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.

(C) Subparagraph (C) amount

An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) Initial price applicability year 2026

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

(ii) Initial price applicability year 2027 and subsequent years

In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

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

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

(2) Plan specific enrollment weighted amount

For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

(A) the negotiated price of the drug under such plan under part D of subchapter 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 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusions

The term ''extended-monopoly drug'' shall not include any of the following:

(i) A vaccine that is licensed under section 262 of this title 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 355(c) of title 21 or since the date of licensure of such drug under section 262(a) of this title, as applicable.

(B) Exclusion

The term ''long-monopoly drug'' shall not include a vaccine that is licensed under section 262 of this title 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) 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 1320f–1(d)(2) of this title 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 355(c) of title 21 or section 262(a) of this title 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 1320f–1(c)(1) of this title 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)[1] shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph[2] (A) or (B), as applicable.

(Aug. 14, 1935, ch. 531, title XI, §1194, as added Pub. L. 117–169, title I, §11001(a), Aug. 16, 2022, 136 Stat. 1843.)

§1320f–4. 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 1320f–2(c) of this title, the explanation for the maximum fair price with respect to the factors as applied under section 1320f–3(e) of this title 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 1320f–2 of this title, 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.

(Aug. 14, 1935, ch. 531, title XI, §1195, as added Pub. L. 117–169, title I, §11001(a), Aug. 16, 2022, 136 Stat. 1849.)

§1320f–5. Administrative duties and compliance monitoring

(a) Administrative duties

For purposes of section 1320f(a)(4) of this title, 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.

[1] So in original. Probably means subparagraph (A) or (B) of paragraph (1) of section 1320f–1(e) of this title.

[2] So in original. Probably should be preceded by ''such''.