

(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 subparagraph² (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

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".

- (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.