CHA EXECUTIVE SUMMARY – JUNE 2024

340B Administrative Dispute Resolution Process Final Rule

Overview

On April 19, the Health Resources and Services Administration (HRSA) released its final administrative dispute resolution (ADR) process rule. The rule is designed to assist covered entities and manufacturers in resolving disputes regarding overcharging, duplicate discounts, or diversion, as set forth in the 340B statute. The final rule creates an ADR process that is more accessible to all covered entities and less formal. The rule is effective June 18, 2024.

Below is a detailed summary of the final rule. For questions, please contact Chad Mulvany, vice president, federal policy, at cmulvany@calhospital.org or Ben McGowan, vice president legal counsel, public policy, at bmcgowan@calhospital.org.

In this rule, HRSA:

- Establishes an ADR process that is reflective of an administrative process instead of a trial-like proceeding; allows covered entities – regardless of size or capability – to bring a claim for review when they are overcharged by a manufacturer for a covered drug
- Revises the structure of the 340B ADR Panel so it is comprised of subject matter experts
- Ensures the parties have attempted to resolve claims through good faith efforts before initiating the ADR process
- Includes a reconsideration process for parties dissatisfied with a 340B ADR decision
- Allows manufacturer claims for alleged instances of duplicate discounts and diversion

ADR Panel Composition and Duties

The Secretary of HHS will appoint a roster of at least 10 eligible individuals consisting of staff within the Office of Pharmacy Affairs (OPA) to serve on a 340B ADR Panel. 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. ADR Panel members will be screened for conflicts of interest prior to reviewing a specific claim.

The 340B ADR Panel will review and evaluate claims, including consolidated and joint claims, and documents and information submitted by (or on behalf of) covered entities and manufacturers. The Panel may 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.

The Panel may also request additional documentation, information, or clarification of an issue from any or all parties involved in the dispute. 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.

Good Faith Effort to Resolve Dispute

When a dispute is filed, covered entities (as well as manufacturers) must provide OPA with a written summary of attempts to work in good faith to resolve the instance of overcharging with the manufacturer at issue. An example of documented good faith efforts could include at least one attempt to enter discussion to resolve disputes, or records of communication between the covered entity and the manufacturer. In certain situations where a covered entity cannot access 340B pricing, HRSA acknowledges that it will facilitate good faith efforts between the parties.

Claims Eligible for the ADR Process

To be eligible for the ADR process, each claim filed by a covered entity must provide the basis for the covered entity's belief that it has been overcharged by a manufacturer. This includes instances of where the manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price. Manufacturers may also submit a claim related to alleged duplicate discounts and/or diversion of covered drugs to an individual who is not a patient of the covered entity if it has conducted an audit.

Claims must be filed within three years of the date of the alleged violation. The basis of the claim must be provided – including all available supporting documentation in addition to any other documentation as may be requested by OPA. A covered entity claim against multiple manufacturers is not permitted.

A covered entity cannot file a claim against multiple manufacturers, even if the basis for the claim is the same. It must file individual claims against each manufacturer. However, two or more covered entities may jointly file claims of overcharges against the same manufacturer for the same drug. Manufacturers may also join together to file a claim for an alleged violation against the same covered entity.

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

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

OPA staff[1] will conduct an initial review of all information submitted by the party filing the

[1] 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.

claim and will decide whether the requirements are met. 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.

OPA will provide written notification to the initiating party that the claim is complete and 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. If OPA finds that the claim meets the requirements and receives the opposing party's response, additional written notification will be sent to both parties advising that the claim will be forwarded to the 340B ADR Panel for review.

If OPA finds that the claim does not meet the requirements, written notification will be sent to both parties stating the reason(s) that the claim did not move forward. 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 finalized in the rule.

Upon receipt of notification by OPA that a claim is deemed complete and has met the requirements, the opposing party in alleged violation will have 30 business days[2] to submit a written response to OPA. 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. 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.

Information and Document Requests

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 request and notify the covered entity if the request is not reasonable and will permit the covered entity to resubmit a revised request if necessary. 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. The manufacturer must fully respond, in writing, to an information/document request from the 340B ADR Panel by the response deadline[3].

ADR Panel Decision Process

The 340B ADR Panel will conduct a review of the claims. The 340B ADR Panel will

[2] A party may submit a request for an extension of the initial 30 business days response.
[3] 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.

review all documents gathered during the 340B ADR process to determine if a violation has occurred. The 340B ADR Panel will prepare a decision letter based on its review which will be completed within one year of receiving a complete claim for review. 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 for each finding. The 340B ADR Panel will transmit its decision letter to all parties and to the OPA Director. The letter will inform the parties involved of their rights for reconsideration. The final agency decision is binding unless invalidated by an order of a federal court. The decision will be effective 30 business days from issuance and serve as the final agency decision unless it is reviewed by the Secretary or via the reconsideration process.

Provide Reconsideration Process

After a decision has been issued by the Panel, if either the initiating party or the opposing party is dissatisfied, they may request a reconsideration of the claim if the requirements are met. The HRSA administrator also has the discretion to initiate a reconsideration if no request is received by the parties. The reconsideration will be conducted by the HRSA administrator, or designee, as their review will be independent of the ADR Panel's decision.

The party requesting a reconsideration must submit its request in writing to the HRSA administrator within 30 business days of receiving the Panel's decision. The request for reconsideration must include a copy of the ADR Panel's decision letter, and the burden lies with the party filing the reconsideration to submit written documentation indicating why a reconsideration is warranted. New information may not be submitted as part of the reconsideration process to remain consistent with the facts that were reviewed by the Panel in determining the final agency decision.