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Change is on the Horizon for 340B Pharmacy Program's Administrative Dispute Resolution Process

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The U.S. Health Resources and Services Administration (HRSA) published a final rule (the Rule) on December 14, 2020, which outlined the requirements and procedures for the 340B pharmacy program's administrative dispute resolution (ADR) process. Effective January 13, 2021, the Rule will replace the 340B Program's current guidelines on the informal dispute resolution process developed to resolve disputes between covered entities and manufacturers.

340B ADR Panels

ADR hearings will occur before a three-member panel (the Panel) selected from a six-member ADR Board comprised of two members from each of the following: the HRSA, the Centers for Medicare and Medicaid Services (CMS), and the Health and Human Services (HHS) Office of General Counsel (OGC).

For each accepted claim, the HRSA Administrator will select the Panel of three members from the ADR Board, including one member from each of the represented HHS divisions. A non-voting representative of HRSA's Office of Pharmacy Affairs (OPA) will also assist the Panel. Notably, the Panel will have significant discretion in determining relevant material to consider and the manner to conduct its evaluation and hearings.

Permissible 340B ADR Claims

The Rule will allow covered entities and 340B Program drug manufacturers to formally request review of alleged 340B program violations. Although 340B claims can be brought by either a covered entity or a manufacturer, a manufacturer must first conduct an audit of a covered entity before it may initiate a claim. A challenge to a manufacturer's [average manufacturer price] or [best price] calculations is beyond the Rule's scope of jurisdiction.

The Rule permits two types of claims:

- *Covered Entity Claims.* A covered entity may pursue a claim "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."
- *Manufacturer Claims.* A manufacturer may pursue a claim, "after it has conducted an audit of a covered entity [pursuant to the 340B statute,] [finding] that the covered entity violated [the duplicate discount prohibition or diversion prohibition], including claims that an individual does not qualify as a patient for 340B Program purposes and claims that a covered entity is not eligible for the 340B Program."

The Rule states that Panels may consider whether an individual qualifies "as a patient for 340B Program purposes" and "claims that a covered entity is not eligible for the 340B Program;" whether a pharmacy is part of a "covered entity," and the appropriateness of other "manufacturer restrictions on 340B sales that the Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim."

340B ADR Claims Filing Requirements

Financial Damages Threshold. The Panel has jurisdiction to entertain a claim only "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 Panel's final agency decision," provided that the filing asserts permissible claims. Although ADR requests by a covered entity must exceed the $25,000 threshold, a covered entity may consolidate multiple claims alleging overcharges by the same manufacturer for the same drug. In addition, trade associations may consolidate and submit small claims on behalf of numerous covered entities if, in aggregate, they exceed the $25,000 threshold.

Timely Filing of Claims. Claims for damages or equitable relief must be filed in writing with HRSA within three years of the date of the alleged violation. Claims may be submitted by sending a written request for relief to HRSA and to the general counsel or senior official of the opposing party at its principal place of business.

Covered Entity Claims Supporting Documentation. Claims must be supported by sufficient documentation. This may include: a 340B purchasing account invoice which shows the purchase price by national drug code (NDC), 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; and documentation of the attempts made to purchase the drug via a 340B account at the ceiling price, which resulted in the instance of overcharging.

Combining Claims. Two or more covered entities may jointly file claims; and, covered entity associations or organizations may further file claims on behalf of two or more covered entities, if each covered entity could have filed the claim on its own and consents to do so, including submission of supporting documentation. Additionally, two or more manufacturers may file a consolidated claim so long as the "Panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of sources." Joint claims by trade associations representing manufacturers are not permitted.

Claims Notification. A covered entity or manufacturer filing a claim under the Rule must notify the respondent by mailing a copy of the filing to the respondent's general counsel or other senior official within three days of filing the claim. The respondent will have 30 days to submit a written response, or the Panel may enter a final decision by default in favor of the complainant. In a proceeding for damages where there is such a ruling on the merits by default, the complainant will still be required to introduce evidence sufficient to support the claim for damages.

340B ADR Hearing Procedural Rules

Hearing Proceedings. The Panel will have wide latitude to define the proper course of conduct, and scope of the process, including any additional deadlines, procedures, or instructions that may be necessary or desirable for a fair, efficient, and expeditious ADR hearing proceedings. The 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." The Panel is required to conduct an evidentiary hearing, unless the claim is resolved through a motion to dismiss or a motion for summary judgment. It is also permitted to "determine, in its own discretion, the most efficient and practical form of the ADR proceeding." The Rule states that "[t]he ADR process will be governed, to the extent applicable, by the Federal Rules of Civil Procedure and Federal Rules of Evidence, unless the parties agree otherwise, and the Panel concurs." Additionally, the Rule specifies that the Panel will "use a 'preponderance of the evidence' standard when making its determinations."

Discovery. The 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" and also will take into account any party's request for further information and "may request additional information from either party." If a party fails to respond to an information request, the 340B ADR Panel may take actions such as holding facts to have been established in the proceeding; precluding a party from presenting or contesting a particular issue; excluding evidence; or judgment in the proceeding or dismissal of proceeding.

The ADR Hearing Decision

Basis and Timing of ADR Hearing Decision. The ADR hearing decision is based on a majority vote and need not be unanimous. Notably, since the ADR Rule does not require the Panel to issue a decision within a specified timeframe, there could be a significant delay in resolution of 340B ADR claims. At the conclusion of the ADR process, the 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 for sanctions, including referrals to the HHS Office of Inspector General for consideration of civil monetary penalties, as appropriate."

Finality of ADR Hearing Decision. The decision resulting from the 340B ADR process "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." Thus, the only way for the decision to be overturned would be by way of a successful appeal in federal district court.

Compliance Best Practices

HRSA has indicated that the Rule is not intended to replace "good faith efforts" between manufacturers and covered entities "to attempt to resolve disputes," and, "should be considered a last resort in the event good faith efforts to resolve disputes have failed." In addition, covered entities and manufacturers should "carefully evaluate whether the ADR process is appropriate for minor claims given the investment of the time and resources required of the parties involved and the government."

Covered entities and manufacturers should carefully review the Rule and develop and implement related policies and procedures. They also should carefully consider 340B ADR strategies that promote cost-effective and efficient dispute resolution and ensure optimal access to 340B Program financing.

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