sanctuary be subjected? As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis by representatives of ORIP/DPCPSI/NIH/HHS . The ORIP/DPCPSI representative will use facility site visits, reports, personal contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by ORIP/DPCPSI/NIH . The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

[73 FR 60423, Oct. 10, 2008, as amended at 85 FR 54273, Sept. 1, 2020]

§ 9.13 Other federal laws, regulations, and statutes that apply to the sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.

PART 10—340B DRUG PRICING PROGRAM

Subpart A—General Provisions

Sec.

10.1 Purpose.
10.2 Summary of 340B Drug Pricing Program.
10.3 Definitions.

Subpart B—340B Ceiling Price

10.10 Ceiling price for a covered outpatient drug.
10.11 Manufacturer civil monetary penalties.

Subpart C—Administrative Dispute Resolution

10.20 340B Administrative Dispute Resolution Panel.
10.21 Claims.
10.22 Covered entity information and document requests.
10.23 340B ADR Panel decision process.
10.24 340B ADR Panel decision reconsideration process.
10.25 Severability.

AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b) (PHSA), as amended.

SOURCE: 82 FR 1229, Jan. 5, 2017, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) ''Limitation on Prices of Drugs Purchased by Covered Entities.''

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily-defined covered entities does not exceed the 340B ceiling price.

§ 10.3 Definitions.

For the purposes of this part, the following definitions apply:

340B Administrative Dispute Resolution (ADR) process means a process used to resolve the following types of claims, including any issues that assist the 340B ADR Panel in resolving such claims:

(1) Claims by covered entities that may have been overcharged for covered outpatient drugs purchased from manufacturers; and

(2) Claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity (pursuant to section 340B(a)(5)(C) of the Public Health Service Act (PHS Act)), that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

Administrative Dispute Resolution Panel (340B ADR Panel) means a decision-making body within the Health Resources and Services Administration's Office of Pharmacy Affairs that reviews and makes decisions for claims filed through the 340B ADR process.

Average Manufacturer Price (AMP) has the meaning set forth in section 1927(k)(1) of the Social Security Act, as implemented in 42 CFR 447.504.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA and this section.

Claim means a written allegation filed by or on behalf of a covered entity or by a manufacturer for resolution under the 340B ADR process.

CMS is the Centers for Medicare & Medicaid Services.

Consolidated claim means a claim resulting from combining multiple manufacturers' claims against the same covered entity.

Covered entity means an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.

Covered outpatient drug has the meaning set forth in section 1927(k) of the Social Security Act.

Joint claim means a claim resulting from combining multiple covered entities' claims (or claims from their membership organizations or associations) against the same manufacturer for the same drug or drugs.

Manufacturer has the meaning set forth in section 1927(k) of the Social Security Act, as implemented in 42 CFR 447.502.

National Drug Code (NDC) has the meaning set forth in 42 CFR 447.502.

Office of Pharmacy Affairs (OPA) means the office, or any successor office assigned to administer the 340B Program, within the Health Resources and Services Administration, or any successor agency, that oversees the 340B Program.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Quarter refers to a calendar quarter unless otherwise specified.

Secretary means the Secretary of the Department of Health and Human Services and any other officer of employee of the Department of Health and Human Services to whom the authority involved has been delegated.

[82 FR 1229, Jan. 5, 2017, as amended at 85 FR 80644, Dec. 14, 2020; 89 FR 28657, Apr. 19, 2024]

Subpart B—340B Ceiling Price

§ 10.10 Ceiling price for a covered outpatient drug.

A manufacturer is required to calculate the 340B ceiling price for each covered outpatient drug, by National Drug Code (NDC) on a quarterly basis.

(a) *Calculation of 340B ceiling price.* The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. HRSA will publish the 340B ceiling price rounded to two decimal places.

(b) *Exception.* When the ceiling price calculation in paragraph (a) of this section results in an amount less than $0.01 the ceiling price will be $0.01.

(c) *New drug price estimation.* A manufacturer must estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale. That estimation should be calculated as wholesale acquisition cost minus the appropriate rebate percentage until an AMP is available, which should occur no later than the 4th quarter that the drug is available for sale. Manufacturers are required to calculate the actual 340B ceiling price as described in paragraph (a) of this section and offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

§ 10.11 Manufacturer civil monetary penalties.

(a) *General.* Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject to a

civil monetary penalty not to exceed $5,000 for each instance of overcharging, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the applicable procedures at 42 CFR part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

(b) *Instance of overcharging.* An instance of overcharging is any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in §10.10, for that covered outpatient drug.

(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent.

(2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.

(3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.

(4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations as defined in §10.10(c) result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

Subpart C—Administrative Dispute Resolution

SOURCE: 89 FR 28657, Apr. 19, 2024, unless otherwise noted.

§10.20 340B Administrative Dispute Resolution Panel.

The Secretary shall appoint a roster of eligible individuals (Roster) consisting of staff within OPA, to serve on a 340B ADR Panel, as defined in §10.3. The OPA Director, or the OPA Director's designee, shall select at least three members from the Roster to form a 340B ADR Panel to review and make decisions regarding one or more claims filed by covered entities or manufacturers.

(a) *Members of the 340B ADR Panel.* (1) The OPA Director shall:

(i) Select at least three members for each 340B ADR Panel from the Roster of appointed staff;

(ii) Have the authority to remove an individual from the 340B ADR Panel and replace such individual; and

(iii) Select replacement 340B ADR Panel members should an individual resign from the panel or otherwise be unable to complete their duties.

(2) No member of the 340B ADR Panel may have a conflict of interest, as set forth in paragraph (b) of this section.

(b) *Conflicts of interest.* (1) All members appointed by the Secretary to the Roster of individuals eligible to be selected for a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. In determining whether a conflict exists, the OPA Director, in consultation with government ethics officials, will consider financial interest(s), current or former business or employment relationship(s), or other involvement of a prospective panel member or close family member who is either employed by or otherwise has a business relationship with an involved party, subsidiary of an involved party, or particular claim(s) expected to be presented to the prospective panel member.

(2) All members of the 340B ADR Panel will undergo an additional screening prior to reviewing a specific claim to ensure that the 340B ADR Panel member was not directly involved in a decision concerning the specific issue of the ADR claim as it relates to the specific covered entity or manufacturer involved, including previous 340B ADR Panel decisions.

(c) *Secretarial authority in the 340B ADR process.* The Secretary may remove any individual from the Roster of 340B ADR Panelists for any reason, including from any 340B ADR Panel to which the individual has already been assigned. The Secretary has the authority to review and reverse, alter, or uphold any 340B ADR Panel or reconsideration decision as outlined in §§10.23 and 10.24. Any such decision of

the Secretary will serve as the final agency decision and will be binding upon the parties involved in the dispute, unless invalidated by an order of a Federal court.

(d) *Duties of the 340B ADR Panel.* The 340B ADR Panel will:

(1) Review and evaluate claims, including consolidated and joint claims, and documents and information submitted by (or on behalf of) covered entities and manufacturers;

(2) Review and may request additional documentation, information, or clarification of an issue from any or all parties to make a decision (if the 340B ADR Panel finds that a party has failed to respond or fully respond to an information request, the 340B ADR Panel may proceed with facts that the 340B ADR Panel determines have been established in the proceeding);

(3) Evaluate claims based on information received, unless, at the 340B ADR Panel's discretion, the nature of the claim necessitates that a meeting with the parties be held;

(4) At its discretion, consult with others, including staff within OPA, other HHS offices, and other Federal agencies while reviewing a claim; and

(5) Make decisions on each claim.

§ 10.21 Claims.

(a) *Claims permitted.* All claims must be specific to the parties identified in the claims and are limited to the following:

(1) Claims by a covered entity that it has been overcharged by a manufacturer for a covered outpatient drug, including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price; and

(2) Claims by a manufacturer, after it has conducted an audit of a covered entity pursuant to section 340B(a)(5)(C) of the PHS Act, that the covered entity has violated section 340B(a)(5)(A) of the PHS Act, regarding the prohibition of duplicate discounts, or section 340B(a)(5)(B) of the PHS Act, regarding the prohibition of the resale or transfer of covered outpatient drugs to a person who is not a patient of the covered entity.

(b) *Requirements for filing a claim.* (1) Absent extenuating circumstances, a covered entity or manufacturer must file a claim under this section in writing to OPA within 3 years of the date of the alleged violation. Any file, document, or record associated with the claim that is the subject of a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision.

(2) A covered entity filing a claim described in paragraph (a)(1) of this section must provide the basis, including all available supporting documentation, for its belief that it has been overcharged by a manufacturer, in addition to any other documentation as may be requested by OPA. A covered entity claim against multiple manufacturers is not permitted.

(3) A manufacturer filing a claim under paragraph (a)(2) of this section must provide documents sufficient to support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts, in addition to any other documentation as may be requested by OPA.

(4) A covered entity or manufacturer filing a claim must provide documentation of good faith efforts, including for example, documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim.

(c) *Combining claims.* (1) Two or more covered entities may jointly file claims of overcharges by the same manufacturer for the same drug or drugs if each covered entity consents to the jointly filed claim and meets the filing requirements.

(i) For covered entity joint claims, the claim must list each covered entity, its 340B ID and include documentation as described in paragraph (b) of this section, which demonstrates that each covered entity meets all of the requirements for filing the ADR claim.

(ii) For covered entity joint claims, a letter requesting the combining of claims must accompany the claim at the time of filing and must document that each covered entity consents to the combining of the claims, including signatures of individuals representing each covered entity and a point of contact for each covered entity.

(2) An association or organization may file on behalf of one or more covered entities representing their interests if:

(i) Each covered entity is a member of the association or the organization representing it and each covered entity meets the requirements for filing a claim;

(ii) The joint claim filed by the association or organization must assert overcharging by a single manufacturer for the same drug(s); and

(iii) The claim includes a letter from the association or organization attesting that each covered entity agrees to the organization or association asserting a claim on its behalf, including a point of contact for each covered entity.

(3) A manufacturer or manufacturers may request to consolidate claims brought by more than one manufacturer against the same covered entity if each manufacturer could individually file a claim against the covered entity, consents to the consolidated claim, meets the requirements for filing a claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources. Consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests are not permitted.

(d) *Deadlines and procedures for filing a claim.* (1) Covered entities and manufacturers must file claims in writing with OPA, in the manner set forth by OPA.

(2) OPA will conduct an initial review of all information submitted by the party filing the claim and will make a determination as to whether the requirements in paragraph (b) of this section are met. The OPA staff conducting the initial review of a claim may not be appointed to serve on the 340B ADR Panel reviewing that specific claim.

(3) Additional information to substantiate a claim may be submitted by the initiating party and may be requested by OPA. If additional information is requested, the initiating party will have 20 business days from the receipt of OPA's request to respond. If the initiating party does not respond to a request for additional information within the specified time frame or request and receive an extension, the claim will not move forward to the 340B ADR Panel for review.

(4) OPA will provide written notification to the initiating party that the claim is complete. Once the claim is complete, OPA will also provide written notification to the opposing party that the claim was submitted. This written notification will provide a copy of the initiating party's claim, and additional instructions regarding the 340B ADR process, including timelines and information on how to submit their response in accordance with the procedures for responding to a claim as outlined in paragraph (e) of this section.

(5) If OPA finds that the claim meets the requirements described in paragraph (b) of this section, and once OPA receives the opposing party's response in accordance with the procedures outlined in paragraph (e) of this section, additional written notification will be sent to both parties advising that the claim will be forwarded to the 340B ADR Panel for review.

(6) If OPA finds that the claim does not meet the requirements described in paragraph (b) of this section, written notification will be sent to both parties stating the reasons that the claim did not move forward.

(7) For any claim that does not move forward for review by the 340B ADR Panel, the claim may be revised and refiled if there is new information to support the alleged statutory violation and the claim meets the criteria set forth in this section.

(e) *Responding to a submitted claim.* (1) Upon receipt of notification by OPA that a claim is deemed complete and has met the requirements in paragraph (b) of this section, the opposing party in alleged violation will have 30 business days to submit a written response to OPA.

(2) A party may submit a request for an extension of the initial 30 business days response period and OPA will make a determination to approve or disapprove such request and notify both parties.

(3) OPA will provide a copy of the opposing party's response to the initiating party and will notify both parties

that the claim has moved forward for review by the 340B ADR Panel.

(4) If an opposing party does not respond or elects not to participate in the 340B ADR process, OPA will notify both parties that the claim has moved forward for review by the 340B ADR Panel and the 340B ADR Panel will render its decision after review of the information submitted in the claim.

§ 10.22 Covered entity information and document requests.

(a) To request information necessary to support its claim from an opposing party, a covered entity must submit a written request for additional information or documents to the 340B ADR Panel within 20 business days of the receipt from OPA that the claim was forwarded to the 340B ADR Panel for review. The 340B ADR Panel will review the information/document request and notify the covered entity if the request is not reasonable, not relevant or beyond the scope of the claim, and will permit the covered entity to resubmit a revised request if necessary.

(b) The 340B ADR Panel will transmit the covered entity's information/document request to the manufacturer who must respond to the request within 20 business days of receipt of the request.

(c) The manufacturer must fully respond, in writing, to an information/document request from the 340B ADR Panel by the response deadline.

(1) A manufacturer is responsible for obtaining relevant information or documents from any wholesaler or other third party that may facilitate the sale or distribution of its drugs to covered entities.

(2) If a manufacturer anticipates that it will not be able to respond to the information/document request by the deadline, it can request one extension by notifying the 340B ADR Panel in writing within 15 business days of receipt of the request.

(3) A request to extend the deadline must include the reason why the specific deadline is not feasible and must outline the proposed timeline for fully responding to the information/document request.

(4) The 340B ADR Panel may approve or disapprove the request for an extension of time and will notify all parties in writing of its decision.

(5) If the 340B ADR Panel finds that a manufacturer has failed to fully respond to an information/document request, the 340B ADR Panel will proceed with the facts that the 340B ADR Panel has determined have been established in the proceeding.

(6) If a manufacturer believes an information request to a covered entity is necessary for the 340B ADR Panel's review, it may make a request to the 340B ADR Panel to make the request to the covered entity.

§ 10.23 340B ADR Panel decision process.

(a) The 340B ADR Panel will conduct a review of the claims. The 340B ADR Panel will review all documents gathered during the 340B ADR process to determine if a violation as described in § 10.21(a)(1) or (2) has occurred.

(b) The 340B ADR Panel will prepare a decision letter based on its review. The 340B ADR Panel's decision letter will be completed within one year of receiving a complete claim for review, except to the extent that there are situations beyond the control of the 340B ADR Panel that may affect the ability to issue a decision on a claim within one year. If the issuance of a 340B ADR Panel decision will exceed one year, the 340B ADR Panel must provide notice to the parties involved. The 340B ADR Panel decision letter will represent the determination of a majority of the 340B ADR Panel members' findings regarding the claim and include an explanation regarding each finding. The 340B ADR Panel will transmit its decision letter to all parties and to the OPA Director.

(c) The 340B ADR Panel decision letter will inform the parties involved of their rights for reconsideration as described in § 10.24. Either party may request reconsideration of the 340B ADR Panel decision or the Health Resources and Service Administration (HRSA) Administrator may decide to initiate a reconsideration without such a request. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court. The 340B ADR Panel's decision letter will be effective

30 business days from issuance and serve as the final agency decision unless:

(1) Within 30 business days of issuance, reconsideration occurs under § 10.24; or

(2) Within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision.

(d) The OPA Director will determine any necessary corrective action or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.24 340B ADR Panel decision reconsideration process.

(a) Either party may initiate a reconsideration request, or the HRSA Administrator may decide to initiate the process without such a request. In the event of a reconsideration request, the 340B ADR Panel's decision is held in abeyance until such time the HRSA Administrator makes a reconsideration decision of the 340B ADR Panel decision (or in the event of a declination). A reconsideration decision will affirm or supersede a 340B ADR Panel decision.

(b) The request for a reconsideration of the 340B ADR Panel's decision must be made to the HRSA Administrator within 30 business days of the date of the 340B ADR Panel's decision letter.

(1) The request for reconsideration must include a copy of the 340B ADR Panel decision letter, and documentation indicating why a reconsideration is warranted.

(2) New facts, information, legal arguments, or policy arguments may not be submitted as part of the reconsideration process in order to remain consistent with the facts that were reviewed by the 340B ADR Panel in determining their decision.

(3) In the case of joint or consolidated claims, the reconsideration request must include an attestation confirming that all of the entities have agreed to be part of the reconsideration process.

(c) The standard for review of the reconsideration request by the HRSA Administrator, or their designee, will include a review of the record, including the 340B ADR Panel decision, and a determination of whether there was an error in the 340B ADR Panel's decision. The HRSA Administrator, or designee, may consult with other HHS officials, as necessary.

(d) The HRSA Administrator, or their designee, will make a determination based on the reconsideration request by either issuing a revised decision or declining to issue a revised decision.

(e) The reconsideration decision letter will be effective 30 business days from issuance and serve as the final agency decision unless within 30 business days of issuance, the Secretary makes a determination that the Secretary will review the decision. The final agency decision will be binding upon the parties involved in the dispute unless invalidated by an order of a Federal court.

(f) The OPA Director will determine any necessary corrective action, or consider whether to take enforcement action, and the form of any such action, based on the final agency decision.

§ 10.25 Severability.

If any provision of this subpart is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof.

PART 11—CLINICAL TRIALS REGISTRATION AND RESULTS INFORMATION SUBMISSION

Subpart A—General Provisions

Sec.

11.2 What is the purpose of this part?
11.4 To whom does this part apply?
11.6 What are the requirements for the submission of truthful information?
11.8 In what format must clinical trial information be submitted?
11.10 What definitions apply to this part?