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Special Bulletin

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HRSA Finalizes Rule on 340B Dispute Resolution Process

The Health Resources and Services Administration (HRSA) Dec. 10 released its long-awaited final rule implementing an Affordable Care Act (ACA) requirement that the agency establish a process to resolve disputes between 340B covered entities and drug manufacturers. The final rule sets forth the administrative dispute process, including the composition of the decision-making body, the scope of claims, the information needed to support such claims, as well as the timeframe for the proceedings. It does not, however, directly address the issues AHA has raised with drug companies restricting 340B hospitals' use of community pharmacies.

AHA Take: In a statement, AHA Executive Vice President Tom Nickels said, "The AHA has long believed that an administrative dispute resolution process for the 340B drug pricing program is an important step forward in protecting 340B hospitals and clinics that have been overcharged by drug manufacturers through the program. This process should have been finalized a full decade ago, as the law and Congress called for.

"However, on its own, this ADR process is not sufficient to address drug companies' repeated illegal attempts to attack 340B hospitals, and the patients and communities they serve. This includes their most recent efforts to undermine the program by limiting the distribution of certain 340B drugs to eligible hospitals, despite no statutory provisions allowing for such actions. These illegal acts require immediate relief rather than an ADR process.

"We continue to urge the Department of Health and Human Services' Health Resources and Services Administration to take swift and decisive action to halt these pernicious tactics from drug companies and ensure that 340B drugs remain available and accessible to vulnerable communities across the country."

Highlights of the final rule follow.

HIGHLIGHTS OF THE FINAL RULE

The final rule implements an ACA requirement that HRSA establish a binding administrative dispute resolution (ADR) process for the 340B program to resolve claims brought by both 340B covered entities and drug companies. Covered entities can bring forward claims where they have been overcharged by drug companies for drugs purchased through the 340B program. Drug companies, in turn, after conducting an authorized audit, can bring forward claims where a covered entity has violated the 340B

statutory prohibitions on diversion to ineligible patients or on Medicaid duplicate discounts. This final rule replaces HRSA's 1996 340B program guidance that sets forth an informal dispute resolution process. The agency notes that the ADR process is intended to be a last resort effort to resolve disputes after good faith efforts have proven unsuccessful. HRSA goes on to caution covered entities and drug companies to carefully evaluate whether the ADR process is the appropriate avenue to resolve disputes for minor claims given the investment of time and resources required by the involved parties and the government.

Administrative Dispute Resolution Panel: The final rule requires the Secretary of Department of Health and Human Services (HHS) to establish a 340B Administrative Dispute Resolution Board (Board) consisting of at least six members appointed by the HHS Secretary with equal representation from HRSA, the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of the General Counsel (OGC). The HRSA Administrator is empowered by the HHS Secretary to select a three-member ADR panel drawn from Board members to review claims and make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers. The composition of each 340B ADR panel member must include one attorney from OGC with complex litigation expertise, one member from HRSA and one member from CMS, each with drug pricing, drug distribution and other relevant 340B expertise. A non-voting, *ex-officio* member from HRSA's Office of Pharmacy Affairs (OPA) will assist each three-member 340B ADR Panel. The ADR panel will not be compensated, and members could be removed for cause.

Process and Information Requests: The Federal Rules of Civil Procedure, to the extent applicable, will govern the ADR process, unless the parties agree otherwise and the 340B ADR Panel concurs. The 340B ADR Panel will have significant discretion in determining relevant material to consider and the manner to conduct its evaluation of claims. A covered entity or manufacturer must file a written claim for administrative dispute resolution with HRSA within three years of the date of the alleged violation. The 340B ADR panel has jurisdiction over any claim where damages or equitable relief exceeds $25,000. The ADR process is limited to the following claims:

- covered entities that have been overcharged by a drug company for a purchased 340B drug, including claims that a drug company has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price; and
- drug companies' claims that a covered entity has violated the 340B statutory prohibitions on diversion to ineligible patients or on Medicaid duplicate discounts after conducting an authorized audit.

Covered entities making a claim must provide documents sufficient to demonstrate that it has been overcharged by a drug company, along with any other documentation requested by the 340B ADR Panel. Such documentation may include:

- a 340B purchasing account invoice that 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.

Drug companies making a claim must include documents sufficient to demonstrate that a covered entity has violated the statutory prohibitions on diversion to ineligible patients or on Medicaid duplicate discounts. HRSA may request additional documentation such as the final audit report to indicate that the company audited the covered entity for compliance with the statutory prohibitions (noted above) or a written summary of attempts to work in good faith to resolve the claim with the covered entity. Limited discovery is permitted for covered entities to obtain information and documents from drug companies and third parties relevant to their claim which will be governed by the Federal Rules of Civil Procedure. Drug companies seeking further information from a covered entity could do so by petitioning the 340B ADR Panel to request such information.

Covered entities can consolidate multiple claims of overcharges by the same drug company for the same drug or drugs. Associations or organizations that represent covered entities also can file claims of overcharges by the same drug company for the same drug or drugs on behalf of multiple covered entities. Drug companies also can file consolidated claims against the same covered entity, however, associations or organizations representing drug companies are not permitted to file claims against covered entities.

The final rule also sets forth the actions the 340B ADR Panel may take if a party fails to fully respond to information requests. In addition, the final rule allows flexibility in how the ADR proceeding may be conducted to include video conference, in-person, or through other means to ensure a fair, efficient, and expeditious process.

Final Decision of Claims: With regard to a final decision, the 340B ADR panel will review the documents submitted and prepare an agency decision, which will represent the decision of a majority of the panel regarding the claim and findings. 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 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.

NEXT STEPS

The final rule becomes effective 30 days after publication in the Federal Register. It is scheduled to be published on Dec. 14. If you have further questions, contact Molly Collins Offner, AHA director of policy, at mcollins@aha.org.