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ALERT

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Back to the Drawing Board? HRSA Proposes Modifying the 340B Program Administrative Dispute Resolution Process

Attorneys
Margaux J. Hall
Stephanie A. Webster
Alex J. Talley
Scott Falin
Colleen S. Roberts

On November 30, 2022, the Health Resources and Services Administration ("HRSA") of the U.S. Department of Health and Human Services ("HHS") issued a proposed rule to revamp the 340B Drug Pricing Program administrative dispute resolution ("ADR") process (the "2022 Proposed Rule").[1] HRSA states it seeks to improve the accessibility and utility of the current ADR process through the 2022 Proposed Rule. Specifically, HRSA proposes to amend the ADR regulations adopted through a 2020 final rule that established an administrative pathway for drug manufacturers and 340B "covered entities" to resolve certain disputes relating to the 340B Program outside of litigation or private arbitration (the "2020 Final Rule").[2] HRSA states that, over the past two years, during which manufacturers and covered entities have been pursuing extensive litigation challenging the legal authority for contract pharmacies in the 340B Program and the lawfulness of the ADR process itself, it has identified "policy and operational challenges" with the 2020 Final Rule process that necessitate revisions to the regulations.[3]

HRSA proposes, and solicits comments on, a range of substantive changes to the ADR process that should be of interest to both providers and manufacturers participating in the 340B Program. The agency believes the proposed changes, if implemented, would improve the ADR process by making it "more accessible, administratively feasible and timely."[4] Significant proposed changes include making the process less formal by removing application of the Federal Rules of Civil Procedure ("FRCP") and the Federal Rules of Evidence ("FRE"), eliminating the $25,000 minimum dispute threshold, redesigning the composition of the ADR panels, and establishing a process for reconsideration of a panel's decision by the HRSA Administrator with no time limit on such reconsideration. Public comments on the proposal are due January 30, 2023.

Background

In order for payment to be available for covered outpatient drugs under the Medicaid and Medicare Part B programs, drug manufacturers must participate in the 340B Program.[5] Manufacturers that participate in the 340B program agree to sell covered outpatient drugs at a discounted price to "covered entities," which in turn must comply with various requirements.[6] For example, covered entities cannot "divert" drugs to ineligible patients and must ensure that no drug claim is subject to a "duplicate discount" (i.e., both a 340B discounted price and a Medicaid rebate). The 340B statute grants HHS and manufacturers audit rights to investigate an individual's status as a patient of a covered entity, or a covered entity's eligibility to participate in the 340B Program.

In 2010, as part of the Affordable Care Act ("ACA"), Congress created an agency-mediated 340B Program administrative dispute resolution process.[7] Under the ACA, HHS was required to establish and implement, by September 19, 2010, "an administrative process for the resolution of claims by covered entities that have been overcharged for drugs purchased…and claims by manufacturers, after the conduct of audits…of violations of [the statutory duplicate discount and diversion prohibitions]."[8] While HRSA issued an advance notice of proposed rulemaking and request for comments related to the ADR process on September 20, 2010, HRSA did not publish a proposed rule to establish an ADR process until 2016 and did not finalize regulations regarding the ADR process until issuing the 2020 Final Rule in December 2020.[9] HRSA now proposes to amend the regulations as described further below.

Summary of the 2022 Proposed Rule

1. Accessibility/Simplification. HRSA proposes revising the ADR process to make it "a more expeditious and less formal process for parties to resolve disputes" that is more akin to the informal dispute resolution process the agency outlined in 1996 subregulatory guidance.[10] Under the 2020 Final Rule, the ADR process is governed by the FRE and FRCP. By relying on the FRE and FRCP, HRSA says that the 2020 Final Rule created a process that requires the involvement of attorneys and specialists who have expert knowledge of these legal frameworks, both as members of the adjudicating ADR panels and as representatives of the disputing parties.[11] According to HRSA, obtaining the legal counsel necessary to navigate the FRE and FRCP requirements can present challenges for certain parties, such as "small, community-based organizations with limited means."[12] Further, HRSA contends the complexity of the FRE and FRCP frameworks may create unnecessary delays that prevent the ADR process from being a timely adjudication process as Congress intended under the statute. HRSA believes that, by removing the trial-like FRE and FRCP requirements, "stakeholders [would] have equal access to the ADR process" and would be able to easily "participate in it without expenditure of significant resources or legal expertise."[13]

   HRSA also states that it proposes eliminating the $25,000 minimum dispute threshold to further increase the flexibility of the ADR process. Currently, to use the ADR process, parties must seek damages or equitable relief with a value of at least $25,000. The agency seeks to remove this dispute threshold, while also encouraging covered entities and manufacturers to "carefully evaluate whether the ADR process is appropriate for minor or de minimis claims" given the time and resource investments the process requires.[14]

   HRSA also proposes to adopt rules that it says would further encourage the resolution of disputes outside of the ADR process. Under the 2020 Final Rule, parties are merely encouraged to work together in good faith to resolve disputes, and HRSA has discretion to request a written summary of the attempts made to find a resolution.[15] In the 2022 Proposed Rule, HRSA proposes requiring parties to document good faith attempts to resolve disputed issues prior to initiating the ADR process.[16] Under the 2022 Proposed Rule, documentation could include communication records between the parties, evidence of attempts to enter into discussions to resolve disputes prior to an audit of a covered entity, or documented responses from a covered entity to audit findings. The agency welcomes comments on other types of evidence that would indicate good faith efforts between the parties to resolve issues, and whether the agency should establish a threshold level of attempts at communication prior to allowing parties to pursue the ADR process.[17]

2. Structure of the ADR Panel. The 2022 Proposed Rule proposes to alter the composition of 340B ADR panels so that each panel is comprised of 340B Program subject matter experts. The 2020 Final Rule requires a 340B ADR Board to consist of at least six members appointed by the HHS Secretary, with equal numbers of members from HRSA, the Centers for Medicare & Medicaid Services ("CMS"), and the HHS Office of General Counsel ("OGC"). Under that Final Rule, for each matter, the HRSA Administrator selects three members from the 340B ADR Board to form a 340B ADR panel, consisting of one member each from HRSA, CMS, and OGC, to review claims and make final agency decisions on the areas in dispute.[18] While the 2020 Final Rule requires HRSA and CMS ADR Board members to have expertise in drug pricing or drug distribution and OGC ADR Board members to have experience in handling complex litigation, it does not mandate that such members have specific knowledge of the 340B statute and program operations.[19]

   The 2022 Proposed Rule proposes replacing the current structure and expertise requirements with a requirement that ADR panels be comprised of three 340B Program subject matter experts from HRSA's Office of Pharmacy Affairs ("OPA") who would be selected by the Secretary.[20] Under the 2022 Proposed Rule, these subject matter experts would undergo additional conflicts screening to ensure that each member was not previously involved in agency actions concerning the issues raised in a particular ADR claim.[21] HRSA solicits specific comments on the

proposed size and composition of the 340B ADR panels, including whether to maintain the panels within OPA as proposed or whether staff from other divisions of HRSA or HHS should serve as members as well.[22]

3. Jurisdiction; Scope of Permissible Claims. HRSA further proposes and solicits public comment on changes to the jurisdiction of the ADR panels under the 2020 Final Rule, including proposals to narrow the types of claims that panels may consider. HRSA says it proposes these changes to be consistent with the statute and preclude ADR review of issues that are the same or similar to those currently pending in federal court.[23]

   As set forth in the statutory language, Congress specified that the ADR process would be provided "for the resolution of claims by covered entities that have been overcharged for drugs purchased…and claims by manufacturers, after the conduct of audits…of violations of [the statutory duplicate discount and diversion prohibitions]."[24] The 2020 Final Rule arguably adopted a more expansive view of the ADR panels' jurisdiction. In the 2020 Final Rule's preamble, HRSA stated that the panels have the jurisdiction to "resolve all issues underlying any claim or defense…relevant for resolving an overcharge, diversion, or duplicate discount claim," including, for example, "whether someone is a 'patient' or whether a pharmacy is part of a 'covered entity.'"[25] The regulations also define the ADR process in an expansive manner as "a process used to resolve the following types of claims, *including any issues that assist the 340B Panel in resolving claims*: (1) claims by covered entities that they may have been overcharged…and (2) claims by manufacturers…after a manufacturer has conducted an audit…that a covered entity may have violated the prohibitions against duplicate discounts or diversion."[26] Additionally, another section of the current regulations defines "claims permitted" as including (1) covered entities' claims of 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*," and (2) manufacturers' claims of duplicate discount and diversion violations, "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."[27]

   HRSA proposes changes it claims are intended to ensure the process is "reserved for those disputes set forth in the statutory ADR provision" and seeks comment on "whether there may be appropriate claims limitations to ensure that ADR is limited to the specific statutory areas (diversion, duplicate discounts, and overcharges)."[28] While the 2022 Proposed Rule would retain the 2020 Final Rule's definition of the "ADR Process," including the language referring to resolution of "any issues that assist the 340B Panel in resolving [overcharge, duplicate discount, and diversion] claims,"[29] it also would (1) amend 42 C.F.R. § 10.21 to clarify that all claims "must be specific to the parties identified in the claims," (2) remove the current regulation's language that covered entities' claims may include claims that a manufacturer has limited the covered entity's ability to purchase drugs at 340B-discounted prices and that manufacturers' claims may include claims that an individual or covered entity is not eligible for 340B purposes, and (3) add more specific requirements for setting forth a claim.[30] HRSA indicates it believes these changes would align the regulation's scope of claims with those set forth in the statute and limit the ADR process to alleged harms that are "specific to the parties identified in the claim."[31] The agency solicits comments on the appropriate regulatory language to ensure that the ADR process is limited to claims of diversion, duplicate discounts, and overcharges.[32]

   HRSA also proposes that any claims pending under the current ADR process would automatically transfer to the new process.[33]

4. Federal Courts and the ADR Process. HRSA proposes rules for how ADR panels should address issues that are also pending in federal court, a topic not addressed in the current regulations. Specifically, the 2022 Proposed Rule would direct ADR panels to conduct an "initial review" of claims submitted by a manufacturer or covered entity to determine whether they are the same or similar to issues pending in a federal court. If a panel were to find that the issues presented also were before a federal court, it would be required to suspend its further review until the issues were no longer pending in a federal forum.[34] The proposed regulation, however, does not

expressly address whether suspension is required if the same or a similar issue is brought in federal court *after* the panel's initial review.

Notably, the ADR process itself has been the subject of multiple lawsuits during its short existence, including challenges from manufacturers alleging that the process set forth in the 2020 Final Rule is unlawful under the Administrative Procedure Act ("APA").[35] Given that the 2022 Proposed Rule maintains the overarching structure of the ADR process, a judicial decision on the validity of the current ADR process could have similar repercussions for the 2022 Proposed Rule.

5. Administrative Appeal Rights. In a shift away from the 2020 Final Rule, the 2022 Proposed Rule would create an administrative appeal process within HRSA for parties dissatisfied with decisions of the ADR panels. The 2020 Final Rule did not incorporate an agency appeals process; the panel's decision represented the agency's final decision and could be overturned only by a federal court under section 10 of the APA.[36] Under the 2022 Proposed Rule, after the 340B ADR panel issues its decision, either party would have 20 business days from receipt of the decision to request reconsideration by the HRSA Administrator.[37] A party would be entitled to reconsideration if it could demonstrate that the panel's decision may have been "inaccurate or flawed" (although neither term is defined by the rule).[38] No new information, however, could be submitted by the parties as a part of the reconsideration process.[39] The HRSA Administrator also may decide to initiate reconsideration at his/her own discretion. While a dissatisfied party must request reconsideration within 20 business days of the panel's decision, there are no requirements as to how quickly the HRSA Administrator must issue his/her decision. The HRSA Administrator's reconsideration would be considered the final agency decision and would be binding upon the parties, but any dissatisfied party may seek judicial review of the decision.[40] The agency invites comments regarding the scope of the reconsideration process.

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Comments on this proposed rule are due January 30, 2023, and we encourage regulated parties to submit comments. If you have any questions, please do not hesitate to contact one of the authors or your usual Ropes & Gray advisor.

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1. *340B Drug Pricing Program Administrative Dispute Resolution Notice of Proposed Rulemaking*, 87 Fed. Reg. 73516 (Nov. 30, 2022), https://www.govinfo.gov/content/pkg/FR-2022-11-30/pdf/2022-25752.pdf.
2. 42 C.F.R. §§ 10.3, 10.20-24; HHS, *340B Drug Pricing Program, Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80632 (Dec. 14, 2020). Ropes & Gray summarized the 2020 Final Rule in a prior client alert. *See* "HRSA Releases Final Rule Establishing Dispute Resolution Process for the 340B Program" (Dec. 22, 2020), *available at* https://www.ropesgray.com/en/newsroom/alerts/2020/12/hrsa-releases-final-rule-establishing-dispute-resolution-process-for-the-340b-program.
3. 87 Fed. Reg. at 73517.
4. *Id.*
5. 42 U.S.C. § 1396r-8(a).
6. 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).

7. 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).
8. *See* 42 U.S.C. § 256(d)(3).
9. HHS, *340B Drug Pricing Program Administrative Dispute Resolution Process*, 75 Fed. Reg. 57233 (Sep. 20, 2010); HHS, *340B Drug Pricing Program Administrative Dispute Resolution Process*, 81 Fed. Reg. 53381 (Aug. 12, 2016); HHS, 340B Drug Pricing Program, *Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80632 (Dec. 14, 2020).
10. 87 Fed. Reg. at 73518. *See Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65406 (Dec. 12, 1996).
11. 87 Fed. Reg. at 73517.
12. *Id*.
13. *Id.*
14. *Id.*
15. 85 Fed. Reg. at 80637.
16. 87 Fed. Reg. at 73520-21.
17. *Id.*
18. *Id.* at 73517. *See also id.* at 73519.
19. *Id.* at 73517.
20. *Id.*
21. *Id.*
22. *Id.* at 73519.
23. *Id.* at 73518, 73522.
24. 42 U.S.C. § 256(d)(3).
25. 85 Fed. Reg. at 80633, 80636.
26. *Id.* at 80644 (emphasis added).
27. *Id.* at 80645 (emphasis added).
28. 87 Fed. Reg. at 73518.
29. *Compare* 42 C.F.R. § 10.3 *with* 87 Fed. Reg. at 73524.
30. *Compare* 42 C.F.R. § 10.21(c) *with* 87 Fed. Reg. at 73525. Specifically, each claim filed by a manufacturer must include "documents sufficient to support its claim that a covered entity has violated the prohibition on diversion and/or duplicate discounts," while each claim filed by a covered entity must "provide the basis, including all available supporting documentation, for its belief that it has been overcharged." 87 Fed. Reg. at 73520-21, 73525.
31. 87 Fed. Reg. at 73520.
32. *Id*. at 73518.
33. *Id*. at 73517.
34. *Id.* at 73522.
35. *See, e.g., Eli Lilly and Company v. Cochran,* 526 F. Supp. 3d 393, 405-410 (S.D. Ind. 2021); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Hum. Servs.*, 570 F. Supp. 3d 129, 161-188 (D.N.J. 2021); Mot. for Summ. J. 22-45, *Pharmaceutical Research Manufacturers of America v. Cochran,* 8:2021-cv-00198 (D. Md. July 26, 2021); Am. Compl. ¶¶ 111-135, *Ryan White Clinics for 340B Access v. Azar,* 1:20-cv-02906 (D.D.C. Nov. 23, 2020), ECF No. 21.
36. 85 Fed. Reg. at 80634. *See also* 5 U.S.C. § 706.
37. 87 Fed. Reg. at 73523.
38. *Id.*
39. *Id.* at 73537.
40. *Id.* at 73522. *See also id.* at 73523 (stating that any dissatisfied party may also seek judicial review of the final agency decision).