California Hospital Association

Federal Regulatory Summary

from the California Hospital Association

CHA EXECUTIVE SUMMARY – DECEMBER 2022

340B Administrative Dispute Resolution Process Proposed Rule

Overview

On Nov. 30, the Health Resources and Services Administration (HRSA) released its proposed 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 proposed rule is intended to be more accessible to all covered entities and less formal. Once finalized, it will replace the existing ADR process. Comments are due on or before Jan. 30, 2023.

Below is a detailed summary of the proposed rule. For questions, please contact Chad Mulvany (cmulvany@calhospital.org) or Robert Ducay (rducay@calhospital.org).

In this rule, HRSA proposes to:

1) Establish an ADR process that is reflective of an administrative process instead of a trial-like proceeding
2) Revise the structure of the 340B ADR Panel (hereafter "Panel") so it is comprised of 340B subject matter experts
3) Ensure the parties have attempted to resolve claims on their own prior to proceeding through the ADR process
4) Align the ADR process with the provisions set forth in the 340B statute
5) Include a reconsideration process for parties dissatisfied with a 340B ADR

Simplify the ADR Process

As proposed, once the Office of Pharmacy Affairs (OPA) determines a claim meets the ADR process requirements set forth and forwards the claim to the Panel, the Panel will review and evaluate all documentation submitted by the party initiating the claim.

The Department of Health and Human Services (HHS) proposes covered entities and manufacturers file a written claim, based on the facts available, to OPA within three years of the alleged specified violation and that any claim not filed within three years shall be time-barred. HHS proposes that, if requested, covered entities or manufacturers may be permitted to combine individual claims. Further, multiple covered entities may jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding.

The Panel may request additional information or clarification from any party involved in the claim during the review and evaluation process. The Panel will also facilitate the review of covered entity requests for information and documents from manufacturers and third parties. If the Panel finds that either party does not fully respond to a request for information or documents from

OPA or the Panel, HHS proposes that the Panel may draw an adverse inference and make a decision on the claim based on the information submitted in the claim package that moved forward for review.

The Panel will conduct a review of the documents submitted by the parties and evaluate claims based on the information received (including from any associations or organizations, or legal counsel representing the parties) unless, at the Panel's discretion, the nature of the claim necessitates that a meeting with the parties is held. HHS proposes that the Panel's decision must represent the decision of a majority of Panel members.
The 2020 final rule also instituted a minimum threshold of $25,000 before the petition could be filed. HHS is not proposing a minimum threshold for accessing the ADR process to increase the flexibility of the process.

Include 340B Experts on the ADR Panel

The role of the Panel is to independently review and apply 340B law and policy to the case-specific factual circumstances at issue in an overcharge, diversion, or duplicate discount dispute. HHS proposes to revise the Panel that will review and resolve these claims. This group will include no less than 10 staff from the OPA and be screened for potential conflicts of interest. These individuals will have subject matter expertise of the 340B authorizing statute and the operational processes of the 340B program, including covered entity registration and program integrity efforts such as audits. HRSA is soliciting specific comments on the proposed size and composition of the Panel, including the proposal to maintain the Panel within OPA or whether staff from other components of HRSA or HHS more generally should serve as members of the Panel.

Good Faith Effort to Resolve Dispute

When a dispute is filed, HHS proposes to require covered entities (as well as manufacturers) to 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 attempts to enter into discussion to resolve disputes or communication records between the covered entity and the manufacturer. HHS is seeking comments on what other types of documentation would indicate good faith effort and whether a threshold for attempts at communication should be established.

Align with 340B Statute

HHS proposes that 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, along with any such documentation as may be requested by OPA to evaluate the accuracy of the claim. Such documentation may include, but is not limited to:

- A 340B purchasing account invoice that shows the purchase price by national drug code, less any taxes and fees
- The 340B ceiling price for the drug during the quarter(s) corresponding to the time period(s) of the claim

- Documentation by the manufacturer or wholesaler of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of alleged overcharging
- Documentation and correspondence with HRSA regarding the alleged overcharge, including price unavailability forms or other correspondence
- An estimate of monetary damages

HHS believes that these documents are readily available to a covered entity in the usual course of business and should not be overly burdensome to produce. However, HHS requests a comment on the feasibility of producing the documentation as proposed.

Provide Reconsideration Process

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

HHS proposes the party requesting a reconsideration must submit its request in writing to both the other party involved in the claim and to the HRSA administrator within 20 business days of receiving the Panel's decision. The request for reconsideration must include a copy of the 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 in order to remain consistent with the facts that were reviewed by the Panel in determining the final agency decision.