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 section 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

1320f(c)(2) of this title 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 1320f–3 of this title, 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 1320f(c)(2) of this title 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 1320f(c)(2) of this title, 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 1320f–3(f) of this title), and for section 1320f–1(f) of this title, with respect to such drug—

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

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

(C) information that the Secretary requires to carry out section 1320f–1(f) of this title, including rebates under paragraph (4) of such section; 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 1320f–1(c) of this title.

(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 [42 U.S.C. 256b(a)(4)], to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)] and the ceiling price (defined in section 340B(a)(1) of such Act [42 U.S.C. 256b(a)(1)]) 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.

(Aug. 14, 1935, ch. 531, title XI, §1193, as added and amended Pub. L. 117–169, title I, §§11001(a), 11002(a)(2), Aug. 16, 2022, 136 Stat. 1841, 1861.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(4). Pub. L. 117–169, § 11002(a)(2)(A), inserted '', and for section 1320f–1(f) of this title,'' after ''section 1320f–3(f) of this title)'' in introductory provisions.

Subsec. (a)(4)(C). Pub. L. 117–169, § 11002(a)(2)(B), (C), added subpar. (C).

§ 1320f–3. Negotiation and renegotiation process

(a) In general

For purposes of this part, under an agreement under section 1320f–2 of this title 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 1320f–2(a)(1) of this title; 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 1320f–2(a)(2) of this title 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 1320f–2(a)(4) of this title, 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 subsection (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 1395w–102(e) of this title), 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 subchapter XVIII, the payment amount under section 1395w–3a(b)(4) of this title 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.