

(4) Section 1320f-2(a) of this title 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 1320f-3(b)(2) of this title 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 1320f-4(a)(1) of this title 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”.

(Aug. 14, 1935, ch. 531, title XI, §1191, as added Pub. L. 117-169, title I, §11001(a), Aug. 16, 2022, 136 Stat. 1833.)

Statutory Notes and Related Subsidiaries

IMPLEMENTATION FOR 2026 THROUGH 2028

Pub. L. 117-169, title I, §11001(c), Aug. 16, 2022, 136 Stat. 1854, provided that: “The Secretary of Health and Human Services shall implement this section [enacting this part and amending sections 1395w-3a, 1395w-22, 1395w-27, 1395w-102, 1395w-104, 1395w-111, 1395w-112, 1395w-115, 1395w-153, and 1396r-8 of this title], including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.”

§ 1320f-1. 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

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)”.

(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 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title 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 subchapter 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.

(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).

(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 subchapter XVIII” were a reference to “total expenditures for such drugs under part D of subchapter XVIII”.

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

(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 355(j) of title 21 using such drug as the listed drug; or

(ii) under section 262(k) of this title 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 1320f-3 of this title with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) Negotiation-eligible drug**(1) In general**

For purposes of this part, subject to paragraph (2), the term “negotiation-eligible drug” means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) Part D high spend drugs

The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of subchapter 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 subchapter 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 subchapter 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 1395w-102(e) of this title) 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 1395w-114a of this title during such year.

(ii) Part B drugs

The total expenditures for the qualifying single source drug under part B of subchapter 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 1395w-114c(g)(4)(B)(ii) of this title, effec-

tive 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 1395w-102(e) of this title) that is described in any of the following or a drug or biological product for which payment may be made under part B of subchapter XVIII that is described in any of the following:

(A) Drug products

A drug—

- (i) that is approved under section 355(c) of title 21 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 355(j) of such title.

(B) Biological products

A biological product—

- (i) that is licensed under section 262(a) of this title and is marketed under section 262 of this title;
- (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 262(k) of this title.

(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 355(j) of title 21) 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 355(t)(3) of title 21); and
- (ii) in the case of a biological product, a product that—
 - (I) has been licensed under section 262(a) of this title;¹ 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 360bb of title 21 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 subchapter 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

¹ See References in Text note below.

(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.

(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 1320f-3(c)(4) of this title) 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 262(k) of this title 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 subsection (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) Information and documents

(I) In general

A request made under clause (i) shall be submitted to the Secretary by such

manufacturer at a time and in a form and manner specified by the Secretary, and contain—

(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and 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 262(k) of this title.

(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 78l(b), 78l(g), 78m(a), or 78o(d) of title 15 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 publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 262(k) of this title, 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 262(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 biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) If not licensed and marketed during the year two delay

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

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

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

(D) Limitations on delays**(i) Limited to 2 years**

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

(ii) Exclusion of biological products that transitioned to a long-monopoly drug during the delay

In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1320f-3(c)(5) of this title) 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 262(k) of this title 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 262(k) of this title 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 clauses² (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 evi-

dence 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 1320f-2 of this title 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 1395w-102(e) of this title), 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 1396r-8 of this title (or, if not reported by such manufacturer under section 1396r-8 of this title, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1320f-2(a) of this title) 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 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; and

(II) the number of units dispensed under part D of subchapter 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 subchapter 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 1395w-3a(b) of this title, with respect to each of the calendar quarters of the price applicability period that would

² So in original.

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 1320f-3 of this title for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1320f-4(b)(1)(A) of this title; 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 1320f-3(c)(5) of this title) 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 subchapter XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title; and

(ii) in the case such biological product is a covered part D drug (as defined in sec-

tion 1395w-102(e) of this title), the Medicare Prescription Drug Account under section 1395w-116 of this title 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 1395w-3a(c)(6) of this title.

(Aug. 14, 1935, ch. 531, title XI, §1192, as added and amended Pub. L. 117-169, title I, §§11001(a), 11002(a)(1), Aug. 16, 2022, 136 Stat. 1836, 1854.)

Editorial Notes

REFERENCES IN TEXT

Section 52 of the Internal Revenue Code of 1986, referred to in subsecs. (d)(2)(B)(i) and (f)(1)(C)(i), is classified to section 52 of Title 26, Internal Revenue Code.

Section 262(a) of this title, referred to in subsec. (e)(2)(B)(ii)(I), was in the original “section 351(a) of such Act” and was translated as reading “section 351(a) of the Public Health Service Act”, to reflect the probable intent of Congress.

Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (f)(1)(B)(ii)(I)(bb), is section 1112 of Pub. L. 108-173, which is set out in a note under section 355 of Title 21, Food and Drugs.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117-169, §11002(a)(1)(A), inserted “and subsection (b)(3)” after “the previous sentence” in concluding provisions.

Subsec. (b)(1)(C). Pub. L. 117-169, §11002(a)(1)(B)(i), added subpar. (C).

Subsec. (b)(3). Pub. L. 117-169, §11002(a)(1)(B)(ii), added par. (3).

Subsec. (f). Pub. L. 117-169, §11002(a)(1)(C), added subsec. (f).

Statutory Notes and Related Subsidiaries

IMPLEMENTATION FOR 2026 THROUGH 2028

Pub. L. 117-169, title I, §11002(c), Aug. 16, 2022, 136 Stat. 1862, provided that: “The Secretary of Health and Human Services shall implement this section [amending this section and sections 1320f-2, 1320f-5 to 1320f-7, and 1396r-8 of this title], including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.”

§ 1320f-2. Manufacturer agreements

(a) In general

For purposes of section 1320f(a)(2) of this title, 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 1320f-3 of this title, 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