 “(C) PHASE-IN FOR SPECIFIED SMALL
9 MANUFACTURERS.—

10 “(i) IN GENERAL.—In the case of an
11 applicable drug of a specified small manu-
12 facturer (as defined in clause (ii)) that is
13 marketed as of the date of enactment of
14 this subparagraph and dispensed for an
15 applicable beneficiary, the term ‘discounted
16 price’ means the specified small manufac-
17 turer percent (as defined in clause (iii)) of
18 the negotiated price of the applicable drug
19 of the manufacturer.

20 “(ii) SPECIFIED SMALL MANUFAC-
21 Turer.—

22 “(I) IN GENERAL.—In this sub-
23 paragraph, subject to subclause (III),
24 the term ‘specified small manufac-

1 turer’ means a manufacturer of an
2 applicable drug for which, in 2021—

3 “(aa) the manufacturer is a
4 specified manufacturer (as de-
5 fined in subparagraph (B)(ii));
6 and

7 “(bb) the total expenditures
8 under part D for any one of the
9 specified small manufacturer
10 drugs of the manufacturer that
11 are covered by the agreement or
12 agreements under section
13 1860D–14A of such manufac-
14 turer for such year and covered
15 under this part during such year
16 are equal to or more than 80 per-
17 cent of the total expenditures
18 under this part for all specified
19 small manufacturer drugs of the
20 manufacturer that are covered by
21 such agreement or agreements
22 for such year and covered under
23 this part during such year.

24 “(II) SPECIFIED SMALL MANU-
25 FACTURER DRUGS.—

1 “(aa) IN GENERAL.—For
2 purposes of this clause, the term
3 ‘specified small manufacturer
4 drugs’ means, with respect to a
5 specified small manufacturer, for
6 2021, an applicable drug that is
7 produced, prepared, propagated,
8 compounded, converted, or proc-
9 essed by the manufacturer.

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

1 “(III) LIMITATION.—The term
2 ‘specified small manufacturer’ shall
3 not include a manufacturer described
4 in subclause (I) if such manufacturer
5 is acquired after 2021 by another
6 manufacturer that is not a specified
7 small manufacturer, effective at the
8 beginning of the plan year imme-
9 diately following such acquisition or,
10 in the case of an acquisition before
11 2024, effective January 1, 2024.

12 “(iii) SPECIFIED SMALL MANUFAC-
13 TURER PERCENT.—In this subparagraph,
14 the term ‘specified small manufacturer per-
15 cent’ means, with respect to a year—

16 “(I) for an applicable drug dis-
17 pensed for an applicable beneficiary
18 who has not incurred costs, as deter-
19 mined in accordance with section
20 1860D–2(b)(4)(C), for covered part D
21 drugs in the year that are equal to or
22 exceed the annual out-of-pocket
23 threshold specified in section 1860D–
24 2(b)(4)(B)(i) for the year—

25 “(aa) for 2024, 99 percent;

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1 “(bb) for 2025, 98 percent;

2 “(cc) for 2026, 95 percent;

3 “(dd) for 2027, 92 percent;

4 and

5 “(ee) for 2028 and each

6 subsequent year, 90 percent; and

7 “(II) for an applicable drug dis-

8 pensed for an applicable beneficiary

9 who has incurred costs, as determined

10 in accordance with section 1860D–

11 2(b)(4)(C), for covered part D drugs

12 in the year that are equal to or exceed

13 the annual out-of-pocket threshold

14 specified in section 1860D–

15 2(b)(4)(B)(i) for the year—

16 “(aa) for 2024, 99 percent;

17 “(bb) for 2025, 98 percent;

18 “(cc) for 2026, 95 percent;

19 “(dd) for 2027, 92 percent;

20 “(ee) for 2028, 90 percent;

21 “(ff) for 2029, 85 percent;

22 and

23 “(gg) for 2030 and each

24 subsequent year, 80 percent.

1 “(D) TOTAL EXPENDITURES.—For pur-
2 poses of this paragraph, the term ‘total expend-
3 itures’ includes, in the case of expenditures with
4 respect to part D, ingredient costs, dispensing
5 fees, sales tax, and, if applicable, vaccine ad-
6 ministration fees. The term ‘total expenditures’
7 excludes, in the case of expenditures with re-
8 spect to part B, expenditures for a drug or bio-
9 logical that are bundled or packaged into the
10 payment for another service.

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

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

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

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

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

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

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

5 “(6) NEGOTIATED PRICE.—The term ‘nego-
6 tiated price’ has the meaning given such term in sec-
7 tion 423.100 of title 42, Code of Federal Regula-
8 tions (or any successor regulation) and, with respect
9 to an applicable drug, such negotiated price shall in-
10 clude any dispensing fee and, if applicable, any vac-
11 cine administration fee for the applicable drug.

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

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

17 “With respect to covered part D drugs that would
18 be applicable drugs (as defined in section 1860D–
19 14C(g)(2) but for the application of subparagraph (B) of
20 such section, the Secretary shall provide a process where-
21 by, in the case of an applicable beneficiary (as defined in
22 section 1860D–14C(g)(1)) who, with respect to a year, is
23 enrolled in a prescription drug plan or is enrolled in an
24 MA–PD plan, has not incurred costs that are equal to or
25 exceed the annual out-of-pocket threshold specified in sec-

tion 1860D–2(b)(4)(B)(i), and is dispensed such a drug the Secretary (periodically and on a timely basis) provides the PDP sponsor or the MA organization offering the plan, a subsidy with respect to such drug that is equal to 10 percent of the negotiated price (as defined in section 1860D–14C(g)(6)) of such drug.”.

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

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

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

“(h) SUNSET OF PROGRAM.—

“(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2024, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

“(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply on and after

1 January 1, 2024, with respect to applicable drugs
2 dispensed prior to such date.”.

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

7 (A) in subsection (b)(2)(C)(iii)—

8 (i) by striking “assumptions regarding
9 the reinsurance” and inserting “assump-
10 tions regarding—

11 “(I) the reinsurance”; and

12 (ii) by adding at the end the fol-
13 lowing:

14 “(II) for 2024 and each subse-
15 quent year, the manufacturer dis-
16 counts provided under section 1860D–
17 14C subtracted from the actuarial
18 value to produce such bid; and”; and

19 (B) in subsection (c)(1)(C)—

20 (i) by striking “an actuarial valuation
21 of the reinsurance” and inserting “an ac-
22 tuarial valuation of—

23 “(i) the reinsurance”;

1 (ii) in clause (i), as inserted by clause
2 (i) of this subparagraph, by adding “and”
3 at the end; and

4 (iii) by adding at the end the fol-
5 lowing:

6 “(ii) for 2024 and each subsequent
7 year, the manufacturer discounts provided
8 under section 1860D–14C;”.

9 (e) CONFORMING AMENDMENTS.—

10 (1) Section 1860D–2 of the Social Security Act
11 (42 U.S.C. 1395w–102) is amended—

12 (A) in subsection (a)(2)(A)(i)(I), by strik-
13 ing “, or an increase in the initial” and insert-
14 ing “or, for a year preceding 2024, an increase
15 in the initial”;

16 (B) in subsection (c)(1)(C)—

17 (i) in the subparagraph heading, by
18 striking “AT INITIAL COVERAGE LIMIT”;
19 and

20 (ii) by inserting “for a year preceding
21 2024 or the annual out-of-pocket threshold
22 specified in subsection (b)(4)(B) for the
23 year for 2024 and each subsequent year”
24 after “subsection (b)(3) for the year” each
25 place it appears; and

1 (C) in subsection (d)(1)(A), by striking “or
2 an initial” and inserting “or, for a year pre-
3 ceding 2024, an initial”.

4 (2) Section 1860D–4(a)(4)(B)(i) of the Social
5 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
6 amended by striking “the initial” and inserting “for
7 a year preceding 2024, the initial”.

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

10 (A) in paragraph (1)—

11 (i) in subparagraph (C), by striking
12 “The continuation” and inserting “For a
13 year preceding 2024, the continuation”;

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

17 (iii) in subparagraph (E), by striking
18 “The elimination” and inserting “For a
19 year preceding 2024, the elimination”; and

20 (B) in paragraph (2)—

21 (i) in subparagraph (C), by striking
22 “The continuation” and inserting “For a
23 year preceding 2024, the continuation”;
24 and

1 (ii) in subparagraph (E), by striking
2 “1860D–2(b)(4)(A)(i)(I)” and inserting
3 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

13 “(i) for years prior to 2024, any dis-
14 count”;

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

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

20 “(ii) for 2024 and each subsequent
21 year, any discount provided pursuant to
22 section 1860D–14C.”.

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

1 (A) by inserting “for a year before 2024”
2 after “1860D–2(b)(3)”; and

3 (B) by inserting “for such year” before the
4 period.

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

7 (A) in subsection (a)—

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

10 “(1) participate in—

11 “(A) for 2011 through 2023, the Medicare
12 coverage gap discount program under section
13 1860D–14A; and

14 “(B) for 2024 and each subsequent year,
15 the manufacturer discount program under sec-
16 tion 1860D–14C;”;

17 (ii) by striking paragraph (2) and in-
18 serting the following:

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

20 “(A) for 2011 through 2023, an agreement
21 described in subsection (b) of section 1860D–
22 14A with the Secretary; and

23 “(B) for 2024 and each subsequent year,
24 an agreement described in subsection (b) of sec-
25 tion 1860D–14C with the Secretary; and”;

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

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

5 “(A) for 2011 through 2023, a contract
6 with a third party that the Secretary has en-
7 tered into a contract with under subsection
8 (d)(3) of section 1860D–14A; and

9 “(B) for 2024 and each subsequent year,
10 a contract with a third party that the Secretary
11 has entered into a contract with under sub-
12 section (d)(3) of section 1860D–14C.”; and

13 (B) by striking subsection (b) and insert-
14 ing the following:

15 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),
16 and (3)(A) of subsection (a) shall apply to covered part
17 D drugs dispensed under this part on or after January
18 1, 2011, and before January 1, 2024, and paragraphs
19 (1)(B), (2)(B), and (3)(B) of such subsection shall apply
20 to covered part D drugs dispensed under this part on or
21 after January 1, 2024.”.

22 (8) Section 1927 of the Social Security Act (42
23 U.S.C. 1396r–8) is amended—

24 (A) in subsection (c)(1)(C)(i)(VI), by in-
25 serting before the period at the end the fol-

1 lowing: “or under the manufacturer discount
2 program under section 1860D–14C”; and

3 (B) in subsection (k)(1)(B)(i)(V), by in-
4 serting before the period at the end the fol-
5 lowing: “or under section 1860D–14C”.

6 (f) IMPLEMENTATION FOR 2024 AND 2025.—Not-
7 withstanding any other provision of this section, the Sec-
8 retary shall implement this section, including the amend-
9 ments made by this section, for 2024 and 2025 by pro-
10 gram instruction or otherwise.

11 (g) FUNDING.—In addition to amounts otherwise
12 available, there are appropriated to the Centers for Medi-
13 care & Medicaid Services, out of any money in the Treas-
14 ury not otherwise appropriated, \$44,000,000 for fiscal
15 year 2022, \$38,000,000 for fiscal year 2023, and
16 \$32,000,000 for each of fiscal years 2024 through 2031,
17 to remain available until expended, to carry out the provi-
18 sions of, including the amendments made by, this section.

19 **SEC. 139202. MAXIMUM MONTHLY CAP ON COST SHARING**
20 **PAYMENTS UNDER PRESCRIPTION DRUG**
21 **PLANS AND MA-PD PLANS.**

22 (a) IN GENERAL.—Section 1860D–2(b) of the Social
23 Security Act (42 U.S.C. 1395w–102(b)), as amended by
24 section 139201, is amended—

25 (1) in paragraph (2)—

1 (A) in subparagraph (A), by striking “and
2 (D)” and inserting “, (D), and (E)”; and

3 (B) by adding at the end the following new
4 subparagraph:

5 “(E) MAXIMUM MONTHLY CAP ON COST
6 SHARING PAYMENTS.—

7 “(i) IN GENERAL.—For plan years be-
8 ginning on or after January 1, 2025, each
9 PDP sponsor offering a prescription drug
10 plan and each MA organization offering an
11 MA–PD plan shall provide to any enrollee
12 of such plan, including an enrollee who is
13 a subsidy eligible individual (as defined in
14 paragraph (3) of section 1860D-14(a)), the
15 option to elect with respect to a plan year
16 to pay cost sharing under the plan in
17 monthly amounts that are capped in ac-
18 cordance with this subparagraph.

19 “(ii) DETERMINATION OF MAXIMUM
20 MONTHLY CAP.—For each month in the
21 plan year for which an enrollee in a pre-
22 scription drug plan or an MA–PD plan has
23 made an election pursuant to clause (i),
24 the PDP sponsor or MA organization shall

1 determine a maximum monthly cap (as de-
2 fined in clause (iv)) for such enrollee.

3 “(iii) BENEFICIARY MONTHLY PAY-
4 MENTS.—With respect to an enrollee who
5 has made an election pursuant to clause
6 (i), for each month described in clause (ii),
7 the PDP sponsor or MA organization shall
8 bill such enrollee an amount (not to exceed
9 the maximum monthly cap) for the out-of-
10 pocket costs of such enrollee in such
11 month.

12 “(iv) MAXIMUM MONTHLY CAP DE-
13 FINED.—In this subparagraph, the term
14 ‘maximum monthly cap’ means, with re-
15 spect to an enrollee—

16 “(I) for the first month for which
17 the enrollee has made an election pur-
18 suant to clause (i), an amount deter-
19 mined by calculating—

20 “(aa) the annual out-of-
21 pocket threshold specified in
22 paragraph (4)(B) minus the in-
23 curred costs of the enrollee as de-
24 scribed in paragraph (4)(C); di-
25 vided by

1 “(bb) the number of months
2 remaining in the plan year; and

3 “(II) for a subsequent month, an
4 amount determined by calculating—

5 “(aa) the sum of any re-
6 maining out-of-pocket costs owed
7 by the enrollee from a previous
8 month that have not yet been
9 billed to the enrollee and any ad-
10 ditional out-of-pocket costs in-
11 curred by the enrollee; divided by

12 “(bb) the number of months
13 remaining in the plan year.

14 “(v) ADDITIONAL REQUIREMENTS.—
15 The following requirements shall apply
16 with respect to the option to make an elec-
17 tion pursuant to clause (i) under this sub-
18 paragraph:

19 “(I) SECRETARIAL RESPONSIBIL-
20 ITIES.—The Secretary shall provide
21 information to part D eligible individ-
22 uals on the option to make such elec-
23 tion through educational materials, in-
24 cluding through the notices provided
25 under section 1804(a).

1 “(II) TIMING OF ELECTION.—An
2 enrollee in a prescription drug plan or
3 an MA–PD plan may make such an
4 election—

5 “(aa) prior to the beginning
6 of the plan year; or

7 “(bb) in any month during
8 the plan year.

9 “(III) PDP SPONSOR AND MA OR-
10 GANIZATION RESPONSIBILITIES.—
11 Each PDP sponsor offering a pre-
12 scription drug plan or MA organiza-
13 tion offering an MA–PD plan—

14 “(aa) may not limit the op-
15 tion for an enrollee to make such
16 an election to certain covered
17 part D drugs;

18 “(bb) shall, prior to the plan
19 year, notify prospective enrollees
20 of the option to make such an
21 election in promotional materials;

22 “(cc) shall include informa-
23 tion on such option in enrollee
24 educational materials;

1 “(dd) shall have in place a
2 mechanism to notify a pharmacy
3 during the plan year when an en-
4 rollee incurs out-of-pocket costs
5 with respect to covered part D
6 drugs that make it likely the en-
7 rollee may benefit from making
8 such an election;

9 “(ee) shall provide that a
10 pharmacy, after receiving a noti-
11 fication described in item (dd)
12 with respect to an enrollee, in-
13 forms the enrollee of such notifi-
14 cation;

15 “(ff) shall ensure that such
16 an election by an enrollee has no
17 effect on the amount paid to
18 pharmacies (or the timing of
19 such payments) with respect to
20 covered part D drugs dispensed
21 to the enrollee; and

22 “(gg) shall have in place a
23 financial reconciliation process to
24 correct inaccuracies in payments
25 made by an enrollee under this

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1 subparagraph with respect to
2 covered part D drugs during the
3 plan year.

4 “(IV) FAILURE TO PAY AMOUNT
5 BILLED.—If an enrollee fails to pay
6 the amount billed for a month as re-
7 quired under this subparagraph, the
8 election of the enrollee pursuant to
9 clause (i) shall be terminated and the
10 enrollee shall pay the cost sharing
11 otherwise applicable for any covered
12 part D drugs subsequently dispensed
13 to the enrollee up to the annual out-
14 of-pocket threshold specified in para-
15 graph (4)(B).

16 “(V) CLARIFICATION REGARDING
17 PAST DUE AMOUNTS.—Nothing in this
18 subparagraph shall be construed as
19 prohibiting a PDP sponsor or an MA
20 organization from billing an enrollee
21 for an amount owed under this sub-
22 paragraph.

23 “(VI) TREATMENT OF UNSET-
24 TLED BALANCES.—Any unsettled bal-
25 ances with respect to amounts owed

1 under this subparagraph shall be
2 treated as plan losses and the Sec-
3 retary shall not be liable for any such
4 balances outside of those assumed as
5 losses estimated in plan bids.”; and

6 (2) in paragraph (4)—

7 (A) in subparagraph (C), by striking “in
8 subparagraph (E)” and inserting “in subpara-
9 graph (E) and subject to subparagraph (F)”;
10 and

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

13 “(F) INCLUSION OF COSTS PAID UNDER
14 MAXIMUM MONTHLY CAP OPTION.—In applying
15 subparagraph (A), with respect to an enrollee
16 who has made an election pursuant to clause (i)
17 of paragraph (2)(E), costs shall be treated as
18 incurred if such costs are paid by a PDP spon-
19 sor or an MA organization under the option
20 provided under such paragraph.”.

21 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
22 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
23 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
24 ing at the end the following new paragraph:

1 “(4) SAME MAXIMUM MONTHLY CAP ON COST
2 SHARING.—For plan years beginning on or after
3 January 1, 2025, the maximum monthly cap on cost
4 sharing payments under the option provided under
5 subsection (b)(2)(E) shall apply to such coverage.”.

6 (c) IMPLEMENTATION FOR 2025.—The Secretary
7 shall implement this section, including the amendments
8 made by this section, for 2025 by program instruction or
9 otherwise.

10 (d) FUNDING.—In addition to amounts otherwise
11 available, there are appropriated to the Centers for Medi-
12 care & Medicaid Services, out of any money in the Treas-
13 ury not otherwise appropriated, \$1,000,000 for each of fis-
14 cal years 2022 through 2031, to remain available until ex-
15 pended, to carry out the provisions of, including the
16 amendments made by, this section.

17 **PART 4—REPEAL OF CERTAIN PRESCRIPTION**

18 **DRUG REBATE RULE**

19 **SEC. 139301. PROHIBITING IMPLEMENTATION OF RULE RE-**
20 **LATING TO ELIMINATING THE ANTI-KICK-**
21 **BACK STATUTE SAFE HARBOR PROTECTION**
22 **FOR PRESCRIPTION DRUG REBATES.**

23 Beginning January 1, 2026, the Secretary of Health
24 and Human Services shall not implement, administer, or
25 enforce the provisions of the final rule published by the

1 Office of the Inspector General of the Department of
2 Health and Human Services on November 30, 2020, and
3 titled “Fraud and Abuse; Removal of Safe Harbor Protec-
4 tion for Rebates Involving Prescription Pharmaceuticals
5 and Creation of New Safe Harbor Protection for Certain
6 Point-of-Sale Reductions in Price on Prescription Phar-
7 maceuticals and Certain Pharmacy Benefit Manager Serv-
8 ice Fees” (85 Fed. Reg. 76666).

9 **PART 5—MISCELLANEOUS**

10 **SEC. 139401. APPROPRIATE COST-SHARING FOR CERTAIN**

11 **INSULIN PRODUCTS UNDER MEDICARE PART**

12 **D.**

13 (a) IN GENERAL.—Section 1860D–2 of the Social
14 Security Act (42 U.S.C. 1395w–102) is amended—

15 (1) in subsection (b)—

16 (A) in paragraph (1)(A), by striking “The
17 coverage” and inserting “Subject to paragraph
18 (8), the coverage”;

19 (B) in paragraph (2)(A), by striking “and
20 (D)” and inserting “and (D) and paragraph
21 (8)”;

22 (C) in paragraph (3)(A), by striking “and
23 (4)” and inserting “(4), and (8)”;

1 (D) in paragraph (4)(A)(i), by striking
2 “The coverage” and inserting “Subject to para-
3 graph (8), the coverage”; and

4 (E) by adding at the end the following new
5 paragraph:

6 “(8) TREATMENT OF COST-SHARING FOR CER-
7 TAIN INSULIN PRODUCTS.—

8 “(A) IN GENERAL.—For plan years begin-
9 ning on or after January 1, 2023, the following
10 shall apply with respect to insulin products (as
11 defined in subparagraph (B)):

12 “(i) NO APPLICATION OF DEDUCT-
13 IBLE.—The deductible under paragraph
14 (1) shall not apply with respect to such in-
15 sulin products.

16 “(ii) APPLICATION OF COST-SHAR-
17 ING.—

18 “(I) PLAN YEAR 2023.—For plan
19 year 2023, the coverage provides ben-
20 efits for such insulin products, regard-
21 less of whether an individual has
22 reached the initial coverage limit
23 under paragraph (3) or the out-of-
24 pocket threshold under paragraph (4),

1 with cost-sharing that is equal to the
2 applicable copayment amount.

3 “(II) PLAN YEAR 2024 AND SUB-
4 SEQUENT PLAN YEARS.—For plan
5 year 2024 and subsequent plan years,
6 the coverage provides benefits for
7 such insulin products, prior to an in-
8 dividual reaching the out-of-pocket
9 threshold under paragraph (4), with
10 cost-sharing that is equal to the appli-
11 cable copayment amount.

12 “(III) APPLICABLE COPAYMENT
13 AMOUNT.—For purposes of this
14 clause, the term ‘applicable copayment
15 amount’ means, with respect to an in-
16 sulin product under a prescription
17 drug plan or an MA–PD plan, an
18 amount that is not more than \$35.

19 “(B) INSULIN PRODUCT.—For purposes of
20 this paragraph, the term ‘insulin product’
21 means an insulin product that is approved
22 under section 505 of the Federal Food, Drug,
23 and Cosmetic Act or licensed under section 351
24 of the Public Health Service Act and marketed
25 pursuant to such approval or licensure, includ-

1 ing any insulin product that has been deemed
2 to be licensed under section 351 of the Public
3 Health Service Act pursuant to section
4 7002(e)(4) of the Biologics Price Competition
5 and Innovation Act of 2009 and marketed pur-
6 suant to such section.”; and

7 (2) in subsection (c), by adding at the end the
8 following new paragraph:

9 “(4) TREATMENT OF COST-SHARING FOR INSU-
10 LIN PRODUCTS.—The coverage is provided in accord-
11 ance with subsection (b)(8).”.

12 (b) CONFORMING AMENDMENTS TO COST-SHARING
13 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
14 of the Social Security Act (42 U.S.C. 1395w–114(a)) is
15 amended—

16 (1) in paragraph (1)—

17 (A) in subparagraph (D)(iii), by adding at
18 the end the following new sentence: “For plan
19 year 2023 and subsequent plan years, the co-
20 payment amount applicable under the preceding
21 sentence to an insulin product (as defined in
22 section 1860D–2(b)(8)(B)) furnished to the in-
23 dividual may not exceed the applicable copay-
24 ment amount for the product under the pre-

1 scripture drug plan or MA–PD plan in which
2 the individual is enrolled.”; and

3 (B) in subparagraph (E), by inserting the
4 following before the period at the end “or under
5 section 1860D–2(b)(8) in the case of an insulin
6 product (as defined in subparagraph (B) of
7 such section)”; and

8 (2) in paragraph (2)—

9 (A) in subparagraph (D), by adding at the
10 end the following new sentence: “For plan year
11 2023 and subsequent plan years, the amount of
12 the coinsurance applicable under the preceding
13 sentence to an insulin product (as defined in
14 section 1860D–2(b)(8)(B)) furnished to the in-
15 dividual may not exceed the applicable copay-
16 ment amount for the product under the pre-
17 scription drug plan or MA–PD plan in which
18 the individual is enrolled.”; and

19 (B) in subparagraph (E), by adding at the
20 end the following new sentence: “For plan year
21 2023, the amount of the copayment or coinsur-
22 ance applicable under the preceding sentence to
23 an insulin product (as defined in section
24 1860D–2(b)(8)(B)) furnished to the individual
25 may not exceed the applicable copayment

1 amount for the product under the prescription
2 drug plan or MA–PD plan in which the indi-
3 vidual is enrolled.”

4 (c) IMPLEMENTATION.—The Secretary shall imple-
5 ment this section for plan years 2023 and 2024 by pro-
6 gram instruction or otherwise.

7 **SEC. 139402. COVERAGE OF ADULT VACCINES REC-**
8 **OMMENDED BY THE ADVISORY COMMITTEE**
9 **ON IMMUNIZATION PRACTICES UNDER MEDI-**
10 **CARE PART D.**

11 (a) ENSURING TREATMENT OF COST SHARING IS
12 CONSISTENT WITH TREATMENT OF VACCINES UNDER
13 MEDICARE PART B.—Section 1860D–2 of the Social Se-
14 curity Act (42 U.S.C. 1395w–102), as amended by section
15 139401, is further amended—

16 (1) in subsection (b)—

17 (A) in paragraph (1)(A), by striking
18 “paragraph (8)” and inserting “paragraphs (8)
19 and (9)”;

20 (B) in paragraph (2)(A), by striking
21 “paragraph (8)” and inserting “paragraphs (8)
22 and (9)”;

23 (C) in paragraph (3)(A), by striking “and
24 (8)” and inserting “(8), and (9)”;