2024 340B ADR Final Rule (Apr. 18, 2024),
Marked Against
2020 340B ADR Final Rule (Dec. 14, 2020)

PART 10—340B DRUG PRICING PROGRAM

§ 10.3 Definitions.

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340B *Administrative Dispute Resolution (ADR)* ~~P~~*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 ~~Act),~~ 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 ~~Department~~ Health Resources and Services Administration's Office of Pharmacy Affairs that~~, acting on an express, written delegation of authority from the Secretary of HHS,~~ reviews and makes ~~a precedential and binding decision~~ decisions for ~~a claim brought under~~ the 340B ADR ~~P~~process.

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

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

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

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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.

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§ 10.20 340B **Administrative Dispute Resolution Panel.**

~~The Secretary shall establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the Secretary with equal numbers from the Health Resources and Service Administration (HRSA), the Centers for Medicare & Medicaid Services (CMS), and the Office of the General Counsel (OGC) from which Administrative Dispute Resolution Panels (340B ADR Panel) of three members shall be selected by the HRSA Administrator (to review claims and, pursuant to authority expressly delegated through this rule by the Secretary, and to make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers). There shall also be one ex-officio, non-voting member chosen from the staff of the HRSA Office of Pharmacy Affairs (OPA). HRSA and CMS Board members shall have relevant expertise and experience in drug pricing or drug distribution. OGC Board members shall have expertise and experience in handling complex litigation.~~

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) ~~For each case, the HRSA Administrator~~ The OPA Director shall:

(i) Select ~~from the Board~~ at least three ~~voting~~ members~~, one from each of the three HHS operating or staff divisions involved (*i.e.*, CMS, HRSA, OGC) to form a~~ for each 340B ADR Panel~~.~~ from the Roster of appointed staff;

(ii) ~~Remove~~ Have the authority to remove an individual from a 340B ADR Panel ~~for cause~~ and replace such individual; and

(iii) ~~Appoint~~ Select replacement 340B ADR Panel members ~~from the Board~~ should an individual resign from the panel or otherwise be unable to complete ~~his or her~~ their duties ~~on a 340B ADR Panel~~.

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

(b) *Conflicts of interest*. ~~All individuals who serve on a 340B ADR Panel will be screened for conflicts of interest prior to reviewing a claim. Conflicts of interest may include:~~

(1) ~~Financial interest in a party involved, a subsidiary of a party involved, or in the claim before a 340B ADR Panel;~~ 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) ~~Family or close relation to a party involved; and~~ 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.

~~(3)Current or former business or employment relation to a party.~~

(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) ~~(c)~~ *Duties of the 340B ADR Panel.* The 340B ADR Panel will ~~adjudicate each claim using the procedures described §§ 10.21, 10.22, 10.23, and 10.24.~~:

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

(2) Review and may ~~R~~request additional documentation, information, or clarification of an issue from any or all parties to make a ~~final agency decision;~~ 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) ~~When necessary, evaluate a claim in a separate session from the parties involved;~~ 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~~Consult with OPA and the parties, as appropriate and necessary, regarding any inquiries or concerns~~ while reviewing a claim; and

(5) ~~Issue a final agency decision on each claim and submit the written decision to the parties, and to HRSA for appropriate action.~~ Make decisions on each claim.

§ 10.21 Claims.

~~(a) *Initiating an action.* Any covered entity or manufacturer may initiate an action for monetary damages or equitable relief against a manufacturer or covered entity, as the case may be, by filing a written petition for relief with HRSA and mailing a copy of the petition with any attachments to the General Counsel or other senior official of the opposing party at its principal place of business by certified mail, return receipt requested, within three days of filing the claim. The petition should satisfy the pleading requirements of Rules 8, 10, and 11 of the Federal Rules of Civil Procedure, including setting forth the factual basis for invoking the 340B ADR Panel's jurisdiction. A claim must include all of the requirements in paragraph (d) of this section. Additional information to substantiate a claim may be submitted.~~

~~(b) *340B ADR Panel's jurisdiction.* The 340B ADR Panel shall have jurisdiction to entertain any petition where the damages sought exceed $25,000 or where the equitable relief sought will likely have a value of more than $25,000 during the twelve month period after the 340B ADR Panel's final agency decision, provided the petition asserts claims of the type set forth below.~~

(a) ~~(c)~~ *Claims permitted.* ~~The ADR process is~~ 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 ~~PHSA~~PHS Act, that the covered entity has violated section 340B(a)(5)(A) of the ~~PHSA~~PHS Act regarding the ~~duplicate discount~~ prohibition of duplicate discounts, or section 340B(a)(5)(B) of the ~~PHSA~~PHS Act regarding the ~~diversion~~ prohibition~~, including claims that an individual does not qualify as~~ of the resale or transfer of covered outpatient drugs to a patient ~~for 340B Program purposes and claims that a~~ of the covered entity ~~is not eligible for the 340B Program~~.

(b) ~~*(d) Limitation of actions.*~~ *Requirements for filing a claim.*

(1) Absent extenuating circumstances, a ~~A~~ covered entity or manufacturer must file a ~~written claim for administrative dispute resolution with HRSA~~ 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 ~~the ADR process~~ a dispute must be maintained by the covered entity and manufacturer until the date of the final agency decision ~~is issued by the 340B ADR Panel~~.

(2) ~~Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a~~ A covered entity filing a claim described in paragraph (~~c~~a)(1) of this section must provide ~~documents sufficient to demonstrate~~ the basis, including all available supporting documentation, for its ~~claim~~belief that it has been overcharged by a manufacturer, ~~along with~~ in addition to any ~~such~~ other documentation as may be requested by ~~the 340B ADR Panel~~ OPA. A covered entity claim against multiple manufacturers is not permitted.

(3) ~~Notwithstanding Rules 8 and 10 of the Federal Rules of Civil Procedure, a~~ A manufacturer filing a claim under paragraph (~~c~~a)(2) of this section must provide documents sufficient to ~~demonstrate~~support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts, ~~along with~~ any ~~such~~other documentation as may be requested by OPA.~~the 340B ADR Panel.~~

(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) ~~(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 ~~that could file a claim against the manufacturer~~ consents to the jointly filed claim ~~, including~~

~~submission of the required documentation, described in paragraph (d) of this section~~ 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 ~~claims of overcharges by the same manufacturer for the same drug or drugs~~ on behalf of ~~multiple~~ one or more covered entities representing their interests if ~~each~~:

(i) Each covered entity ~~represented could file a claim against the manufacturer,~~ is a member of the association or the organization~~,~~ ~~meets the requirements described in paragraph (d) of this section, including submission of the required documentation,~~ representing it and each covered entity ~~has agreed to representation by the association or organization on its behalf.~~ 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 ~~filing of the~~ consolidated claim, meets the requirements ~~described in paragraph (d) of this section~~ for filing a ~~that~~ claim, and the 340B ADR Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of ~~sources. The 340B ADR Panel will not permit consolidated~~ resources. Consolidated claims filed on behalf of manufacturers by associations or organizations representing their interests are not permitted.

~~(4) Joinder, consolidation, and other third-party practice not referenced in this paragraph (e) shall be governed by the Federal Rules of Civil Procedure, as relevant, unless the parties and 340B ADR Panel agree otherwise.~~

(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) ~~(f)~~ *Responding to a submitted claim.*

(1) Upon receipt of ~~service of petition, the respondent must file with the 340B ADR Panel~~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.~~the Petition as set forth in Rule 12 or 56.~~

(2) A Party may ~~The 340B ADR Panel may issue additional instructions as may be necessary or desirable governing the conduct of ADR proceedings, including instructions pertaining to deadlines for submission of additional information.~~ 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 ~~the petition,~~ participate in the 340B ADR process, OPA will notify both parties that the claim has moved forward for review by the 340B ADR Panel ~~may enter a final agency~~ and the 340B ADR Panel will render its decision ~~by default in favor~~ after review of the ~~Petitioner.~~ information submitted in the claim. ~~In a proceeding for damages, the Petitioner must still introduce evidence sufficient to support its claim for damages even though the merits have been resolved through default.~~

§ 10.22 Covered entity Information and document requests.

(a) ~~Discovery. The 340B ADR Panel may permit a covered entity limited discovery to obtain such information and documents as may be relevant to demonstrate the merits of a claim. Such discovery shall be governed, to the extent applicable, by the Federal Rules of Civil Procedure.~~ 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) ~~340B ADR Panel information requests. Taking into account any party's request for further information, the 340B ADR Panel may request additional information from either party.~~ 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) ~~*Failure to respond to information requests.* If the 340B ADR Panel finds that a party has failed to respond or fully respond to an information request, the 340B ADR Panel make take the following actions, including:~~ The manufacturer must fully respond, in writing, to an information/document request from the 340B ADR Panel by the response deadline.

~~(1) Holding facts to have been established in the proceeding;~~ 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) ~~Precluding a party from presenting or contesting a particular issue;~~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) ~~Excluding evidence; or~~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) ~~Judgment in the proceeding or dismissal of proceeding.~~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 that 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 ~~Conduct of the~~340B ADR ~~proceeding~~Panel decision process.

(a) ~~The 340B ADR Panel will determine, in its own discretion, the most efficient and practical form of the ADR proceeding. Unless the matter is resolved through a motion to dismiss or summary judgment under Rule 56, the 340B ADR Panel shall conduct an evidentiary hearing when there are material facts in dispute. The ADR proceeding may be conducted by video conference, in person, or through other means.~~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 violation as described in § 10.21(a)(1) or (2) has occurred.

(b) ~~The 340B ADR Panel will determine the proper course of conduct in an ADR proceeding. Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Civil Procedure, to the extent applicable, shall govern the proceedings.~~ 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) ~~Unless the parties agree otherwise and the 340B ADR Panel concurs, the Federal Rules of Evidence shall apply to the proceedings.~~ 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 340B ADR Panel may issue additional instructions or guidance as may be necessary or desirable governing the conduct of ADR proceedings.~~ 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 ~~Final agency decision.~~ 340B ADR Panel decision reconsideration process.

(a) ~~The 340B ADR Panel will review the evidence submitted by the parties and determine if the preponderance of the evidence supports the conclusion that a violation as described in § 10.21(c)(1) or (2) has occurred.~~ 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 340B ADR Panel will prepare an agency decision based on its review and evaluation of the evidence submitted by the parties, including documents provided as required in § 10.21(d), information requests in support of a claim, and responses to a claim.~~ 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 agency decision will represent the decision of a majority of the 340B ADR Panel's findings regarding the claim and discuss the findings supporting the decision.~~ 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 agency decision constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of~~

~~competent jurisdiction.~~ 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 340B ADR Panel will submit the final agency decision to all parties, and to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities.~~ 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.