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# 42 U.S. Code § 1320f-3

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## Negotiation and renegotiation process

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### **(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
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(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.

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