Subtitle B—Prescription Drug Pricing Reform

PART 1—LOWERING PRICES THROUGH DRUG PRICE NEGOTIATION

SEC. 11001. 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) MANUFACTURER.—The term 'manufacturer' has the meaning given that term in section 1847A(c)(6)(A).

"(2) 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 in a prescription drug plan under part D of title XVIII or an MA–PD plan

under part C of such title if coverage is provided 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 in an MA plan under part C of such title, if payment may be made under part B for such selected drug.

"(3) 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.

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

"(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.

"(6) 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.

"(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, for which data are available'; and

"(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'.

"(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)(1) shall be applied by substituting 'September 1, 2024' for 'November 30 of the year that is 2 years 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 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 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).

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), 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 reference 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'.

"(c) 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 publica-

tion 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 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

"(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 12-month period, as described in subparagraph (A).

"(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 for which payment may be made 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 for which payment may be made 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.—A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

"(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 for which payment may be made 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 in accordance with subsection (d)(3)(B)—

"(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

"(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

"(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the

year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

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

"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)(2) 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 the period of renegotiation, 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)(2) 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 applicability 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)(2), 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—

"(1) 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; and

"(2) shall be required to provide access to 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 such 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 the selected drug with a written

initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on 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 the 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.

"(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 initial price applicability 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 for which payment may be made 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 pre-

scription 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 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.

"(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, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

"(1) MANUFACTURER-SPECIFIC DATA.—The following data, with respect to such selected drug, 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) Current unit costs of production and distribution of the drug.

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

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

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

"(2) EVIDENCE ABOUT ALTERNATIVE TREATMENTS.—The following evidence, as available, 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 the costs of such existing therapeutic alternatives.

"(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to 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 to 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 using evidence described in subparagraph (C), the Secretary shall not use evidence 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-eligible 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.—For each year (beginning with 2028), 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.—

"(A) IN GENERAL.—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.

"(B) CONSISTENT WITH NEGOTIATION PROCESS.—The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) 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.

"(g) 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, 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 the July immediately preceding such November 30; 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 in 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 in 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 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

"(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1860D-14A and the date on which any subsequent agreement under such program is entered into;

"(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1860D-14C and the date on which any subsequent agreement under such program is entered into; and

"(C) the date on which the Secretary receives notification of any termination of a rebate

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

"(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 equal to or less than the maximum fair 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)(2) 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).

"SEC. 1198. LIMITATION ON ADMINISTRATIVE AND JUDICIAL REVIEW.

"There shall be no administrative or judicial review of any of the following:

"(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1191(c)(6).

"(2) The selection of drugs under section 1192(b), the determination of negotiation-eligible drugs under section 1192(d), and the determination of qualifying single source drugs under section 1192(e).

"(3) The determination of a maximum fair price under subsection (b) or (f) of section 1194.

"(4) The determination of renegotiation-eligible drugs under section 1194(f)(2) and the selection of renegotiation-eligible drugs under section 1194(f)(3).".

(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)(3)) 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 "or institute a price structure for the reimbursement of covered part D drugs." 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)(3)) 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 a maximum fair price (as defined in section 1191(c)(3)) is in effect with respect to the year.

"(ii) CLARIFICATION.—Nothing in clause (i) shall be construed as prohibiting a PDP sponsor from removing such a selected 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 for purposes of carrying out section 1194.".

(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).".

(G) CONDITIONS FOR COVERAGE.—

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

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

(II) by striking "AGREEMENTS.—Subsection" and inserting the following: "AGREEMENTS.—

"(1) IN GENERAL.—Subject to paragraph (2), subsection"; and

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

"(2) EXCEPTION.—Paragraph (1)(A) shall not apply to a covered part D drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.".

(ii) MEDICAID AND MEDICARE PART B.—Section 1927(a)(3) of the Social Security Act (42 U.S.C. 1396r–8(a)(3)) is amended by adding at the end the following new sentence: "The preceding sentence shall not apply to a single source drug or innovator multiple source drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.".

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

(i) CONTRACT REQUIREMENTS.—Section 1860D–12(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1395w–112(b)(3)(D)(i)) is amended by inserting ", or carrying out part E of title XI" after "appropriate)".

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

U.S.C. 1395w–115(f)(2)(A)(i)) is amended by inserting "or part E of title XI" after "this section".

(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)(3)) 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. 11002. 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 11001, is amended—

(1) in section 1192—

(A) in subsection (a), in the flush matter following paragraph (4), 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 subsection (a) the biological products described in such subpara-

graphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).''; and

(C) by adding at the end 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 may 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 sub-

section (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 including, to the extent available, items described in subclause (III); 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 Prescription

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.

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

"(aa) 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).

"(bb) 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.

"(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 publi-

cation 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 section 351(k) of the Public Health Service Act, 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 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 information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) 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 bi-

ological 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) of the Public Health Service Act 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 Secretary determined that 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 treated as being the same pursuant to paragraph (1)(C); or

"(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

"(aa) requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B); or

"(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

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

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

"(A) an application for licensure under section 351(k) of the Public Health Service Act for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

"(B) information from items described in sub clauses (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph 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.

"(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 as described in section 1195(b)(1)(A); and

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

"(ii) in the case of a biological product for which payment may be made 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 as described in section 1195(b)(1)(A); 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 inclusion 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) DEFINITIONS OF BIOSIMILAR BIOLOGICAL PRODUCT.—In this subsection, the term 'biosimilar biological product' has the meaning given such term in section 1847A(c)(6).";

(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 striking "section 1192(d)(2)(B)" and inserting "subsections (d)(2)(B) and (f)(1)(C) of section 1192";

(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."; and

(5) in section 1198(b)(2), by inserting "the application of section 1192(f)," after "section 1192(e)".

(b) CONFORMING AMENDMENTS FOR DISCLOSURE OF CERTAIN INFORMATION.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by striking "or to carry out section 1847B" and inserting "or to carry out section 1847B or 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. 11003. EXCISE TAX IMPOSED ON DRUG MANUFACTURERS 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—DESIGNATED DRUGS

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

"(a) IN GENERAL.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated 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 designated 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 date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—

"(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

"(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated 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 earlier of—

"(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

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

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

"(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

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

"(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, 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) SUSPENSION OF TAX.—

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

"(A) beginning on the first date on which—

"(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

"(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

"(B) ending on the last day of February following the earlier of—

"(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

"(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

"(2) APPLICABLE AGREEMENT.—For purposes of this subsection, the term 'applicable agreement' means the following:

"(A) An agreement under—

"(i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

"(ii) the manufacturer discount program under section 1860D-14C of such Act.

"(B) A rebate agreement described in section 1927(b) of such Act.

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

"(1) in the case of sales of a designated 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.

"(e) DEFINITIONS.—For purposes of this section—

"(1) DESIGNATED DRUG.—The term 'designated drug' means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such 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) OTHER TERMS.—The terms 'initial price applicability year', 'price applicability period', and 'maximum fair price' have the meaning given such terms in section 1191 of the Social Security Act.

"(f) SPECIAL RULES.—

"(1) 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.

"(2) 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).

"(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 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) 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—DESIGNATED DRUGS".

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

SEC. 11004. 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. 11101. MEDICARE PART B REBATE BY MANUFACTURERS.

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

crease 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)), for which payment is made 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 aver-

age) 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 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 subsection (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 subsection, 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 UNITS.—For purposes of subparagraph (A)(i), the total number of units for the billing and payment code with respect to a part B rebatable drug furnished dur-

ing a calendar quarter described in subparagraph (A) is equal to—

"(i) the number of units for the billing and payment code of such drug furnished during such calendar quarter, minus

"(ii) the number of units for such billing and payment code of such drug furnished during such calendar quarter—

"(I) with respect to which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act or a rebate under section 1927; or

"(II) that are packaged into the payment amount for an item or service and are not separately payable.

"(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).

"(8) LIMITATION ON ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review of any of the following:

"(A) The determination of units under this subsection.

"(B) The determination of whether a drug is a part B rebatable drug under this subsection.

"(C) The calculation of the rebate amount under this subsection.

"(D) The computation of coinsurance under paragraph (5) of this subsection.

"(E) 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 11001(b)(3), 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. 11102. 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 of such dosage form and strength for each rebatable covered part D drug dispensed under this part during the applicable 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), beginning with plan year 2026, 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, units of each dosage form and strength of such part D rebatable drug for which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act.

"(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 ap-

plicable 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 para-

graph (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 INFORMATION.—The Secretary shall provide for a method and process under which, in the case where a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan submits revisions to the number of units of a rebatable covered part D drug dispensed, 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—

"(1) manufacturers under section 1927(b)(3);

"(2) States under section 1927(b)(2)(A); and

"(3) PDP sponsors of prescription drug plans and MA organization offering MA–PD plans under this part.

"(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 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) LIMITATION ON ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review of any 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 is 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 consumers (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 11101(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 11101(c)(2), is amended by striking "or section 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 sections 11002(b) and

11101(c)(3), is amended by striking "or section 1192(f), including rebates under paragraph (4) of such section" and inserting ", section 1192(f), including rebates under paragraph (4) of such section, 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 11001(b)(3) and section 11101(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. 11201. 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