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Summary of 340B Administrative Dispute Resolution Final Rule

To: Powers 340B Clients and Friends

Date: December 18, 2020

Subject: 340B Administrative Dispute Resolution Final Rule

On December 14, 2020, the Department of Health and Human Services (HHS) published a final rule to establish a 340B administrative dispute resolution (ADR) process (the Rule).[1] The Rule allows covered entities to file petitions against drug manufacturers regarding overcharges for drugs purchased under the 340B Program.[2] The Rule also permits manufacturers to file a petition against a covered entity for alleged violations of the diversion and duplicate discount prohibitions, but only after the manufacturer has conducted a formal audit of the covered entity. The Rule creates an ADR Board, from which an ADR Panel is selected to review the petitions and issue final decisions.[3] Final decisions can be challenged in court. The Rule becomes effective on January 13, 2021 and parties may begin to file claims at that time.

The ADR Board and Panel

The ADR Board consists of at least six members selected by the Secretary of HHS, in equal numbers, from the Health Resources and Services Administration (HRSA), the Centers for Medicare and Medicaid Services (CMS) and the HHS Office of General Counsel (OGC).[4] The Administrator of HRSA selects a three-member panel from this group, consisting of a representative of HRSA, CMS and OGC.[5] A non-voting staff member from HRSA's Office of Pharmacy Affairs assists the panel. The ADR panelists cannot have any conflict of interests.[6] The primary responsibility of the ADR Panel is to review petitions, conduct proceedings, and make binding and final decisions.[7]

Administrative Dispute Resolution Process

The ADR process consists of: (1) initiation of an action; (2) request for additional information; (3) proceedings or hearings; and a (4) final agency decision.

Initiation of an Action. A covered entity or manufacturer initiates an action by filing a petition with HRSA along with sufficient documentation to support the claim within three years of the alleged violation.[8] The petition must allege damages that exceed $25,000.[9] The preamble to the Rule states that a three-year

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[1] The Rule incorporates provisions of the Federal Rules of Civil Procedure (FRCP) and Federal Rules of Evidence. Thus, the ADR process is similar to litigation in federal court. The Rule will be codified at 42 C.F.R. § 10.2 - § 10.24.
[2] Associations or organizations may file petitions on behalf their covered entity members.
[3] The ADR Board is made of at least six members equally taken from three federal agencies within HHS.
[4] 42 C.F.R. § 10.20; 85 Fed. Reg. 80,644.
[5] 42 C.F.R. § 10.20; 85 Fed. Reg. 80,632, 80,644.
[6] 42 C.F.R. § 10.20(b); 85 Fed. Reg. 80,632, 80,644.
[7] 42 C.F.R. § 10.20(c); 85 Fed. Reg. 80,632, 80,644.
[8] This petition must be written and satisfy the pleading requirements of the Federal Rules of Civil Procedure 8, 10, and 11. The petitioner must provide a copy of the petition to the respondent within 3 days of filing a petition. 42 C.F.R. § 10.21(a); 85 Fed. Reg. 80,632, 80,645.
[9] 42 C.F.R. § 10.21(b); 85 Fed. Reg. 80,632, 80,645.

limitation period was selected because it corresponds to the period that both covered entities and manufacturers are required to maintain documents for 340B Program purposes. According to HHS, the parties should attempt to resolve the dispute in good faith before filing a petition.[10] Multiple parties may consolidate claims against another party and associations may bring claims on behalf of covered entities, but not manufacturers.[11]

Covered entities may claim that they have been overcharged by a manufacturer for a covered outpatient drug, including that the manufacturer has limited the covered entity's ability to purchase the drugs at the 340B price.[12] Manufacturers may claim that a covered entity has violated the duplicate discount or diversion prohibitions, which may include a claim that the covered entity is not eligible to participate in the 340B Program.[13] An opposing party must respond in a designated timeframe.[14] Notably, a manufacturer must conduct a formal audit of the covered entity before submitting a petition through the ADR process.[15] If the opposing party fails to respond, the ADR Panel may decide in favor of the petitioner.[16]

Request for Additional Information. The ADR Panel may allow a covered entity to request additional information from a manufacturer. The ADR Panel may also request additional information from either party.[17] If a party has failed to respond to an information request, the ADR Panel may decide against the party regarding the evidence or take other adverse action.[18]

Proceedings or Hearings. The ADR Panel is free to determine and design the ADR proceedings and may issue additional instructions to the parties.[19] Federal rules applicable to court proceedings and evidentiary matters apply to ADR proceedings unless the parties agree otherwise or the ADR Panel dictates otherwise.[20] If the ADR Panel determines that "material" facts are in dispute, the ADR Panel will conduct an evidentiary hearing, which may be in-person or through video conference.[21]

Final Agency Decision. The ADR Panel issues a decision based on a vote by a majority of the panel that the "preponderance" of evidence demonstrates that a violation has occurred.[22] This decision is "precedential" and binding on the parties unless the case is appealed to court.[23] The preponderance of the evidence standard means that there is a greater than 50 percent likelihood that the claim is accurate (as compared to higher evidentiary standards typically applied in criminal cases). A decision that is precedential establishes case law that will be followed by the ADR Panel in subsequent cases. So, for

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[10] 85 Fed. Reg. 80,632, 80,633 ("The ADR process is not intended to replace these good faith efforts, [sic] but should be considered as a last resort in the event good faith efforts to resolve disputes have failed.").
[11] A combined claim is referred to as a "joint claim" for multiple covered entities and a "consolidated claim" for multiple manufacturers.
[12] 42 C.F.R. § 10.21 (c)(1); 85 Fed. Reg. 80,632, 80,645.
[13] 42 C.F.R. § 10.21 (c)(2); 85 Fed. Reg. 80,632, 80,645.
[14] The respondent must generally file its response to the petition within 21 days after its receipt of the petition. Fed. R. Civ P. 12.
[15] 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21 (c)(2); 85 Fed. Reg. 80,632, 80,645.
[16] The petitioner must submit evidence sufficient to support its claim for damages. 42 C.F.R. § 10.21(f); 85 Fed. Reg. 80,632, 80,645.
[17] 42 C.F.R. § 10.22(b); 85 Fed. Reg. 80,632, 80,645.
[18] The ADR Panel may (1) decide that facts have been established against the interest of the nonresponsive party; (2) prohibit the party from presenting or contesting a particular issue; (3) exclude evidence; or (4) issue a judgement in the proceeding or dismiss a proceeding. 42 C.F.R. § 10.22(c); 85 Fed. Reg. 80,632, 80,645.
[19] 42 C.F.R. § 10.23(b)-(d); 85 Fed. Reg. 80,632, 80,645.
[20] 42 C.F.R. § 10.23(a)-(c); 85 Fed. Reg. 80,632, 80,645.
[21] 42 C.F.R. § 10.23(a); 85 Fed. Reg. 80,632, 80,645.
[22] 42 C.F.R. § 10.24(a); 85 Fed. Reg. 80,632, 80,645.
[23] 42 C.F.R. § 10.24(d); 85 Fed. Reg. 80,632, 80,646.

example, if the ADR Panel decides that a prescription written outside the covered entity can be filled with 340B drugs if the covered entity made a referral to the outside entity, that holding will be followed in subsequent cases that involve the same fact pattern. Significantly, the ADR Panel does not have any authority to enforce the decision. The ADR Panel sends the decision to the parties and to HRSA "for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities."[24] HHS' comments indicate that final decisions will be published, presumably on HRSA's website.[25]

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We hope that this summary will assist your organization. If you have any questions regarding the ADR process, please do not hesitate to contact Barbara Straub Williams at Barbara.Williams@PowersLaw.com or 202-872-6733 or Mark Ogunsusi at Mark.Ogunsusi@PowersLaw.com or 202-872-6759.

[24] 42 C.F.R. § 10.24(e); 85 Fed. Reg. 80,632, 80,646.
[25] 85 Fed. Reg. 80,632, 80,641.