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Special Bulletin

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HRSA Proposes Revised 340B Administrative Dispute Resolution Process

The Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) Nov. 29 issued a new proposed rule revising the 2020 final rule that established the 340B Administrative Dispute Resolution (ADR) process. HHS notes that the proposed rule better aligns with the statutory requirements for the ADR process that was first put in place by the Affordable Care Act (ACA). Public comments will be accepted through **Monday, Jan. 30, 2023.**

Key Highlights

The rule specifically proposes to:

- move the ADR process away from a trial-like proceeding and establish a more conventional administrative process;
- revise the ADR panel structure to consist of 340B program subject matter experts from HRSA's Office of Pharmacy Affairs;
- ensure parties resolve disputes in good faith prior to invoking the ADR process;
- align the ADR process to statutory provisions on overcharges, duplicate discounts and diversion; and
- include a reconsideration process for parties dissatisfied with the 340B ADR panel decision.

The proposed rule notes that any dispute between 340B covered entities and drug manufacturers that are subject to federal court review would not be eligible for the ADR process until the court process concludes.

AHA TAKE

The Administration's ADR process proposal for the 340B Drug Pricing Program is an important step in ensuring the integrity of the 340B Program. While we are reviewing the proposal in more detail, we are encouraged that the Administration has proposed changes that would make the process more accessible for 340B providers seeking dispute resolutions. We plan to submit comments to further improve the final rule and to ensure that the ADR process is effective. In addition, we continue to urge the Department of Health and Human Services to aggressively use all tools available to stop the harmful tactics of drug companies that violate the law and diminish 340B hospitals' ability to deliver care as Congress intended.

HIGHLIGHTS OF THE PROPOSED RULE

This rule proposes to revise the 340B ADR process established in a 2020 final rule by making the ADR process more accessible, administratively feasible and timely. The ACA first established the ADR process as a formal way to resolve claims by 340B covered entities (hospitals, clinics and community health centers) that a drug manufacturer has overcharged for covered outpatient drugs and claims by drug manufacturers that a covered entity has violated the prohibition on diversion or duplicate discounts after a drug manufacturer conducted an authorized audit.

The following is a summary of the key proposed changes.

Minimum Threshold. To make the ADR process more accessible, the proposed rule would eliminate a minimum threshold value of the disputed claims necessary for accessing the ADR process. The 2020 final rule instituted a minimum threshold value for disputed claims of $25,000 or where the equitable relief sought will likely have a value of more than $25,000 to be met before the petition could be filed. HHS and HRSA are asking for public comment on whether a minimum threshold should be retained or eliminated.

Revised Role and Structure of the ADR Panel. The proposed rule envisions that the role of the ADR panel would be to independently review and apply 340B law and policy to specific circumstances of potential overcharges, diversions or duplicate discounts. The rule further proposes that the panel members be 340B subject matter experts with specific knowledge of the authorizing statute and the operational processes of the 340B Program including covered entity registration and program integrity efforts such as audits. These proposed changes are consistent with the Administration's effort to move away from a trial-like process to a more administrative process that requires specific operational knowledge of the 340B program. Specifically, the rule proposes that the HHS Secretary appoint a roster of eligible individuals consisting of staff from HRSA's Office of Pharmacy Affairs (OPA) that manage the 340B Program to serve on the 340B ADR panel. The ADR roster would include no less than 10 staff from OPA. HHS is soliciting specific comments on the proposed size and composition of the 340B ADR Panel, including the proposal to maintain the 340B ADR Panel within OPA or whether staff from other areas HRSA or HHS more generally should serve as members of the panel.

Good-faith Efforts to Resolve Claim Disputes. HRSA's longstanding policy has encouraged 340B covered entities and drug manufacturers to work in good faith to resolve disputes. The proposed rule emphasizes the importance of engaging in good faith resolution efforts prior to filing an ADR claim. As a matter of statute, drug manufacturers can challenge covered entities only pertaining to issues of diversion and duplicate discounts but must first conduct an audit of the covered entity's violation of the 340B statutory prohibitions on diversion and duplicate discounts prior to filing an ADR claim. As such, the rule proposes to limit the ADR claims to those provisions set forth in

statute on overcharging, diversion and duplicate discounts. The proposed rule also would require that the ADR panel suspend its review of any claims that involve issues pending adjudication in Federal court. The ADR review could continue once the issue is no longer pending in Federal court.

More specifically the rule proposes that, in cases where the drug manufacturer is accused of overcharging a covered entity, the 340B covered entity must submit documentation that OPA staff could review for accuracy for the claims to be eligible for the ADR process. Such required documentation could include the following:

- a 340B purchasing account invoice which 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 and HRSA request comment on the feasibility of covered entities to produce the required documentation listed above. In addition, they seek comment on what other types of documentation would indicate good faith effort and whether a threshold for attempts at communication should be established.

Reconsideration. The proposed rule also allows for a reconsideration process if either of the disputing parties is dissatisfied with the 340B ADR panel's decision. This reconsideration process was not included in the 2020 Final rule. HHS and HRSA are proposing that the reconsideration would be conducted by the HRSA Administrator or their designee, and their review will be independent of the 340B ADR Panel's decision.

WHAT YOU CAN DO

- Review the proposal rule with your policy and legal teams.
- Look for AHA's model comment letter which we will share soon, and plan to submit your comments no later than the deadline of Jan. 30, 2023.

FURTHER QUESTIONS

If you have further questions, please contact AHA at 800-424-4301 or contact Molly Collins Offner, AHA's director of policy, at mcollins@aha.org, or Bharath Krishnamurthy, AHA's director of policy and health analytics, at bkrishnamurthy@aha.org.