

(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.

(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 subchapter XVIII or an MA-PD plan under part C of such subchapter; and

(B) maximum fair price eligible individuals who are enrolled under part B of such subchapter, including who are enrolled in an MA plan under part C of such subchapter.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1320f-3 of this title.

(5) The establishment of a process for manufacturers to submit information described in section 1320f-3(b)(2)(A) of this title.

(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 1395w-114a of this title 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 1395w-114c of this title 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 1396r-8(b) of this title 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 subsections (d)(2)(B) and (f)(1)(C) of section 1320f-1 of this title.

(b) Compliance monitoring

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1320f-2 of this title and establish a mechanism through which violations of such terms shall be reported.

(Aug. 14, 1935, ch. 531, title XI, §1196, as added and amended Pub. L. 117-169, title I, §§11001(a), 11002(a)(3), Aug. 16, 2022, 136 Stat. 1849, 1861.)

Editorial Notes

REFERENCES IN TEXT

Section 5000D of the Internal Revenue Code of 1986, referred to in subsec. (a)(6), is classified to section 5000D of Title 26, Internal Revenue Code.

AMENDMENTS

2022—Subsec. (a)(7). Pub. L. 117-169, §11002(a)(3), substituted “subsections (d)(2)(B) and (f)(1)(C) of section

1320f-1 of this title” for “section 1320f-1(d)(2)(B) of this title”.

§ 1320f-6. 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 1320f-2 of this title, 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 1320f(c)(2) of this title 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 relating to providing rebates

Any manufacturer that fails to comply with the rebate requirements under section 1320f-1(f)(4) of this title 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.

(c) Violations of certain terms of agreement

Any manufacturer of a selected drug that has entered into an agreement under section 1320f-2 of this title, 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 1320f-2(a)(5) of this title, including the requirement to submit information pursuant to section 1320f-2(a)(4) of this title, shall be subject to a civil monetary penalty equal to \$1,000,000 for each day of such violation.

(d) False information

Any manufacturer that knowingly provides false information pursuant to section 1320f-5(a)(7) of this title shall be subject to a civil monetary penalty equal to \$100,000,000 for each item of such false information.

(e) Application

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply