Subtitle I—Prescription Drug Pricing Reform

PART 1—LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION

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

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

"PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

"SEC. 1191. ESTABLISHMENT OF PROGRAM.

''(a) IN GENERAL.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

''(1) publish a list of selected drugs in accordance with section 1192;

''(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

''(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194;

''(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1195 and 1196.

''(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

''(1) INITIAL PRICE APPLICABILITY YEAR.—The term 'initial price applicability year' means a year (beginning with 2026).

''(2) PRICE APPLICABILITY PERIOD.—The term 'price applicability period' means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

''(3) SELECTED DRUG PUBLICATION DATE.—The term 'selected drug publication date' means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

''(4) NEGOTIATION PERIOD.—The term 'negotiation period' means, with respect to an initial price

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

"(A) beginning on the sooner of—

"(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

"(ii) February 28 following the selected drug publication date with respect to such selected drug; and

"(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

"(c) OTHER DEFINITIONS.—For purposes of this part:

"(1) MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL.—The term 'maximum fair price eligible individual' means, with respect to a selected drug—

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

vided under such plan for such selected drug; and

''(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled under an MA plan under part C of such title, if such selected drug is covered under such part.

''(2) MAXIMUM FAIR PRICE.—The term 'maximum fair price' means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price negotiated pursuant to section 1194, and updated pursuant to section 1195(b), as applicable, for such drug and year.

''(3) REFERENCE PRODUCT.—The term 'reference product' has the meaning given such term in section 351(i) of the Public Health Service Act.

''(4) UNIT.—The term 'unit' means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished. The

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

''(5) TOTAL EXPENDITURES.—The term 'total expenditures' includes, in the case of expenditures with respect to part D of title XVIII, the total gross covered prescription drug costs (as defined in section 1860D–15(b)(3)). The term 'total expenditures' excludes, in the case of expenditures with respect to part B of such title, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

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

''(1) Subsection (b)(3) shall be applied by substituting 'September 1, 2023' for ', with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year'.

''(2) Subsection (b)(4) shall be applied—

''(A) in subparagraph (A)(ii), by substituting 'October 1, 2023' for 'February 28

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

"(B) in subparagraph (B), by substituting 'August 1, 2024' for 'November 1 of the year that begins 2 years prior to the initial price applicability year'.

"(3) Section 1192 shall be applied—

"(A) in subsection (b)(1)(A), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year';

"(B) in subsection (d)(1)(A), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year'; and

"(C) in subsection (e)(3)(B), by substituting 'during the period beginning on June 1, 2022, and ending on May 31, 2023' for 'during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year'.

"(4) Section 1193(a) shall be applied by substituting 'October 1, 2023' for 'February 28 following the selected drug publication date with respect to such selected drug '.

"(5) Section 1194(b)(2) shall be applied—

"(A) in subparagraph (A), by substituting 'October 2, 2023' for 'March 1 of the year of the selected drug publication date, with respect to the selected drug';

"(B) in subparagraph (B), by substituting 'February 1, 2024' for 'the June 1 following the selected drug publication date'; and

"(C) in subparagraph (E), by substituting 'August 1, 2024' for 'the first day of November following the selected drug publication date,

with respect to the initial price applicability year '.

''(6) Section 1195(a) shall be applied—

''(A) in paragraph (1), by substituting 'September 1, 2024' for 'November 30 of the year that is 2 years prior to such initial price applicability year'; and

''(B) in paragraph (2), by substituting 'March 1, 2025' for 'March 1 of the year prior to such initial price applicability year'.

''SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

''(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

''(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

''(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs de-

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

''(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

''(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year); and

Subject to subsection (c)(2) and section 1194(f)(5), each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

''(b) SELECTION OF DRUGS.—

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

''(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

''(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

''(2) HIGH SPEND PART D DRUGS FOR 2026 AND 2027.—With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to 'negotiation-eligible drugs described in subsection (d)(1)' were a ref-

erence to 'negotiation-eligible drugs described in subsection (d)(1)(A)' and as if the reference to 'total expenditures for such drugs under parts B and D of title XVIII' were a reference to 'total expenditures for such drugs under part D of title XVIII'.

"(e) SELECTED DRUG.—

"(1) IN GENERAL.—For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a 'selected drug' with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

"(A) is approved or licensed (as applicable)—

"(i) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

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

"(B) is marketed pursuant to such approval or licensure.

"(2) CLARIFICATION.—A negotiation-eligible drug—

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

"(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1194 with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

"(d) NEGOTIATION-ELIGIBLE DRUG.—

"(1) IN GENERAL.—For purposes of this part, subject to paragraph (2), the term 'negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either

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

"(A) PART D HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year.

"(B) PART B HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent period, as described in clause (i).

"(2) EXCEPTION FOR SMALL BIOTECH DRUGS.—

"(A) IN GENERAL.—Subject to subparagraph (C), the term 'negotiation-eligible drug' shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

"(i) PART D DRUGS.—The total expenditures for the qualifying single source drug under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

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

"(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1860D–14A during such year.

"(ii) PART B DRUGS.—The total expenditures for the qualifying single source drug under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

"(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs covered under such part B during such year; and

"(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer that are covered under such part B during such year.

"(B) CLARIFICATIONS RELATING TO MANUFACTURERS.—

"(i) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

"(ii) LIMITATION.—A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii), effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

"(C) DRUGS NOT INCLUDED AS SMALL BIOTECH DRUGS.—The following shall not be considered a qualifying single source drug described in subparagraph (A):

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

"(ii) A new formulation, such as an extended release formulation, of a qualifying single source drug.

"(3) CLARIFICATIONS AND DETERMINATIONS.—

"(A) PREVIOUSLY SELECTED DRUGS AND SMALL BIOTECH DRUGS EXCLUDED.—In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

"(i) drugs that are already selected drugs; and

"(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

"(B) USE OF DATA.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

"(e) QUALIFYING SINGLE SOURCE DRUG.—

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

in any of the following or a drug or biological product covered under part B of title XVIII that is described in any of the following:

"(A) DRUG PRODUCTS.—A drug—

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

"(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

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

"(B) BIOLOGICAL PRODUCTS.—A biological product—

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

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

will have elapsed since the date of such licensure; and

"(iii) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of such Act.

"(2) TREATMENT OF AUTHORIZED GENERIC DRUGS.—

"(A) IN GENERAL.—In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 505(j) of the Federal Food, Drug, and Cosmetic Act) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

"(B) AUTHORIZED GENERIC DRUG DEFINED.—For purposes of this paragraph, the term 'authorized generic drug' means—

"(i) in the case of a drug, an authorized generic drug (as such term is defined

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

''(ii) in the case of a biological product, a product that—

''(I) has been licensed under section 351(a) of such Act; and

''(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

''(3) EXCLUSIONS.—In this part, the term 'qualifying single source drug' does not include any of the following:

''(A) CERTAIN ORPHAN DRUGS.—A drug that is designated as a drug for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the only approved indication (or indications) is for such disease or condition.

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

"(i) with respect to 2021, $200,000,000; or

"(ii) with respect to a subsequent year, the dollar amount specified in this subparagraph for the previous year increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with September of such previous year.

"(C) PLASMA-DERIVED PRODUCTS.—A biological product that is derived from human whole blood or plasma.

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

section (d), the determination of qualifying single source drugs under subsection (e), and the selection of drugs under this section are not subject to administrative or judicial review.

"SEC. 1193. MANUFACTURER AGREEMENTS.

"(a) IN GENERAL.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

"(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

"(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair

price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

''(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

''(2) the Secretary and the manufacturer shall, in accordance with section 1194, renegotiate (and, by not later than the last date of such period, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

''(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(1) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price appli-

cability period (beginning after such renegotiation) with respect to such selected drug; and

"(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

"(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

"(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(1), at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

"(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

"(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f)) with respect to such drug—

"(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the drug for the applicable year or period; and

"(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

"(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

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

''(c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

''(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug, except that

the manufacturer shall provide for the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if the maximum fair price is below the ceiling price for such selected drug.

"SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.

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

"(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

"(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1193(a)(2) if such drug is a renegotiation-eligible drug under such subsection.

"(b) NEGOTIATION PROCESS REQUIREMENTS.—

"(1) METHODOLOGY AND PROCESS.—The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

"(2) SPECIFIC ELEMENTS OF NEGOTIATION PROCESS.—As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

"(A) SUBMISSION OF INFORMATION.—Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1193(a)(4), the information described in such section.

"(B) INITIAL OFFER BY SECRETARY.—Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of a selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of

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

''(C) RESPONSE TO INITIAL OFFER.—

''(i) IN GENERAL.—Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

''(ii) COUNTEROFFER REQUIREMENTS.—If a manufacturer proposes a counteroffer, such counteroffer—

''(I) shall be in writing; and

''(II) shall be justified based on the factors described in subsection (e).

''(D) RESPONSE TO COUNTEROFFER.—After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

''(E) DEADLINE.—All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

"(F) LIMITATIONS ON OFFER AMOUNT.—In negotiating the maximum fair price of a selected drug, with respect to an initial price applicability year for the selected drug, and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

"(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

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

"(G) TREATMENT OF DETERMINATION.—The determination of a maximum fair price under this section is not subject to administrative or judicial review.

"(c) CEILING FOR MAXIMUM FAIR PRICE.—

"(1) GENERAL CEILING.—

"(A) IN GENERAL.—The maximum fair price negotiated under this section for a selected drug, with respect to the first year of the

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

"(B) SUBPARAGRAPH (B) AMOUNT.—An amount equal to the following:

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

"(ii) PART B DRUG OR BIOLOGICAL.—In the case of a drug or biological product covered under part B of title XVIII, the payment amount under section 1847A(b)(4) for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

"(C) SUBPARAGRAPH (C) AMOUNT.—An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

"(i) INITIAL PRICE APPLICABILITY YEAR 2026.—In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

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

"(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

"(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

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

plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

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

"(B) a fraction—

"(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

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

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

"(A) SHORT-MONOPOLY DRUGS AND VACCINES.—With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

"(B) EXTENDED-MONOPOLY DRUGS.—With respect to an extended-monopoly drug, 65 percent.

"(C) LONG-MONOPOLY DRUGS.—With respect to a long-monopoly drug, 40 percent.

"(4) EXTENDED-MONOPOLY DRUG DEFINED.—

"(A) IN GENERAL.—In this part, subject to subparagraph (B), the term 'extended-monopoly drug' means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

"(B) EXCLUSIONS.—The term 'extended-monopoly drug' shall not include any of the following:

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

"(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

"(C) CLARIFICATION.—Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the selected drug meets the definition of a long-monopoly drug.

"(5) LONG-MONOPOLY DRUG DEFINED.—

"(A) IN GENERAL.—In this part, subject to subparagraph (B), the term 'long-monopoly drug' means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

"(B) EXCLUSION.—The term 'long-monopoly drug' shall not include a vaccine that is licensed under section 351 of the Public Health

Service Act and marketed pursuant to such section.

''(6) AVERAGE NON-FEDERAL AVERAGE MANUFACTURER PRICE.—In this part, the term 'average non-Federal average manufacturer price' means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the 4 calendar quarters of the year involved.

''(d) TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS.—In the case of a selected drug that is a qualifying single source drug described in section 1192(d)(2) and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or De-

cember of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

''(e) FACTORS.—For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors (and, with respect to extended-monopoly drugs and long-monopoly drugs, shall not, except in making a determination of a material change under subsection (f)(2)(D), consider factors other than those described in subparagraphs (B) and (C) of paragraph (1)):

''(1) MANUFACTURER-SPECIFIC INFORMATION.—The following information, with respect to such selected drug, including as submitted by the manufacturer:

''(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

''(B) Market data for the drug.

''(C) Unit costs of production and distribution of the drug.

"(D) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

"(E) Data on patents and on existing and pending exclusivity for the drug.

"(F) National sales data for the drug.

"(G) Information on clinical trials for the drug.

"(2) INFORMATION ON ALTERNATIVE TREATMENTS.—The following information, with respect to such selected drug and therapeutic alternatives to such drug:

"(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives.

"(B) Approval by the Food and Drug Administration of such drug and therapeutic alternatives of such drug.

"(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives of such drug on specific populations, such as individuals with

disabilities, the elderly, the terminally ill, children, and other patient populations.

''(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

''(f) RENEGOTIATION PROCESS.—

''(1) IN GENERAL.—In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

''(2) RENEGOTIATION-ELIGIBLE DRUG DEFINED.—In this section, the term 'renegotiation-eli-

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

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

"(B) CHANGE OF STATUS TO AN EXTENDED-MONOPOLY DRUG.—A selected drug that—

"(i) is not an extended-monopoly or a long-monopoly drug; and

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

"(C) CHANGE OF STATUS TO A LONG-MONOPOLY DRUG.—A selected drug that—

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

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

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

"(3) SELECTION OF DRUGS FOR RENEGOTIATION.—Each year the Secretary shall select among

renegotiation-eligible drugs for renegotiation as follows:

"(A) ALL EXTENDED-MONOPOLY NEGOTIATION-ELIGIBLE DRUGS.—The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

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

"(C) REMAINING DRUGS.—Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

"(4) RENEGOTIATION PROCESS.—The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection. Such process shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c) and (d), and for pur-

poses of applying subsections (c) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

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

''(6) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The determination of renegotiation-eligible drugs under paragraph (2) and the selection of renegotiation-eligible drugs under paragraph (3) are not subject to administrative or judicial review.

''(g) LIMITATION.—

''(1) IN GENERAL.—In no case shall the maximum fair price negotiated under this section for a

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

''(A) in the case the selected drug is a qualifying single source drug described in subparagraph (A) of section 1192(e)(1), the date that is 9 years after the day on which the drug was approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act; and

''(B) in the case the selected drug is a qualifying single source drug described in subparagraph (B) of section 1192(e)(1), the date that is 13 years after the day on which the drug was licensed under section 351(a) of the Public Health Service Act.

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

''SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.

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

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

''(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1193(c), the explanation for the maximum fair price with respect to the factors as applied under section 1194(e) for such drug described in paragraph (1).

''(b) UPDATES.—

''(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1193, not later than November 30 of the year that is 2 years prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—

''(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, in-

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

''(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

''(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

''SEC. 1196. ADMINISTRATIVE DUTIES AND COMPLIANCE MONITORING.

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

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

''(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

''(B) any other discounts.

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

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

''(A) maximum fair price eligible individuals who are enrolled under a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title; and

''(B) maximum fair price eligible individuals who are enrolled under part B of such title, including who are enrolled under an MA plan under part C of such title.

''(4) The establishment of a negotiation process and renegotiation process in accordance with section 1194.

''(5) The establishment of a process for manufacturers to submit information described in section 1194(b)(2)(A).

''(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 4192 of the Internal Revenue Code of 1986 (relating to enforcement of this part).

''(7) The establishment of procedures for purposes of applying section 1192(d)(2)(B).

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

''SEC. 1197. CIVIL MONETARY PENALTIES.

''(a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the price applicability period with respect to such drug, that does not provide access

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

"(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(1) and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

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

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

''(b) VIOLATIONS OF CERTAIN TERMS OF AGREEMENT.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1193(a)(5), including the requirement to submit information pursuant to section 1193(a)(4), shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

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

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

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

(1) UNDER MEDICARE.—

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

amended by inserting ''or in the case of such a drug or biological product that is a selected drug (as referred to in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(2)) applicable for such drug and a year during such period'' after ''paragraph (4)''.

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

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

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

''(VII) A drug or biological product that is a selected drug (as referred to in section 1192(c)).''.

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

(i) in paragraph (1), by striking ''and'' at the end;

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

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

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

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

(i) in subparagraph (B), by inserting '', subject to subparagraph (D),'' after ''negotiated prices''; and

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

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

period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be no greater than the maximum fair price (as defined in section 1191(c)(2)) for such drug and for each year during such period plus any dispensing fees for such drug.''.

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

''(I) REQUIRED INCLUSION OF SELECTED DRUGS.—

''(i) IN GENERAL.—For 2026 and each subsequent year, the PDP sponsor offering a prescription drug plan shall include each covered part D drug that is a selected drug under section 1192 for which an agreement for such drug is in effect under section 1193 with respect to the year.

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

lected drug from a formulary if such removal would be permitted under section 423.120(b)(5)(iv) of title 42, Code of Federal Regulations (or any successor regulation).''.

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

(i) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

''(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary in accordance with section 1194(g).''.

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

''(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).''.

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

(A) in clause (i)(VI), by striking ''any prices charged'' and inserting ''subject to clause (ii)(V), any prices charged''; and

(B) in clause (ii)—

(i) in subclause (III), by striking ''; and'' at the end;

(ii) in subclause (IV), by striking the period at the end and inserting ''; and''; and

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

''(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as referred to in section 1192(c)) during such rebate period, shall be inclusive of the maximum fair price (as defined in section

1191(c)(2)) for such drug with respect to such period.''.

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

(A) in subclause (IV) by striking ''; and'' at the end;

(B) in subclause (V) by striking the period at the end and inserting ''; and''; and

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

''(VI) any reduction in price paid during the rebate period to the manufacturer for a drug by reason of application of part E of title XI.''.

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

SEC. 129002. SPECIAL RULE TO DELAY SELECTION AND NEGOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET ENTRY.

(a) IN GENERAL.—Part E of title XI of the Social Security Act, as added by section 129001, is amended—

(1) in section 1192—

(A) in subsection (a), in the flush matter following paragraph (2), by inserting ''and subsection (b)(3)'' after ''the previous sentence'';

(B) in subsection (b)—

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

''(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).''; and

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

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

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

(C) by redesignating subsection (f) as subsection (g);

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

''(f) SPECIAL RULE TO DELAY SELECTION AND NEGOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET ENTRY.—

''(1) APPLICATION.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1194(c)(4)) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section

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

"(B) REQUEST REQUIRED.—

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

"(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product would have been included as a selected drug on such list but for subparagraph (2)(A); or

"(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the

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

"(ii) INFORMATION AND DOCUMENTS.—

"(I) IN GENERAL.—A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

"(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary; and

"(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescrip-

tion Drug, Improvement, and Modernization Act of 2003.

''(II) ADDITIONAL INFORMATION AND DOCUMENTS.—After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

''(C) AGGREGATION RULE.—

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

''(ii) PARTNERSHIP DEFINED.—In clause (i), the term 'partnership' means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer

of the biological product and the manufacturer of the biosimilar biological product.

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

''(A) DELAYED SELECTION AND NEGOTIATION FOR 1 YEAR.—If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

''(B) IF NOT LICENSED AND MARKETED DURING THE INITIAL DELAY.—

''(i) IN GENERAL.—If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1

year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under such section 351(k), the Secretary shall, at the request of such manufacturer—

''(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be licensed and marketed under such section 351(k) before the selected drug publication date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

"(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on the items described in paragraph (3)(B)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

"(ii) SELECTION AND NEGOTIATION.—If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

"(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year

after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

''(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

''(iii) SECOND 1-YEAR DELAY.—If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such

list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

''(C) IF NOT LICENSED AND MARKETED DURING THE YEAR TWO DELAY.—If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

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

such biological product would have been included as a selected drug on such list; and

''(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

''(D) LIMITATIONS ON DELAYS.—

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

''(ii) EXCLUSION OF BIOLOGICAL PRODUCTS THAT TRANSITIONED TO A LONG-MONOPOLY DRUG DURING THE DELAY.—In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1194(c)(5)) if such

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

''(iii) EXCLUSION OF BIOLOGICAL PRODUCTS IF MORE THAN 1 YEAR SINCE LICENSURE.—In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 351(k) and marketing has not commenced for such biosimilar biological product.

''(iv) CERTAIN MANUFACTURERS OF BIOSIMILAR BIOLOGICAL PRODUCTS EXCLUDED.—In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

''(I) is the same as the manufacturer of the reference product described in such paragraph or is treat-

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

"(II) has—

"(aa) in the past 5 years, been subject to exclusion under section 1128(b)(7) or to the imposition of civil monetary penalties under section 1128A; or

"(bb) an integrity agreement in effect with the Inspector General of the Department of Health and Human Services that was entered into in lieu of exclusion under section 1128(b)(7);

"(III) is currently subject to a cease and desist order or an injunction in a proceeding or civil action brought by the Federal Trade Commission except for proceedings or actions related solely to a merger or acquisition; or

"(IV) has entered into any agreement described in paragraph (1)(B)(ii)(I)(bb) with the manufacturer of the reference product de-

scribed in paragraph (1)(A) that requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B).

''(E) PUBLIC NOTIFICATION.—If the Secretary delays the inclusion of a biological product as a selected drug on the list published under this section pursuant to subparagraph (A) or (B)(iii), the Secretary shall, within 30 days of making the determination with respect to such delay, provide notification to the public of such delay in a form and manner determined by the Secretary.

''(3) HIGH LIKELIHOOD.—

''(A) IN GENERAL.—For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

''(i) an application for licensure under such section 351(k) for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

"(ii) information from documents described in paragraph (1)(B)(ii) submitted by the manufacturer requesting a delay under paragraph (1)(B) to the Secretary provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

"(B) ITEMS DESCRIBED.—The items described in this subparagraph are the following:

"(i) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 351(k).

"(ii) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the

year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

''(iii) Agreements filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

''(4) REBATE.—

''(A) IN GENERAL.—For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and entered into an agreement under section 1193 with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

"(B) AMOUNT.—Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

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

"(I) 75 percent of the amount by which—

"(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1927 (or, if not reported by such manufacturer under section 1927, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1193(a)) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

"(bb) in the initial price applicability year that would have applied but for a delay under—

"(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

"(BB) paragraph (2)(B)(iii), such maximum fair price, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with September of such previous year; and

"(II) the number of units dispensed under part D of title XVIII for such covered part D drug during each such quarter of such price applicability period; and

"(ii) in the case of a biological product covered under part B of title XVIII, that is the sum of the products of—

"(I) 80 percent of the amount by which—

"(aa) the payment amount for such biological product under section 1847A(b), with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

"(bb) in the initial price applicability year that would have applied but for a delay under—

"(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

"(BB) paragraph (2)(B)(iii), such maximum fair price, increased by the annual percentage increase

in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with September of such previous year; and

''(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

''(C) SPECIAL RULE FOR DELAYED BIOLOGICAL PRODUCTS THAT ARE LONG-MONOPOLY DRUGS.—

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

sion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause (ii) shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

''(ii) AMOUNT DESCRIBED.—The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication

date with respect to the initial price applicability year that would have applied but for this subsection.

''(D) REBATE DEPOSITS.—Amounts paid as rebates under this paragraph shall be deposited into—

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

''(ii) in the case such biological product is a covered part D drug (as defined in section 1860D–2(e)), the Medicare Prescription Drug Account under section 1860D–16 in such Trust Fund.

''(5) DETERMINATIONS.—The determinations of high likelihood and significant amount of progress under this subsection and the determinations required under paragraph (2)(D)(iv) shall be based on information available to the Secretary, including information required by the Secretary from the manufacturer of the biosimilar biological product making a request for a delay under this subsection.

''(6) DEFINITIONS OF BIOSIMILAR BIOLOGICAL PRODUCT.—In this subsection, the term 'biosimilar biological product' has the meanings given such term in section 1847A(c)(6).''; and

(E) in subsection (g), as redesignated by subparagraph (C), by inserting ''the application of subsection (f),'' after ''subsection (e),'';

(2) in section 1193(a)(4)—

(A) in the matter preceding subparagraph (A), by inserting ''and for section 1192(f)'' after ''section 1194(f)'';

(B) in subparagraph (A), by striking ''and'' at the end;

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

''(C) information that the Secretary requires to carry out section 1192(f), including rebates under paragraph (4) of such section; and'';

(3) in section 1196(a)(7), by inserting '', 1192(f)(1)(C),'' after ''sections 1192(d)(2)(B)''; and

(4) in section 1197—

(A) by redesignating subsections (b), (c), and (d) as subsections (c), (d), and (e), respectively; and

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

''(b) VIOLATIONS RELATING TO PROVIDING REBATES.—Any manufacturer that fails to comply with the rebate requirements under section 1192(f)(4) shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.''.

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

(1) in clause (vi), by striking ''and'' at the end;

(2) in clause (vii), by striking the period at the end and inserting ''; and''; and

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

''(viii) as the Secretary determines necessary to carry out section 1192(f), including rebates under paragraph (4) of such section.''.

(c) IMPLEMENTATION FOR 2026 THROUGH 2028.—The Secretary of Health and Human Services shall implement this section, including the amendments made by this

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

SEC. 129003. SELECTED DRUG MANUFACTURER EXCISE TAX IMPOSED DURING NONCOMPLIANCE PERIODS.

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

"CHAPTER 50A—SELECTED DRUGS

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

"SEC. 5000D. SELECTED DRUGS DURING NONCOMPLIANCE PERIODS.

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

"(1) such tax, divided by

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

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

"(1) The period beginning on the March 1st (or, in the case of initial price applicability year

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

''(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the first date during which the manufacturer of the drug and the Secretary of Health and Human Services have agreed to a maximum fair price under such agreement.

''(3) In the case of a selected drug with respect to which the Secretary of Health and Human Services has specified a renegotiation period under such agreement, the period beginning on the first date after the last date of such renegotiation period and ending on the first date during which the manufacturer of the drug has agreed to a renegotiated maximum fair price under such agreement.

''(4) With respect to information that is required to be submitted to the Secretary of Health

and Human Services under such agreement, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

''(c) APPLICABLE PERCENTAGE.—For purposes of this section, the term 'applicable percentage' means—

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

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

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

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

''(d) SELECTED DRUG.—For purposes of this section—

''(1) IN GENERAL.—The term 'selected drug' means any selected drug (within the meaning of section 1192(c) of the Social Security Act) which is manufactured or produced in the United States or

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

''(2) UNITED STATES.—The term 'United States' has the meaning given such term by section 4612(a)(4).

''(3) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

''(e) OTHER DEFINITIONS.—For purposes of this section, the terms 'initial price applicability year', 'selected drug publication date', and 'maximum fair price' have the meaning given such terms in section 1191 of the Social Security Act.

''(f) SPECIAL RULES.—

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

''(2) PROHIBITION ON ADMINISTRATIVE APPEALS.—Any tax controversy with respect to the tax imposed by this section shall not be referred to, or considered by, the Internal Revenue Service Independent Office of Appeals.

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

''(h) REGULATIONS.—The Secretary shall prescribe such regulations and other guidance as may be necessary or appropriate to carry out this section.''.

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

(c) CIVIL ACTIONS FOR REFUND.—Section 7422 of the Internal Revenue Code of 1986 is amended by inserting after subsection (g) the following new subsection:

''(h) SPECIAL RULES FOR EXCISE TAX IMPOSED BY CHAPTER 50A.—No suit or proceeding shall be maintained in any court for the recovery of any tax imposed under section 5000D until payment has been made by the taxpayer in an amount equal to the full amount of the tax imposed under such section (including any interest or penalties in connection with such tax) with respect to any sales of a selected drug (as defined in section 5000D(d)(1)) during the period for which a return is required to be made with respect to such tax (as determined under regulations prescribed by the Secretary).''.

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

"CHAPTER 50A—SELECTED DRUGS".

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

SEC. 129004. FUNDING.

In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $3,000,000,000 for fiscal year 2022, to remain available until expended, to carry out the provisions of, including the amendments made by, this part.

PART 2—PRESCRIPTION DRUG INFLATION REBATES

SEC. 129101. MEDICARE PART B REBATE BY MANUFACTURERS.

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

(1) by redesignating subsection (i) as subsection (j) and by inserting after subsection (h) the following subsection:

"(i) REBATE BY MANUFACTURERS FOR SINGLE SOURCE DRUGS AND BIOLOGICALS WITH PRICES INCREASING FASTER THAN INFLATION.—

"(1) REQUIREMENTS.—

"(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after January 1, 2023, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

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

"(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such drug and calendar quarter.

"(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

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

than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

''(C) TRANSITION RULE FOR REPORTING.—The Secretary may, for each part B rebatable drug, delay the timeframe for reporting the information described in subparagraph (A) for calendar quarters beginning in 2023 and 2024 until not later than September 30, 2025.

''(2) PART B REBATABLE DRUG DEFINED.—

''(A) IN GENERAL.—In this subsection, the term 'part B rebatable drug' means a single source drug or biological (as defined in subparagraph (D) of subsection (c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such subsection) but excluding a qualifying biosimilar biological product (as defined in subsection (b)(8)(B)(iii)), that would be payable under this part if such drug were furnished to an individual enrolled under

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

"(i) if, as determined by the Secretary, the average total allowed charges for such drug or biological under this part for a year per individual that uses such a drug or biological are less than, subject to subparagraph (B), $100; or

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

"(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

"(i) for 2024, shall be the dollar amount specified under such subparagraph for 2023, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

"(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year (without application of subparagraph (C)), increased by the percentage increase in the

consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

''(C) ROUNDING.—Any dollar amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

''(3) REBATE AMOUNT.—

''(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to subparagraphs (B) and (G) and paragraph (4), the estimated amount equal to the product of—

''(i) the total number of billing units determined under subparagraph (B) for the billing and payment code of such drug; and

''(ii) the amount (if any) by which—

''(I) the amount equal to—

''(aa) in the case of a part B rebatable drug described in paragraph (1)(B) of section

1847A(b), 106 percent of the amount determined under paragraph (4) of such section for such drug during the calendar quarter; or

''(bb) in the case of a part B rebatable drug described in paragraph (1)(C) of such section, the payment amount under such paragraph for such drug during the calendar quarter; exceeds

''(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

''(B) TOTAL NUMBER OF BILLING UNITS.—For purposes of subparagraph (A)(i), the total number of billing units with respect to a part B rebatable drug is determined as follows:

''(i) Determine the total number of units equal to—

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

for each National Drug Code of such drug during the calendar quarter that is two calendar quarters prior to the calendar quarter as described in subparagraph (A), minus

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

"(ii) Convert the units determined under clause (i) to billing units for the billing and payment code of such drug, using a methodology similar to the methodology used under this section, by dividing the units determined under clause (i) for each National Drug Code of such drug by the billing unit for the billing and payment code of such drug.

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

"(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

"(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

"(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

"(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term 'payment amount benchmark quarter' means the calendar quarter beginning July 1, 2021.

"(E) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for January 2021.

"(F) REBATE PERIOD CPI–U.—The term 'rebate period CPI–U' means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

"(G) REDUCTION OR WAIVER FOR SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part B rebatable drug and a calendar quarter—

"(i) in the case of a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the calendar quarter; or

"(ii) in the case of a biosimilar biological product, when the Secretary determines there is a severe supply chain disruption during the calendar quarter, such

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

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

"(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'January 2021' under such paragraph were a reference to 'the first month of the first full calendar quarter after the day on which the drug was first marketed'.

"(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020,

paragraph (1)(B) shall be applied as if the reference to 'January 1, 2023' under such paragraph were a reference to 'the later of the 6th full calendar quarter after the day on which the drug was first marketed or January 1, 2023'.

"(C) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) with respect to a price applicability period (as defined in section 1191(b)(2)), in the case such drug is no longer considered to be a selected drug under section 1192(c), for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term 'payment amount benchmark quarter' were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term 'benchmark period CPI–U' were defined under paragraph (3)(E) as if the reference to 'January 2021' under

such paragraph were a reference to 'the July of the year preceding such last year'.

''(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug furnished on or after April 1, 2023, if the payment amount described in paragraph (3)(A)(ii)(I) (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)), the payment amount described in subsection (b)(1)(B) for such drug) for a calendar quarter exceeds the inflation adjusted payment for such quarter—

''(A) in computing the amount of any coinsurance applicable under this part to an individual to whom such drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

''(B) the amount of such coinsurance for such calendar quarter, as computed under subparagraph (A), shall be applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply under subparagraphs (B) or (C) of subsection (b)(1).

''(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

''(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).''; and

(2) in subsection (j), as redesignated by paragraph (1)—

(A) in paragraph (4), by striking at the end ''and'';

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

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

''(6) the determination of units under subsection (i);

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

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

''(9) the computation of coinsurance under subsection (i)(5); and

''(10) the computation of amounts paid under section 1833(a)(1)(EE).''.

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

(1) in subsection (a)(1)—

(A) in subparagraph (G), by inserting '', subject to subsection (i)(9),'' after ''the amounts paid'';

(B) in subparagraph (S), by striking ''with respect to'' and inserting ''subject to subparagraph (EE), with respect to'';

(C) by striking ''and (DD)'' and inserting ''(DD)''; and

(D) by inserting before the semicolon at the end the following: ", and (EE) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) furnished on or after April 1, 2023, for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c) for which, the payment amount described in section 1847A(b)(1)(B)) for such drug for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be equal to the percent of the payment amount under paragraph (3)(A)(ii)(I) of such section or section 1847A(b)(1)(B), as applicable, that equals the difference between (i) 100 percent, and (ii) the percent applied under section 1847A(i)(5)(B)";

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

"(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) for which payment under this subsection is not packaged into a payment

for a service furnished on or after April 1, 2023, under the revised payment system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection.''; and

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

''(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i), except if such drug does not have a copayment amount as a result of application of subparagraph (E)) for which payment under this part is not packaged into a payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under this subsection is the same as the amount for a calendar quarter under paragraph (3)(A)(ii)(I) of section 1847A(i), under the system under this subsection, in lieu of calculation of the copayment amount and the amount of

payment otherwise applicable under this subsection (other than the application of the limitation described in subparagraph (C)), the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection.''.

(c) CONFORMING AMENDMENTS.—

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

(2) EXCLUDING PART B DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting ''or section 1847A(i)'' after ''this section''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by inserting ''and the rebate'' after ''the payment amount''.

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

(A) in subclause (V), by striking ''and'' at the end;

(B) in subclause (VI), by striking the period at the end and inserting a semicolon; and

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

''(VII) rebates paid by manufacturers under section 1847A(i); and''.

(d) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $80,000,000 for fiscal year 2022, including $12,500,000 to carry out the provisions of, including the amendments made by, this section in fiscal year 2022, and $7,500,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2023 through 2031, to remain available until expended.

SEC. 129102. MEDICARE PART D REBATE BY MANUFACTURERS.

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

"SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN DRUGS WITH PRICES INCREASING FASTER THAN INFLATION.

"(a) REQUIREMENTS.—

"(1) SECRETARIAL PROVISION OF INFORMATION.—Not later than 9 months after the end of each applicable period (as defined in subsection (g)(7)), subject to paragraph (3), the Secretary shall, for each part D rebatable drug, report to each manufacturer of such part D rebatable drug the following for such period:

"(A) The amount (if any) of the excess annual manufacturer price increase described in subsection (b)(1)(A)(ii) for each dosage form and strength with respect to such drug and period.

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

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

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

''(3) TRANSITION RULE FOR REPORTING.—The Secretary may, for each rebatable covered part D drug, delay the timeframe for reporting the information and rebate amount described in subparagraphs (A) and (B) of such paragraph for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

''(b) REBATE AMOUNT.—

''(1) IN GENERAL.—

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

"(i) subject to subparagraph (B) of this paragraph, the total number of units that are used to calculate the average manufacturer price of such dosage form and strength with respect to such part D rebatable drug, as reported by the manufacturer of such drug under section 1927 for each month, with respect to such period; and

"(ii) the amount (if any) by which—

"(I) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the period; exceeds

"(II) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and strength with respect to such part D rebatable drug for the period.

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

rebatable drug, with respect to an applicable period, the following:

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

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

"(C) REDUCTION OR WAIVER FOR SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part D rebatable drug and an applicable period—

"(i) in the case of a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the applicable period;

"(ii) in the case of a generic part D rebatable drug (described in subsection (g)(1)(C)(ii)) or a biosimilar (defined as a biological product licensed under section 351(k) of the Public Health Service Act), when the Secretary determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and

"(iii) in the case of a generic Part D rebatable drug (as so described), if the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.

"(2) DETERMINATION OF ANNUAL MANUFACTURER PRICE.—The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable period, is the sum of the products of—

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

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

''(B) the ratio of—

''(i) the total number of units of such dosage form and strength reported under section 1927 with respect to each such calendar quarter of such period; to

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

''(3) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D rebatable drug for an applicable period, subject to paragraph (5), is—

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

''(B) the percentage by which the applicable period CPI–U (as defined in subsection (g)(5)) for the period exceeds the benchmark period CPI–U (as defined in subsection (g)(4)).

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

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

''(B) the ratio of—

''(i) the total number of units reported under section 1927 of such dosage form and strength with respect to each such calendar quarter of such payment amount benchmark period; to

''(ii) the total number of units reported under section 1927 of such dosage form and strength with respect to such payment amount benchmark period.

''(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

"(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after October 1, 2021, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark period' were defined under subsection (g)(3) as the first calendar year beginning after the day on which the drug was first marketed and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (g)(4) as if the reference to 'January 2021' under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed'.

"(B) TREATMENT OF NEW FORMULATIONS.—

"(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the rebate amount under paragraph (1) and the inflation adjusted payment amount under

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

''(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line extension' means, with respect to a part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

''(C) SELECTED DRUGS.—In the case of a part D rebatable drug that is a selected drug (as defined in section 1192(c)) with respect to a price applicability period (as defined in section 1191(b)(2)), in the case such drug is no longer considered to be a selected drug under section 1192(c), for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect to

such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark period' were defined under subsection (g)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (g)(4) as if the reference to 'January 2021' under such subsection were a reference to 'January of the last year beginning during such price applicability period with respect to such drug'.

''(6) RECONCILIATION IN CASE OF REVISED AMP REPORTS.—The Secretary shall provide for a method and process under which, in the case of a manufacturer of a part D rebatable drug that submits revisions to information submitted under section 1927 by the manufacturer with respect to such drug, the Secretary determines, pursuant to such revisions, adjustments, if any, to the calculation of the amount specified in this subsection for a dosage form and strength with respect to such part D rebatable drug and an applicable period and reconciles any overpayments or underpayments in

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

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

''(d) INFORMATION.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3) and information submitted by States under section 1927(b)(2)(A).

''(e) CIVIL MONEY PENALTY.—If a manufacturer of a part D rebatable drug has failed to comply with the requirement under subsection (a)(2) with respect to such drug for an applicable period, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to 125 percent of the amount specified in subsection (b) for such drug for such period. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this

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

''(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review of the following:

''(1) The determination of units under this section.

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

''(3) The calculation of the rebate amount under this section.

''(g) DEFINITIONS.—In this section:

''(1) PART D REBATABLE DRUG.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the term 'part D rebatable drug' means, with respect to an applicable period, a drug or biological described in subparagraph (C) that would (without application of this section) be a covered part D drug (as such term is defined under section 1860D–2(e)).

''(B) EXCLUSION.—

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

period per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to clause (ii), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

''(ii) INCREASE.—The dollar amount applied under clause (i)—

''(I) for the applicable period beginning October 1, 2023, shall be the dollar amount specified under such clause for the applicable period beginning October 1, 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with October of 2023; and

''(II) for a subsequent applicable period, shall be the dollar amount specified in this clause for the previous applicable period, increased by the percentage increase in the consumer price index for all urban con-

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

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

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

''(i) a drug approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act;

''(ii) a drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act, in the case where—

''(I) the reference listed drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including any 'authorized generic drug' (as that term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act), is not being

marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

"(II) there is no other drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act that is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations') and that is being marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

"(III) the manufacturer is not a 'first applicant' during the '180-day exclusivity period', as those terms are defined in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act; and

"(IV) the manufacturer is not a 'first approved applicant' for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v)

of the Federal Food, Drug, and Cosmetic Act; or

''(iii) a biological licensed under section 351 of the Public Health Service Act.

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

''(3) PAYMENT AMOUNT BENCHMARK PERIOD.—The term 'payment amount benchmark period' means the period beginning January 1, 2021, and ending in the month immediately prior to October 1, 2021.

''(4) BENCHMARK PERIOD CPI–U.—The term 'benchmark period CPI–U' means the consumer price index for all urban consumers (United States city average) for January 2021.

''(5) APPLICABLE PERIOD CPI–U.—The term 'applicable period CPI–U' means, with respect to an applicable period, the consumer price index for all urban consumers (United States city average) for the first month of such applicable period.

''(6) AVERAGE MANUFACTURER PRICE.—The term 'average manufacturer price' has the meaning,

with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.

''(7) APPLICABLE PERIOD.—The term 'applicable period' means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

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

(b) CONFORMING AMENDMENTS.—

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

(2) EXCLUDING PART D DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by section 129101(c)(2), is amended by striking ''or sec-

tion 1847A(i)'' and inserting '', section 1847A(i), or section 1860D–14B''.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)), as amended by section 129101(c)(3), is amended by striking ''or to carry out section 1847B'' and inserting ''or to carry out section 1847B or section 1860D–14B''.

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

(A) in subclause (VI), by striking ''and'' at the end;

(B) in subclause (VII), by striking the period at the end and inserting a semicolon; and

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

''(VIII) rebates paid by manufacturers under section 1860D–14B.''.

(c) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $80,000,000 for fiscal year 2022, including $12,500,000 to carry out the provisions of, including the amendments made by, this section in fiscal year 2022, and $7,500,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2023 through 2031, to remain available until expended.

PART 3—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

SEC. 129201. MEDICARE PART D BENEFIT REDESIGN.

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

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting ''for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year'' after ''paragraph (3)'';

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting ''for a year preceding 2025,'' after ''paragraph (4),''; and

(ii) in clause (ii)(III), by striking ''and each subsequent year'' and inserting ''through 2024''; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting ''for a year preceding 2025,'' after ''paragraph (4),''; and

(II) in subclause (I)(bb), by striking ''a year after 2018'' and inserting ''each of years 2019 through 2024''; and

(ii) in clause (ii)(V), by striking ''2019 and each subsequent year'' and inserting ''each of years 2019 through 2024'';

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting ''for a year preceding 2025,'' after ''and (4),''; and

(B) in clause (ii), by striking ''for a subsequent year'' and inserting ''for each of years 2007 through 2024''; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

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

(II) in the matter preceding item (aa), as redesignated by subclause (I), by striking ''is equal to the greater of—'' and inserting ''is equal to—

''(I) for a year preceding 2024, the greater of—'';

(III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting ''; and''; and

(IV) by adding at the end the following:

''(II) for 2024 and each succeeding year, $0.''; and

(ii) in clause (ii)—

(I) by striking ''clause (i)(I)'' and inserting ''clause (i)(I)(aa)''; and

(II) by adding at the end the following new sentence: ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1860D–14(a)(1)(D)(iii).'';

(B) in subparagraph (B)—

(i) in clause (i)—

(I) in subclause (V), by striking ''or'' at the end;

(II) in subclause (VI)—

(aa) by striking ''for a subsequent year'' and inserting ''for each of years 2021 through 2024''; and

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

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

''(VII) for 2025, is equal to $2,000; or

''(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.''; and

(ii) in clause (ii), by striking ''clause (i)(II)'' and inserting ''clause (i)'';

(C) in subparagraph (C)—

(i) in clause (i), by striking ''and for amounts'' and inserting ''and, for a year preceding 2025, for amounts''; and

(ii) in clause (iii)—

(I) by redesignating subclauses (I) through (IV) as items (aa) through (dd) and indenting appropriately;

(II) by striking ''if such costs are borne or paid'' and inserting ''if such costs—

''(I) are borne or paid—''; and

(III) in item (dd), by striking the period at the end and inserting ''; or''; and

(IV) by adding at the end the following new subclause:

''(II) for 2025 and subsequent years, are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage (as defined in subsection (a)(3)) or any payments by a manufacturer under the manufacturer discount program under section 1860D–14C.''; and

(D) in subparagraph (E), by striking ''In applying'' and inserting ''For each of years 2011 through 2024, in applying''.

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

(1) in paragraph (1)—

(A) by striking ''equal to 80 percent'' and inserting ''equal to—

''(A) for a year preceding 2025, 80 percent'';

(B) in subparagraph (A), as added by subparagraph (A), by striking the period at the end and inserting ''; and''; and

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

''(B) for 2025 and each subsequent year, the sum of—

''(i) with respect to applicable drugs (as defined in section 1860D–14C(g)(2)), an amount equal to 20 percent of such allowable reinsurance costs attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B); and

"(ii) with respect to covered part D drugs that are not applicable drugs (as so defined), an amount equal to 40 percent of such allowable reinsurance costs attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).";

(2) in paragraph (2)—

(A) by striking "COSTS.—For purposes" and inserting "COSTS.—

"(A) IN GENERAL.—Subject to subparagraph (B), for purposes"; and

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

"(B) INCLUSION OF MANUFACTURER DISCOUNTS ON APPLICABLE DRUGS.—For purposes of applying subparagraph (A), the term 'allowable reinsurance costs' shall include the portion of the negotiated price (as defined in section 1860D–14C(g)(6)) of an applicable drug (as defined in section 1860D–14C(g)(2)) that was

paid by a manufacturer under the manufacturer discount program under section 1860D–14C.''; and

(3) in paragraph (3)—

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

(B) in the second sentence, by inserting ''(or, with respect to 2025 and subsequent years, in the case of an applicable drug, as defined in section 1860D–14C(g)(2), by a manufacturer)'' after ''by the individual or under the plan''.

(c) MANUFACTURER DISCOUNT PROGRAM.—

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

''SEC. 1860D–14C. MANUFACTURER DISCOUNT PROGRAM.

''(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the 'program'). Under the program, the Secretary shall enter into agreements described in subsection

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

"(b) TERMS OF AGREEMENT.—

"(1) IN GENERAL.—

"(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries on or after January 1, 2025.

"(B) CLARIFICATION.—Nothing in this section shall be construed as affecting—

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

"(ii) the application of the copayment amount described in paragraph (4)(A) of such section, with respect to costs described in such paragraph.

"(C) TIMING OF AGREEMENT.—

"(i) SPECIAL RULE FOR 2025.—In order for an agreement with a manufacturer to be in effect under this section with

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

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

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

''(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary, as applicable, for purposes of administering the program, including any determination under

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

"(4) LENGTH OF AGREEMENT.—

"(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

"(B) TERMINATION.—

"(i) BY THE SECRETARY.—The Secretary shall provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

"(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

"(I) if the termination occurs before January 31 of a plan year, as of the day after the end of the plan year; and

"(II) if the termination occurs on or after January 31 of a plan year, as of the day after the end of the succeeding plan year.

"(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

"(5) EFFECTIVE DATE OF AGREEMENT.—An agreement under this section shall take effect at the start of a calendar quarter or another date specified by the Secretary.

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

''(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

''(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

''(B) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

''(i) the negotiated price of the applicable drug; and

''(ii) the discounted price of the applicable drug;

''(C) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as specified by the Secretary; and

''(D) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, prescription drug plans and MA–PD plans, and the Secretary.

''(2) MONITORING COMPLIANCE.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

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

''(d) ADMINISTRATION.—

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

''(2) LIMITATION.—In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

''(e) ENFORCEMENT.—

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

''(2) CIVIL MONEY PENALTY.—

''(A) IN GENERAL.—A manufacturer that fails to provide discounted prices for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with such agreement shall be subject to a civil money penalty for each such failure in an amount the Secretary determines is equal to the sum of—

''(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

''(ii) 25 percent of such amount.

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

''(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

''(g) DEFINITIONS.—In this section:

''(1) APPLICABLE BENEFICIARY.—The term 'applicable beneficiary' means an individual who, on the date of dispensing a covered part D drug—

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

''(B) is not enrolled in a qualified retiree prescription drug plan; and

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

''(2) APPLICABLE DRUG.—The term 'applicable drug', with respect to an applicable beneficiary—

''(A) means a covered part D drug—

''(i) approved under a new drug application under section 505(c) of the Federal

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

''(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

''(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

''(III) is provided through an exception or appeal; and

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

"(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term 'applicable number of calendar days' means—

"(A) with respect to claims for reimbursement submitted electronically, 14 days; and

"(B) with respect to claims for reimbursement submitted otherwise, 30 days.

"(4) DISCOUNTED PRICE.—

"(A) IN GENERAL.—The term 'discounted price' means, subject to subparagraphs (B) and (C), with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary—

"(i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, 90 percent of the negotiated price of such drug; and

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

80 percent of the negotiated price of such drug.

"(B) PHASE-IN FOR CERTAIN DRUGS DISPENSED TO LIS BENEFICIARIES.—

"(i) IN GENERAL.—In the case of an applicable drug of a specified manufacturer (as defined in clause (ii)) that is marketed as of the date of enactment of this subparagraph and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3)), the term 'discounted price' means the specified LIS percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

"(ii) SPECIFIED MANUFACTURER.—

"(I) IN GENERAL.—In this subparagraph, subject to subclause (II), the term 'specified manufacturer' means a manufacturer of an applicable drug for which, in 2021—

"(aa) the manufacturer had a coverage gap discount agreement under section 1860D–14A;

"(bb) the total expenditures for all of the specified drugs of the manufacturer covered by such agreement or agreements for such year and covered under this part during such year represented less than 1.0 percent of the total expenditures under this part for all covered Part D drugs during such year; and

"(cc) the total expenditures for all of the specified drugs of the manufacturer that are single source drugs and biological products covered under part B during such year represented less than 1.0 percent of the total expenditures under part B for all drugs or biological products covered under such part during such year.

"(II) SPECIFIED DRUGS.—

"(aa) IN GENERAL.—For purposes of this clause, the term 'specified drug' means, with re-

spect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

''(bb) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

''(III) LIMITATION.—The term 'specified manufacturer' shall not include a manufacturer described in subclause (I) if such manufacturer is

acquired after 2021 by another manufacturer that is not a specified manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

''(iii) SPECIFIED LIS PERCENT.—In this subparagraph, the 'specified LIS percent' means, with respect to a year—

''(I) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

''(aa) for 2025, 99 percent;

''(bb) for 2026, 98 percent;

''(cc) for 2027, 95 percent;

''(dd) for 2028, 92 percent; and

"(ee) for 2029 and each subsequent year, 90 percent; and

"(II) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

"(aa) for 2025, 99 percent;

"(bb) for 2026, 98 percent;

"(cc) for 2027, 95 percent;

"(dd) for 2028, 92 percent;

"(ee) for 2029, 90 percent;

"(ff) for 2030, 85 percent; and

"(gg) for 2031 and each subsequent year, 80 percent.

"(C) PHASE-IN FOR SPECIFIED SMALL MANUFACTURERS.—

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

facturer (as defined in clause (ii)) that is marketed as of the date of enactment of this subparagraph and dispensed for an applicable beneficiary, the term 'discounted price' means the specified small manufacturer percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

''(ii) SPECIFIED SMALL MANUFACTURER.—

''(I) IN GENERAL.—In this subparagraph, subject to subclause (III), the term 'specified small manufacturer' means a manufacturer of an applicable drug for which, in 2021—

''(aa) the manufacturer is a specified manufacturer (as defined in subparagraph (B)(ii)); and

''(bb) the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section

1860D–14A of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for such year and covered under this part during such year.

''(II) SPECIFIED SMALL MANUFACTURER DRUGS.—

''(aa) IN GENERAL.—For purposes of this clause, the term 'specified small manufacturer drugs' means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

''(bb) AGGREGATION RULE.—All persons treated as a single employer under subsection

(a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

''(III) LIMITATION.—The term 'specified small manufacturer' shall not include a manufacturer described in subclause (I) if such manufacturer is acquired after 2021 by another manufacturer that is not a specified small manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

''(iii) SPECIFIED SMALL MANUFACTURER PERCENT.—In this subparagraph,

the term 'specified small manufacturer percent' means, with respect to a year—

"(I) for an applicable drug dispensed for an applicable beneficiary who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

"(aa) for 2025, 99 percent;

"(bb) for 2026, 98 percent;

"(cc) for 2027, 95 percent;

"(dd) for 2028, 92 percent; and

"(ee) for 2029 and each subsequent year, 90 percent; and

"(II) for an applicable drug dispensed for an applicable beneficiary who has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold

specified in section 1860D–2(b)(4)(B)(i) for the year—

"(aa) for 2025, 99 percent;

"(bb) for 2026, 98 percent;

"(cc) for 2027, 95 percent;

"(dd) for 2028, 92 percent;

"(ee) for 2029, 90 percent;

"(ff) for 2030, 85 percent; and

"(gg) for 2031 and each subsequent year, 80 percent.

"(D) TOTAL EXPENDITURES.—For purposes of this paragraph, the term 'total expenditures' includes, in the case of expenditures with respect to part D, the total gross covered prescription drug costs as defined in section 1860D–15(b)(3). The term 'total expenditures' excludes, in the case of expenditures with respect to part B, expenditures for a drug or biological that are bundled or packaged into the payment for another service.

"(E) SPECIAL CASE FOR CERTAIN CLAIMS.—

"(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire

amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls above such annual deductible.

''(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

''(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

''(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

''(5) MANUFACTURER.—The term 'manufacturer' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

''(6) NEGOTIATED PRICE.—The term 'negotiated price' has the meaning given such term for purposes of section 1860D–2(d)(1)(B), and, with respect to an applicable drug, such negotiated price shall include any dispensing fee and, if applicable, any vaccine administration fee for the applicable drug.

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

"SEC. 1860D–14D. SELECTED DRUG SUBSIDY PROGRAM.

''With respect to covered part D drugs that would be applicable drugs (as defined in section 1860D–14C(g)(2)) but for the application of subparagraph (B) of such section, the Secretary shall provide a process whereby, in the case of an applicable beneficiary (as defined in section 1860D–14C(g)(1)) who, with respect to a year, is enrolled in a prescription drug plan or is enrolled in an MA–PD plan, has not incurred costs that are equal to or exceed the annual out-of-pocket threshold specified in section 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. 1395w–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, 2025, 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 January 1, 2025, with respect to applicable drugs dispensed prior to such date.''.

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

(A) in subparagraph (C), by striking ''and'' at the end;

(B) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

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

''(E) payments under section 1860D–14D (relating to selected drug subsidy payments).''.

(d) MEDICARE PART D PREMIUM STABILIZATION.—

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

(A) in subsection (a)—

(i) in paragraph (1)(A), by inserting ''or (8) (as applicable)'' after ''paragraph (2)'';

(ii) in paragraph (2), in the matter preceding subparagraph (A), by striking ''The base'' and inserting ''Subject to paragraph (8), the base'';

(iii) in paragraph (7)—

(I) in subparagraph (B)(ii), by inserting ''or (8) (as applicable)'' after ''paragraph (2)''; and

(II) in subparagraph (E)(i), by inserting ''or (8) (as applicable)'' after ''paragraph (2)''; and

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

''(8) PREMIUM STABILIZATION.—

''(A) IN GENERAL.—The base beneficiary premium under this paragraph for a prescription drug plan for a month in 2024 through 2029 shall be computed as follows:

''(i) 2024.—The base beneficiary premium for a month in 2024 shall be equal to the lesser of—

''(I) the base beneficiary premium computed under paragraph (2) for a month in 2023 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2024 that would have applied if this paragraph had not been enacted.

''(ii) 2025.—The base beneficiary premium for a month in 2025 shall be equal to the lesser of—

''(I) the base beneficiary premium computed under clause (i) for a month in 2024 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2025 that would have applied if this paragraph had not been enacted.

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

''(I) the base beneficiary premium computed under clause (ii) for a month in 2025 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2026 that would have applied if this paragraph had not been enacted.

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

''(I) the base beneficiary premium computed under clause (iii) for a month in 2026 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2027 that would have applied if this paragraph had not been enacted.

''(v) 2028.—The base beneficiary premium for a month in 2028 shall be equal to the lesser of—

''(I) the base beneficiary premium computed under clause (iv) for a month in 2027 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2028 that would have applied if this paragraph had not been enacted.

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

''(I) the base beneficiary premium computed under clause (v) for a month in 2028 increased by 6 percent; or

''(II) the base beneficiary premium computed under paragraph (2) for a month in 2029 that would have applied if this paragraph had not been enacted.

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

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

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

(A) in paragraph (3)(A), by inserting "(or, for 2030 and each subsequent year, the percent specified under paragraph (9))" after "25.5 percent"; and

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

"(9) PERCENT SPECIFIED.—

"(A) IN GENERAL.—Subject to subparagraph (B), for purposes of paragraph (3)(A), the percent specified under this paragraph for 2030 and each subsequent year is the percent that the Secretary determines is necessary to

ensure that the base beneficiary premium computed under paragraph (2) for a month in 2030 is equal to the lesser of—

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

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

"(B) FLOOR.—The percent specified under subparagraph (A) may not be less than 20 percent.".

(3) CONFORMING AMENDMENTS.—

(A) Section 1854(b)(2)(B) of the Social Security Act 42 U.S.C. 1395w–24(b)(2)(B)) is amended by striking "section 1860D–13(a)(2)" and inserting "paragraph (2) or (8) (as applicable) of section 1860D–13(a)".

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

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

(i) in subclause (I), by inserting ''(or, for 2030 and each subsequent year, the percent specified under paragraph (9))'' after ''25.5 percent''; and

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

(D) Section 1860D–15(a) of the Social Security Act (42 U.S.C. 1395w–115(a)) is amended—

(i) in the matter preceding paragraph (1), by inserting ''(or, for each of 2024 through 2029, the percent applicable as a result of the application of section 1860D–13(a)(8), or, for 2030 and each subsequent year, 100 percent minus the percent specified under section 1860D–13(a)(9))'' after ''74.5 percent''; and

(ii) in paragraph (1)(B), by striking ''paragraph (2) of section 1860D–13(a)''

and inserting ''paragraph (2) or (8) of section 1860D–13(a) (as applicable)''.

(e) CONFORMING AMENDMENTS.—

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

(A) in subsection (a(2)(A)(i)(I), by striking '', or an increase in the initial'' and inserting ''or, for a year preceding 2025, an increase in the initial'';

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking ''AT INITIAL COVERAGE LIMIT''; and

(ii) by inserting ''for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year'' after ''subsection (b)(3) for the year'' each place it appears; and

(C) in subsection (d)(1)(A), by striking ''or an initial'' and inserting ''or, for a year preceding 2025, an initial''.

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

amended by striking ''the initial'' and inserting ''for a year preceding 2025, the initial''.

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

(A) in paragraph (1)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2025, the continuation'';

(ii) in subparagraph (D)(iii), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa)''; and

(iii) in subparagraph (E), by striking ''The elimination'' and inserting ''For a year preceding 2024, the elimination''; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking ''The continuation'' and inserting ''For a year preceding 2025, the continuation''; and

(ii) in subparagraph (E), by striking ''1860D–2(b)(4)(A)(i)(I)'' and inserting ''1860D–2(b)(4)(A)(i)(I)(aa) (for a year preceding 2024)''.

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

by striking ''section 1860D–2(b)(4)(B)(i)'' and inserting ''section 1860D–2(b)(4)(C)(i)''.

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

(A) by striking ''the value of any discount'' and inserting the following: ''the value of—

''(i) for years prior to 2025, any discount'';

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting ''; and''; and

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

''(ii) for 2025 and each subsequent year, any discount provided pursuant to section 1860D–14C.''.

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

(A) by inserting ''for a year before 2025'' after ''1860D–2(b)(3)''; and

(B) by inserting ''for such year'' before the period.

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

(A) in subsection (a)—

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

''(1) participate in—

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

''(B) for 2025 and each subsequent year, the manufacturer discount program under section 1860D–14C;'';

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

''(2) have entered into and have in effect—

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

''(B) for 2025 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and''; and

(iii) in paragraph (3), by striking ''such section'' and inserting ''section 1860D–14A''; and

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

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

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

(A) in subsection (c)(1)(C)(i)(VI), by inserting before the period at the end the following: "or under the manufacturer discount program under section 1860D–14C"; and

(B) in subsection (k)(1)(B)(i)(V), by inserting before the period at the end the following: "or under section 1860D–14C".

(f) IMPLEMENTATION FOR 2024 THROUGH 2026.—The Secretary shall implement this section, including the amendments made by this section, for 2024, 2025, and 2026 by program instruction or other forms of program guidance.

(g) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $341,000,000 for fiscal

year 2022, including $20,000,000 and $65,000,000 to carry out the provisions of, including the amendments made by, this section in fiscal years 2022 and 2023, respectively, and $32,000,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2024 through 2031, to remain available until expended.

SEC. 129202. MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS UNDER PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

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

(1) in paragraph (2)—

(A) in subparagraph (A), by striking ''and (D)'' and inserting '', (D), and (E)''; and

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

''(E) MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS.—

''(i) IN GENERAL.—For plan years beginning on or after January 1, 2025, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee of such plan, including an enrollee who is

a subsidy eligible individual (as defined in paragraph (3) of section 1860D–14(a)), the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped in accordance with this subparagraph.

''(ii) DETERMINATION OF MAXIMUM MONTHLY CAP.—For each month in the plan year for which an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

''(iii) BENEFICIARY MONTHLY PAYMENTS.—With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

''(iv) MAXIMUM MONTHLY CAP DEFINED.—In this subparagraph, the term

'maximum monthly cap' means, with respect to an enrollee—

"(I) for the first month for which the enrollee has made an election pursuant to clause (i), an amount determined by calculating—

"(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

"(bb) the number of months remaining in the plan year; and

"(II) for a subsequent month, an amount determined by calculating—

"(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by

"(bb) the number of months remaining in the plan year.

"(v) ADDITIONAL REQUIREMENTS.—The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

"(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1804(a).

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

"(aa) prior to the beginning of the plan year; or

"(bb) in any month during the plan year.

"(III) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

"(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

"(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

"(cc) shall include information on such option in enrollee educational materials;

"(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

"(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

"(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

"(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

"(IV) FAILURE TO PAY AMOUNT BILLED.—If an enrollee fails to pay the amount billed for a month as required under this subparagraph—

"(aa) the election of the enrollee pursuant to clause (i) shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the

annual out-of-pocket threshold specified in paragraph (4)(B); and

''(bb) the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.

''(V) CLARIFICATION REGARDING PAST DUE AMOUNTS.—Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

''(VI) TREATMENT OF UNSETTLED BALANCES.—Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.''; and

(2) in paragraph (4)—

(A) in subparagraph (C), by striking ''subparagraph (E)'' and inserting ''subparagraph (E) or subparagraph (F)''; and

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

''(F) INCLUSION OF COSTS PAID UNDER MAXIMUM MONTHLY CAP OPTION.—In applying subparagraph (A), with respect to an enrollee who has made an election pursuant to clause (i) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the option provided under such paragraph.''.

(b) APPLICATION TO ALTERNATIVE PRESCRIPTION DRUG COVERAGE.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

''(4) SAME MAXIMUM MONTHLY CAP ON COST-SHARING.—The maximum monthly cap on cost-sharing payments shall apply to coverage with respect to an enrollee who has made an election pursuant to clause (i) of subsection (b)(2)(E) under the option provided under such subsection.''.

(c) IMPLEMENTATION FOR 2025.—The Secretary shall implement this section, including the amendments

made by this section, for 2025 by program instruction or other forms of program guidance.

(d) FUNDING.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $10,000,000 for fiscal year 2023, to remain available until expended, to carry out the provisions of, including the amendments made by, this section.

PART 4—REPEAL OF PRESCRIPTION DRUG REBATE RULE

SEC. 129301. PROHIBITING IMPLEMENTATION OF RULE RELATING TO ELIMINATING THE ANTI-KICKBACK STATUTE SAFE HARBOR PROTECTION FOR PRESCRIPTION DRUG REBATES.

Section 90006 of division I of the Infrastructure Investment and Jobs Act (42 U.S.C. 1320a–7b note), as amended by section 13101 of division A of the Bipartisan Safer Communities Act, is amended by striking ‘‘, prior to January 1, 2027,’’.

PART 5—MISCELLANEOUS

SEC. 129401. COVERAGE OF ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES UNDER MEDICARE PART D.

(a) ENSURING TREATMENT OF COST-SHARING AND DEDUCTIBLE IS CONSISTENT WITH TREATMENT OF VACCINES UNDER MEDICARE PART B.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by sections 129201 and 129202, is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A), by striking ''The coverage'' and inserting ''Subject to paragraph (8), the coverage'';

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''and paragraph (8)'' after ''and (E)'';

(ii) in subparagraph (C)(i), in the matter preceding subclause (I), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (8)''; and

(iii) in subparagraph (D)(i), in the matter preceding subclause (I), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (8)'';

(C) in paragraph (4)(A)(i), by striking ''The coverage'' and inserting ''Subject to paragraph (8), the coverage''; and

(D) by adding at the end the following new paragraph:

''(8) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES CONSISTENT WITH TREATMENT OF VACCINES UNDER PART B.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in subparagraph (B))—

''(i) the deductible under paragraph (1) shall not apply; and

''(ii) there shall be no coinsurance or other cost-sharing under this part with respect to such vaccine.

''(B) ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For purposes of this paragraph, the term 'adult vaccine recommended by the Advisory Committee on Immunization Prac-

tices' means a covered part D drug that is a vaccine licensed under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.''; and

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

''(5) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—The coverage is in accordance with subsection (b)(8).''.

(b) CONFORMING AMENDMENTS TO COST-SHARING FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 129201, is amended—

(1) in paragraph (1)(D), in each of clauses (ii) and (iii), by striking ''In the case'' and inserting ''Subject to paragraph (6), in the case'';

(2) in paragraph (2)—

(A) in subparagraph (B), by striking ''A reduction'' and inserting ''Subject to section 1860D–2(b)(8), a reduction'';

(B) in subparagraph (D), by striking ''The substitution'' and inserting ''Subject to paragraph (6), the substitution''; and

(C) in subparagraph (E), by striking ''and subsection (c)'' and inserting '', paragraph (6) of this subsection, and subsection (c)''; and

(3) by adding at the end the following new paragraph:

''(6) NO APPLICATION OF COST-SHARING OR DEDUCTIBLE FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in section 1860D–2(b)(8)(B))—

''(A) the deductible under section 1860D–2(b)(1) shall not apply; and

''(B) there shall be no cost-sharing under this section with respect to such vaccine.''.

(c) TEMPORARY RETROSPECTIVE SUBSIDY.—Section 1860D–15 of the Social Security Act (42 U.S.C. 1395w–115) is amended by adding at the end the following new subsection:

''(h) TEMPORARY RETROSPECTIVE SUBSIDY FOR REDUCTION IN COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES DURING 2023.—

''(1) IN GENERAL.—In addition to amounts otherwise payable under this section to a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan, for plan year 2023, the Secretary shall provide the PDP sponsor or MA organization offering the plan subsidies in an amount equal to the aggregate reduction in cost-sharing by reason of the application of section 1860D–2(b)(8) for individuals under the plan during the year.

''(2) TIMING.—The Secretary shall provide a subsidy under paragraph (1), as applicable, not later than 18 months following the end of the applicable plan year.''.

(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as limiting coverage under part D of title XVIII of the Social Security Act for vaccines that are not recommended by the Advisory Committee on Immunization Practices.

(e) IMPLEMENTATION FOR 2023 THROUGH 2025.—The Secretary shall implement this section, including the

amendments made by this section, for 2023, 2024, and 2025, by program instruction or other forms of program guidance.

SEC. 129402. PAYMENT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.

Section 1847A(c)(4) of the Social Security Act (42 U.S.C. 1395w–3a(c)(4)) is amended—

(1) in each of subparagraphs (A) and (B), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and moving such subclauses 2 ems to the right;

(2) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii) and moving such clauses 2 ems to the right;

(3) by striking ''UNAVAILABLE.—In the case'' and inserting ''UNAVAILABLE.—

''(A) IN GENERAL.—Subject to subparagraph (B), in the case''; and

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

''(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2024, during the initial period described

in subparagraph (A) with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

''(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

''(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.''.

SEC. 129403. TEMPORARY INCREASE IN MEDICARE PART B PAYMENT FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS.

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

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

(2) by striking ''PRODUCT.—The amount'' and inserting the following: ''PRODUCT.—

''(A) IN GENERAL.—Subject to subparagraph (B), the amount''; and

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

"(B) TEMPORARY PAYMENT INCREASE.—

"(i) IN GENERAL.—In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting '8 percent' for '6 percent'.

"(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a qualifying biosimilar biological product is—

"(I) in the case of such a product for which payment was made under this paragraph as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

"(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning October 1, 2022, and ending

December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

"(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For purposes of this subparagraph, the term 'qualifying biosimilar biological product' means a biosimilar biological product described in paragraph (1)(C) with respect to which—

"(I) in the case of a product described in clause (ii)(I), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product; and

"(II) in the case of a product described in clause (ii)(II), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is

not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product.''.

SEC. 129404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 129201, is amended—

(1) in the subsection heading, by striking ''INDIVIDUALS'' and all that follows through ''LINE'' and inserting ''CERTAIN INDIVIDUALS'';

(2) in paragraph (1)—

(A) by striking the paragraph heading and inserting ''INDIVIDUALS WITH CERTAIN LOW INCOMES''; and

(B) in the matter preceding subparagraph (A), by inserting ''(or, with respect to a plan year beginning on or after January 1, 2024, 150 percent)'' after ''135 percent''; and

(3) in paragraph (2)—

(A) by striking the paragraph heading and inserting ''OTHER LOW-INCOME INDIVIDUALS''; and

(B) in the matter preceding subparagraph (A), by striking ''In the case of a subsidy'' and inserting ''With respect to a plan year beginning before January 1, 2024, in the case of a subsidy''.

SEC. 129405. IMPROVING ACCESS TO ADULT VACCINES UNDER MEDICAID AND CHIP.

(a) MEDICAID.—

(1) REQUIRING COVERAGE OF ADULT VACCINATIONS.—

(A) IN GENERAL.—Section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)) is amended in the matter preceding clause (i) by inserting ''(13)(B),'' after ''(5),''.

(B) MEDICALLY NEEDY.—Section 1902(a)(10)(C)(iv) of such Act (42 U.S.C. 1396a(a)(10)(C)(iv)) is amended by inserting '', (13)(B),'' after ''(5)''.

(2) NO COST SHARING FOR VACCINATIONS.—

(A) GENERAL COST-SHARING LIMITATIONS.—Section 1916 of the Social Security Act (42 U.S.C. 1396o) is amended—

(i) in subsection (a)(2)—

(I) in subparagraph (G), by inserting a comma after ''State plan'';

(II) in subparagraph (H), by striking ''; or'' and inserting a comma;

(III) in subparagraph (I), by striking ''; and'' and inserting '', or''; and

(IV) by adding at the end the following new subparagraph:

''(J) vaccines described in section 1905(a)(13)(B) and the administration of such vaccines; and''; and

(ii) in subsection (b)(2)—

(I) in subparagraph (G), by inserting a comma after ''State plan'';

(II) in subparagraph (H), by striking ''; or'' and inserting a comma;

(III) in subparagraph (I), by striking ''; and'' and inserting '', or''; and

(IV) by adding at the end the following new subparagraph:

''(J) vaccines described in section 1905(a)(13)(B) and the administration of such vaccines; and''.

(B) APPLICATION TO ALTERNATIVE COST SHARING.—Section 1916A(b)(3)(B) of the Social Security Act (42 U.S.C. 1396o–1(b)(3)(B)) is amended by adding at the end the following new clause:

''(xiv) Vaccines described in section 1905(a)(13)(B) and the administration of such vaccines.''.

(3) INCREASED FMAP FOR ADULT VACCINES AND THEIR ADMINISTRATION.—Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended—

(A) by striking ''and (5)'' and inserting ''(5)'';

(B) by striking ''services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines'' and inserting ''services described in subsection (a)(13)(A), and prohibits cost-sharing for such services'';

(C) by striking ''medical assistance for such services and vaccines'' and inserting ''medical assistance for such services''; and

(D) by inserting '', and (6) during the first 8 fiscal quarters beginning on or after the effective date of this clause, in the case of a State which, as of the date of enactment of the Act titled 'An Act to provide for reconciliation pursuant to title II of S. Con. Res. 14', provides medical assistance for vaccines described in subsection (a)(13)(B) and their administration and prohibits cost-sharing for such vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y), shall be increased by 1 percentage point with respect to medical assistance for such vaccines and their administration'' before the first period.

(b) CHIP.—

(1) REQUIRING COVERAGE OF ADULT VACCINATIONS.—Section 2103(c) of the Social Security Act (42 U.S.C. 1397cc(c)) is amended by adding at the end the following paragraph:

''(12) REQUIRED COVERAGE OF APPROVED, RECOMMENDED ADULT VACCINES AND THEIR AD-

MINISTRATION.—Regardless of the type of coverage elected by a State under subsection (a), if the State child health plan or a waiver of such plan provides child health assistance or pregnancy-related assistance (as defined in section 2112) to an individual who is 19 years of age or older, such assistance shall include coverage of vaccines described in section 1905(a)(13)(B) and their administration.''.

(2) NO COST-SHARING FOR VACCINATIONS.—Section 2103(e)(2) of such Act (42 U.S.C. 1397cc(e)(2)) is amended by inserting ''vaccines described in subsection (c)(12) (and the administration of such vaccines),'' after ''in vitro diagnostic products described in subsection (c)(10) (and administration of such products),''.

(c) EFFECTIVE DATE.—The amendments made by this section take effect on the 1st day of the 1st fiscal quarter that begins on or after the date that is 1 year after the date of enactment of this Act and shall apply to expenditures made under a State plan or waiver of such plan under title XIX of the Social Security Act (42 U.S.C. 1396 through 1396w–6) or under a State child health plan or waiver of such plan under title XXI of such Act (42 U.S.C. 1397aa through 1397mm) on or after such effective date.