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New ADR Rule to Govern Disputes Between 340B Covered Entities and Drug Manufacturers

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Disputes between 340B Drug Pricing Program-covered entities and the drug manufacturers required to sell outpatient drugs to those entities at discounted prices will be governed by an alternative dispute resolution (ADR) process under a Final Rule published on April 19, by the US Department of Health and Human Services' Health Resources and Services Administration (HRSA).

Taking effect June 18, the Final Rule implements HRSA's authority under the Affordable Care Act (ACA) to create an ADR process for resolution of claims involving manufacturer overcharging for purchases of 340B drugs. The ADR process is also designed to address manufacturers' claims of duplicate discounts or diversion by covered entities. 340B Program stakeholders have long awaited the establishment of the ADR process, which the ACA required HRSA to finalize in 2010. Although the agency previously attempted to implement an ADR process under a prior rule issued in 2020, HRSA determined that process to be unworkable and did not adjudicate any claims under that rule.

The Final Rule arrives amid mounting tensions between covered entities and manufacturers about the administration of the 340B Program, particularly with respect to certain manufacturers' practices of restricting covered entities' usage of contract pharmacies for dispensing 340B discounted drugs. Several states have passed legislation to curb those manufacturer restrictions, which has led to manufacturers challenging that state legislation in the courts.

Components of the ADR Process

The Final Rule outlines a set of administrative requirements and procedures for the ADR process, codified under 42 C.F.R. Part 10, that HRSA describes as "more accessible, administratively feasible and timely than the 2020 final rule." Core components of the updated process include the following:

1. The ADR Panel

The authority to resolve ADR claims lies with a 340B ADR panel, comprising at least three staff

members from HRSA's Office of Pharmacy Affairs (OPA). All members of a panel must undergo conflict-of-interest screenings prior to reviewing a claim. HRSA is expected to publish policies and procedures for screening panel members by August 2024.

2. Filing and Responding to Claims

The ADR process begins with a covered entity or manufacturer filing a claim with OPA. A covered entity may file claims that a manufacturer overcharged it 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[.]" A manufacturer may file claims that a covered entity violated the 340B statute's prohibitions on a covered entity receiving a 340B discount on the same drug for which the manufacturer provides a rebate to Medicaid (*i.e.*, the duplicate discount prohibition), or on the resale or transfer of a 340B drug to an individual who is not a patient of the covered entity (*i.e.*, the diversion prohibition). Consistent with the ACA, a manufacturer may file a claim only after it audits the covered entity for compliance with the duplicate discount or diversion prohibition.

Notably, the Final Rule removes a limit on the ADR panel's jurisdiction under the 2020 rule to only those petitions in which the claimant seeks more than $25,000 in damages or equitable relief that will likely have a value of more than $25,000 during the 12-month period after the panel's decision. The Final Rule also removes requirements that parties comply with the Federal Rules of Civil Procedure (FRCP) when submitting a petition and accompanying documents or responding to a petition. In these respects, HRSA intends to "create a more accessible process where stakeholders have equal access to the ADR process and can easily understand and participate in it without having legal expertise or expending significant resources."

Absent "extenuating circumstances," a party must file a claim within three years of the alleged violation. As under the 2020 rule, the Final Rule permits two or more covered entities to jointly file, or an association or organization acting on behalf of one or more covered entities to file, claims of overcharges against a single manufacturer for the same drug or drugs. The Final Rule also preserves manufacturers' right to request consolidation of claims by more than one manufacturer against a single covered entity.

3. Collecting Evidence

To develop evidentiary support for a claim, a covered entity may submit information or document requests to the ADR panel, which will transmit those requests to the manufacturer for a response. In contrast to the 2020 rule, the Final Rule does not require a covered entity to comply with the FRCP's discovery rules. Manufacturers are expected to collect information and documents for their claims during the pre-claim audit, though a manufacturer may request the panel issue an information request to a covered entity if it believes the request is "necessary for the 340B ADR Panel's review[.]"

4. Decision-Making

The ADR process concludes with a binding decision letter that the panel generally must issue within one year after receiving a complete claim and reviewing all documents gathered during the ADR process. To make the review process "more expeditious and less trial-like," the Final Rule omits the 2020 rule's requirement that the ADR panel conduct proceedings in accordance with the FRCP and Federal Rules of Evidence. The Final Rule also removes a provision in the proposed version of the

rule that would have permitted the panel to suspend review of a claim if a specific issue in the claim is the same as or similar to an issue pending in federal court. Thus, under the Final Rule, a covered entity or manufacturer may file an ADR claim even if issues relevant to that claim are the subject of ongoing litigation.

5. Reconsideration

The Final Rule adds a new procedure for either party to request reconsideration within 30 business days after the ADR panel issues its decision letter. A requesting party must include "documentation indicating why a reconsideration is warranted" but may not present "[n]ew facts, information, legal arguments, or policy arguments[.]" HRSA's Administrator will review the record to determine if "there was an error in the 340B ADR Panel's decision" and thereafter affirm the panel's decision or issue a revised decision. Although the ADR regulations do not specify a timeline for issuance of the reconsideration decision, HRSA stated in the Final Rule that the Administrator will "make efforts to issue a reconsideration decision within 180 calendar days from the initiation of the reconsideration process."

Key Takeaways

Covered entities and manufacturers alike should assess whether they have any potential claims subject to HRSA's new ADR process, and the potential costs and benefits of pursuing those claims through ADR. Given the Final Rule's loosening of the 2020 rule's requirements, including removal of the $25,000 jurisdictional threshold, the ADR process may be an attractive option. This is especially so for covered entities, which the US Supreme Court ruled in the 2011 case of *Astra USA, Inc. v. Santa Clara County* otherwise lack the right to sue overcharging manufacturers directly in court.

Before filing an ADR claim, however, both covered entities and manufacturers must engage in documented good-faith efforts to resolve conflicts. HRSA explained in the Final Rule that ADR "should be considered only when good faith efforts to resolve disputes have been exhausted and failed." Legal counsel can help parties in conducting such resolution efforts and in navigating the procedures of ADR if an informal resolution is unachievable.

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