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HRSA Releases Final Rule Establishing Dispute Resolution Process for the 340B Program

Attorneys
Thomas N. Bulleit
Deborah Kantar Gardner
Margaux J. Hall
Ryan B. Marcus
Robert G. Baxter

On December 10, 2020, the U.S. Department of Health and Human Services ("HHS"), Health Resources and Services Administration ("HRSA") issued a long-anticipated regulation of interest to drug makers and providers: the 340B Drug Pricing Program Alternative Dispute Resolution Final Rule ("ADR Final Rule").[1] The ADR Final Rule establishes an alternative dispute resolution ("ADR") process that offers manufacturers and 340B "covered entities" a means of negotiating certain disputes in a more formal setting without resorting to litigation or private arbitration. In the ADR Final Rule, HRSA notes that its intention is for the ADR process to replace its 1996 dispute resolution guidance for pharmaceutical manufacturers and 340B covered entities.[2] The ADR Final Rule is set to go into effect on January 13; however, the ADR Final Rule's implementation could be subject to legal challenges connected to HHS's delegation of authority to ADR panels. The ADR Final Rule also may come into play in connection with active 340B-related litigation filed by the hospital industry in response to certain drug manufacturers' recent steps to limit 340B covered entities' use of contract pharmacy arrangements. Among other things, that litigation seeks to compel the government to complete the ADR rulemaking process in order to provide a forum for covered entities to bring claims against drug manufacturers – a request that is now arguably moot given the issuance of the ADR Final Rule.

This Alert summarizes the key provisions of the ADR Final Rule.

Background

In order for payment to be available for covered outpatient drugs under the Medicaid and Medicare Part B programs, pharmaceutical manufacturers must participate in the 340B program, under which they must sell outpatient drugs to covered entities at a discounted price.[3] Covered entities, in turn, are legally bound to adhere to 340B program requirements, including, among others, the requirement that a particular drug claim not be subject to a "duplicate discount" (i.e., a 340B discounted price and a Medicaid rebate claim), and the requirement that covered entities not inappropriately "divert" drugs (through resale or another transfer) to ineligible patients. Manufacturers are provided with audit rights under the 340B statute – including to investigate an individual's status as a patient of a covered entity, and a covered entity's eligibility to participate in the 340B program. Historically, there have been questions regarding the utility of the audit process, given that HRSA generally has failed to enforce audit findings and manufacturers themselves have limited means to enforce and ensure covered entity compliance with the terms of the 340B statute.

Congress sought to create an agency-mediated 340B program dispute resolution process by adding Section 7102 to the Public Health Service Act through the Patient Protection and Affordable Care Act.[4] Under Section 7102, HHS is required to establish and implement an administrative process for the resolution of claims by covered entities and manufacturers by September 19, 2010.[5] While HRSA issued an advance notice of proposed rulemaking and request relating to such an ADR process on September 20, 2010, HRSA did not publish a proposed rule to establish the ADR process until six years later – in 2016.[6] Finalization of that proposed rule was placed on hold pursuant to a Trump Administration freeze on new rulemaking.[7]

After this long history, the ADR Final Rule has finally arrived, but it has done so in the immediate wake of a National Association of Community Health Centers lawsuit that seeks to compel the agency to take action against drug manufacturers that limit 340B pricing for therapies dispensed through hospital-affiliated contract pharmacy arrangements.[8] The American Hospital Association also recently filed suit in the Northern District of California challenging HHS's determination that the agency does not have the statutory authority to require drug manufacturers to offer certain drugs to covered hospitals and other facilities at discounted prices under the 340B program.[9] It remains to be seen whether or how those lawsuits will evolve in light of the issuance of the ADR Final Rule. Further, the ADR Final Rule itself may be subject to legal challenge, given, for instance, the substantial amount of precedential decision-making power being delegated to ADR panels.

Overview of the ADR Process

1. Jurisdiction; Scope of Permissible Claims. ADR panels will be empowered to hear covered entity claims of alleged 340B program overcharges, "including claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."[10] ADR panels also will be permitted to hear manufacturer claims related to covered entity and patient eligibility, as well as claims of alleged covered entity violations of the duplicate discount and diversion prohibitions.[11] Unlike covered entities, drug manufacturers may only bring claims after conducting a formal audit of a covered entity, using an independent auditor and a HRSA-approved audit protocol.[12] In all cases, the claims must involve damages exceeding $25,000 or the desired equitable relief must be likely to have a value of more than $25,000 during the twelve-month period after the ADR panel's final decision.[13] Claims that address disputes that arose more than three years prior to the action being initiated will be barred from resolution through the ADR process.[14] Notably, the ADR process set forth in the ADR Final Rule is not intended to replace HHS's longstanding guidance to drug manufacturers and covered entities to work with each other, pre-ADR process, to attempt to resolve disputes in good faith. Instead, the agency emphasizes that the ADR process "should be considered as a last resort in the event good faith efforts to resolve disputes have failed."

2. Makeup of the ADR Board. The ADR Final Rule establishes a "340B Administrative Dispute Resolution Board" that will consist of at least six members appointed by the Secretary of HHS, with equal numbers of members from HRSA, the Centers for Medicare & Medicaid Services ("CMS") and the HHS Office of General Counsel ("OGC").[15] Three-member ADR panels consisting of one member each from HRSA, CMS, and OGC will be responsible for reviewing claims and making final agency decisions, and will be appointed by the HRSA Administrator.[16] Members of ADR panels will be screened for conflicts of interest, must have specific experience,[17] and may be removed for cause.[18]

3. Procedure. A covered entity or manufacturer may initiate an action for damages or equitable relief by filing a written petition for relief with HRSA and mailing a copy of the petition to the general counsel or other senior official of the opposing party at its principal place of business within three days of filing the claim.[19] A petition must comply with the Federal Rules of Civil Procedure's pleading requirements by setting forth the factual basis for the ADR panel's jurisdiction.[20] The ADR may consult the Office of Pharmacy Affairs for subject matter expertise. Further, many ADR panel procedures are governed by the Federal Rules of Civil Procedure. The ADR panel can entertain motions to dismiss and motions for summary judgment, and can hold evidentiary hearings. Decisions only require a majority of the panel to concur. In short, the panels' procedural operations will resemble a quasi-hybrid of a federal district court and appellate court, with substantial discretion.

4. Combined Claims. Covered entities may jointly file claims alleging overcharges by the same manufacturer for the same therapy; and an organization may file consolidated claims on behalf of multiple covered entities if each covered entity could file a claim against the manufacturer, is a member of the association or organization, and has agreed to be represented by the association or organization.[21] Multiple manufacturers may request to consolidate claims against the same covered entity if the ADR panel determines that such consolidation is appropriate and consistent with the goals of fairness and economy of resources.[22] Notably, associations representing drug manufacturers are not permitted to file consolidated claims on behalf of association members.[23]

5. Timeline for Review; Discovery. The ADR Final Rule does not reference a time frame for the ADR panel's review of claims. However, HHS noted that the panel would provide parties with an "approximate timeframe" for completion of its review.[24] During its review of claims, the ADR panel may request additional information from either party, and if the relevant party fails to respond to such a request, the panel may (i) hold certain facts as having been established in the proceeding; (ii) preclude the party from contesting particular issues; (iii) exclude evidence; and/or (iv) dismiss the proceeding or file a judgment in the proceeding.[25] The ADR Final Rule also permits a covered entity to engage in "limited discovery" with respect to the manufacturer, with consent from the ADR panel.[26] The manufacturer has no corresponding right to limited discovery from the covered entity.

6. Consequences of Decision; Appeal Rights. Following its review, the ADR panel will submit its final decision to all affected parties and will coordinate with HSRA for subsequent actions concerning refunds, penalties, removal, or referral to other authorities.[27] Additionally, the ADR panel may make recommendations to the HHS Office of Inspector General for consideration of civil monetary penalties, depending upon the types of violations that occurred.[28] An ADR panel's decisions will be binding on the parties and will constitute final agency action such that the dispute raised by the covered entity and drug manufacturer will not be subject to further agency review. However, the parties may appeal the panel's decisions in federal court.[29]

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If you have any questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

1. HHS, 340B Drug Pricing Program, *Administrative Dispute Resolution Regulation*, Dec. 14, 2020.
2. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996), *available at* https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/disputeresolutionprocess121296.pdf.
3. Covered entities include various public and not-for-profit hospitals, community health centers, and federally funded clinics that serve large numbers of patients with low incomes. A complete list of qualifying categories of covered entities is set forth at 42 U.S.C.§ 256b(a)(4).
4. Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111–152).
5. *See* 42 U.S.C. § 256(d)(3).
6. HHS, *340B Drug Pricing Program Administrative Dispute Resolution Process*, Sep. 20, 2010; HHS, *340B Drug Pricing Program Administrative Dispute Resolution Process*, Aug. 12, 2016.
7. Reince Preibus, Memorandum for the Heads of Executive Departments and Agencies (Jan. 20, 2017), *available at* https://www.whitehouse.gov/presidential-actions/memorandum-heads-executive-departments-agencies/.
8. *See Ryan White Clinics for 340B Access et al v. Azar et al*, 1:20cv2906 (U.S. District Court for the District of Columbia); *National Association of Community Health Centers v. Azar et al*, 1:20cv3032 (U.S. District Court for the District of Columbia).
9. Complaint at 2–3, *American Hospital Association v. HHS*, No. 3:20-cv-08806 (N.D. Cal. Dec. 11, 2020).
10. *Id*. at 80645.
11. *Id*.
12. *Id*. at 80636.
13. *Id*. at 80633–80634.
14. *Id*. at 80637.
15. HHS, 340B *Drug Pricing Program Administrative Dispute Resolution Regulation* 80634, Dec. 14, 2020.
16. *Id*.
17. The OGC attorney representative must have complex litigation experience, and the HRSA and CMS members must have drug pricing, drug distribution, and other relevant 340B expertise. A non-voting, ex-officio member from the Office of Pharmacy Affairs will consult with the panel. *Id*.
18. *Id*.
19. *Id*. at 80645.
20. *Id*.
21. *Id*.
22. *Id*.
23. *Id*.
24. *Id*.
25. *Id*. at 80645.
26. *Id*.
27. *Id*. at 80646.
28. *Id*. at 80642.
29. *Id*. at 80634.