HRSA RELEASES PROPOSED RULE GOVERNING THE ADMINISTRATIVE DISPUTE RESOLUTION PROCESS FOR 340B-RELATED CLAIMS

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Food, Drugs, Medical Devices and Cosmetics (FDA) Alert

On August 12, 2016, the Health Resources and Services Administration ("HRSA") released a notice of proposed rulemaking (the "Proposed Rule") to formally regulate the administrative dispute resolution ("ADR") process for reviewing claims and resolving disputes under the 340B Drug Pricing Program (340B Program).[1] The Proposed Rule addresses the implementation of a binding ADR process to resolve two types of disputes arising under the 340B Program: (1) covered entity claims alleging an overcharge on the 340B pricing of a covered drug sold by a manufacturer, and (2) manufacturer claims pursuant to an audit of a covered entity alleging the covered entity has violated the prohibition on duplicate discounts or the prohibition on reselling or transferring 340B drugs to any person that is not a "patient" of the covered entity — i.e., drug diversion. The Proposed Rule develops a formal ADR process with the establishment of a 340B ADR Panel ("ADR Panel" or "Panel") to resolve the two categories of claims listed above and issue a binding agency decision on both parties.

HRSA states the ADR process is a "last resort in the event good faith efforts to resolve disputes have not been successful." HRSA notes that it has otherwise encouraged manufacturers and covered entities to work in good faith to resolve 340B Program compliance disputes, as they have traditionally done. In this regard, the 340B Program is a unique federal program, since HRSA referees the 340B Program, but any noncompliance in almost every instance only harms one of two competing market participants: drug manufacturers or safety net facilities eligible to participate in the 340B Program.
HRSA is accepting public comments on the Proposed Rule until October 11, 2016.

BACKGROUND

Section 340B of the Public Health Services Act requires the Secretary of the Department of Health and Human Services to promulgate regulations to establish and implement an administrative dispute resolution process for claims by covered entities and manufacturers pursuant to drugs purchased and sold under the 340B Program.[2] In 1996, HRSA published an informal dispute resolution process,[3] and in 2010, issued another advanced notice of proposed rulemaking ("ANPRM") requesting comments on the development of the ADR process.[4] The Proposed Rule replaces the 1996 informal guidance and takes into consideration 14 comments received from the 2010 ANPRM.

ESTABLISHMENT OF A 340B ADR PANEL (42 C.F.R. § 10.20)

The Proposed Rule establishes a mechanism for the staffing of an uncompensated 340B ADR Panel comprised

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of three members chosen from a roster of eligible individuals in addition to one ex officio, non-voting member of the Office of Pharmacy Affairs staff. The roster of eligible individuals will be comprised of federal employees, such as from the Centers for Medicare and Medicaid Services or the U.S. Department of Veterans Affairs with an expertise with the 340B Program. With this said, HRSA specifically sought comment on the proposed size and composition of the ADR Panel. Any member of the Panel may be removed for cause in the event of a conflict of interest involving a financial interest, a family or close relation to a party involved, and current or former business or employment relation to a party.[5]

CLAIMS (42 C.F.R. § 10.21)

The ADR process is limited to two claims: (1) claims by a covered entity where it has been overcharged by manufacturers for purchased 340B drugs, and (2) claims by a manufacturer, after conducting an audit, where the covered entity has violated the prohibition on diversion and/or duplicate discounts. In order to file a claim, covered entities and manufacturers must submit their claims to the ADR Panel within three years of the date of the alleged violation. HRSA notes that this claims filing deadline is consistent with current 340B compliance records retention requirements. Further, the Proposed Rule requires that any records relevant to a claim must be maintained until a final agency decision is issued (presumably even beyond the current three-year records retention window).[6] The provision is noteworthy in establishing a clear HRSA standard for when a remedy related to a 340B compliance violation may be consider time barred.

As part of the formal ADR process, HRSA proposes that the parties submit documentation supporting a claimant's allegations. For example, a manufacturer must submit documentation involving a final audit report of the covered entity evidencing duplicate discounts or reselling or transferring 340B drugs to a person who is not a patient of the covered entity. The covered entity's documentation may include an invoice evidencing purchases at the 340B drug price that resulted in the overcharge. In this regard, HRSA notes in commentary that pursuant to its authority under Section 340B(d)(1)(B) of the Public Health Service Act, it is developing a system to verify the 340B ceiling price and allow covered entities access to that data so that they can better assess if they are receiving an appropriate 340B price.

In addition, under the Proposed Rule, covered entities would be permitted to file information requests through the ADR process to assess if they have a 340B pricing claim. A covered entity seeking discovery of information and documentation from a manufacturer may submit a written request to the ADR Panel no later than 20 business days after HRSA notifies the entity that its claim will proceed for review to the Panel. Notably, there is no equivalent process for the manufacturer to request discovery from a covered entity.

CONSOLIDATION OF CLAIMS (42 C.F.R. § 10.21(C))

The ADR process permits covered entities and manufacturers to file joint claims. Thus, multiple covered entities may file joint claims of overcharges against one manufacturer, and multiple manufacturers may file joint claims against a single covered entity.

However, there are several key distinctions between the parties when permitting such consolidation of claims. First, an association or organization may file overcharge claims on behalf of multiple covered entities

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against the same manufacturer; however, the Proposed Rule does not permit joint claims filed by associations or organizations on behalf of manufacturers. Second, unlike covered entities, manufacturers are required to request a consolidation of claims from the ADR Panel, and the Panel must determine that such consolidation is "appropriate and consistent with the goals of fairness and economy of resources."[7] Finally, HRSA notes that manufacturers will likely have a difficult time consolidating claims in light of the fact that manufacturer claims must each be predicated by a prior audit of the covered entity. HRSA specifically requests comment on how manufacturers can meet this obligation.

ADR PROCESS (42 C.F.R. §§ 10.20, 23)

[8]Under the Proposed Rule, the ADR Process is then designed to proceed as follows:

- As noted above, covered entities and manufacturers would have 3 years from the date of payment or sale, respectively, to file a written claim.[9]
- Within 3 business days of submitting the claim, the party must send a written notice to the opposing party, including a summary of the documents submitted as part of the claim. Of note, in the Proposed Rule, the opposing party is not required to be provided a complete copy of all documents submitted in the claim against it.
- As evidence demonstrating that the requirements for filing a claim have been satisfied, the opposing party must submit confirmation of the receipt or acknowledgement of receipt within 3 business days.
- The Healthcare Systems Bureau ("HSB") housed within HRSA will be responsible for making a determination as to whether a claim is reviewed by the ADR Panel.
- The party filing the claim must respond to HSB's request for additional information within 20 business days of such request.
- HSB will make a determination within 20 business days after receiving the claim whether the required documentation satisfies the requirements of permitted claims before forwarding onto the ADR Panel for review.
- The opposing party will have 20 business days from the time HSB notifies the parties the claim will proceed to the Panel for review to submit a written response to the ADR Panel; if no response is received, the Panel will proceed with its review based on the information submitted by the party filing the claim.
- The Panel will make its deliberations regarding the claim in a closed session, and based on the Proposed Rule, no opportunity for oral argument or presentations to the ADR Panel will be afforded.
- The Panel will draft an agency decision letter, which is then circulated to the parties prior to issuance. The parties will have 20 business days to respond. After a review of the responses, the Panel will issue a final agency decision letter, representing a majority decision of the Panel.

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- The final decision will also be forwarded to the HSB for enforcement action or to apply sanctions as appropriate. Of note, while HRSA does not preclude more substantial sanctions, the Proposed Rule only discusses compensation to the affected party related to the violation.

Notably, the Proposed Rule does not impose any timelines on the ADR Panel for reviewing a party's claim nor does it discuss an appeal process, although HRSA notes that the decision of the ADR Panel will be binding "unless invalidated by a court of competent jurisdiction in accordance with Section 340B(d)(3)(C)." HRSA also notes that it may begin publishing summaries of the claims that go through the process, including the parties' names and key findings, which would appear to be akin to their process for publishing HRSA audit findings.

CONCLUSION

In summary, the Proposed Rule introduces a formal mechanism by which an ADR Panel reviews claims from manufacturers and covered entities as they pertain to 340B-related claims. Consistent with the 340B statute's limitations on the scope of the ADR process, the Proposed Rule does not include disputes involving orphan drug classifications or group purchasing organization prohibition violations.[10] Thus, HRSA anticipates the volume of claims to be low and, therefore, takes the position that the Proposed Rule will not be economically significant.

Notwithstanding that assessment, particularly given the opportunity to consolidate claims, the ADR process, if finalized, will likely open a significant new front in the ongoing battle between manufacturers and covered entities that have continued to clash in Congress, with HRSA, and in the day-to-day operation of their 340B Programs as a result of the growth in size and scope of the 340B Program and their fundamentally differing views on the appropriate purpose of the 340B Program. Further, particularly if ADR claims are appealed beyond the ADR Panel, it may also open the 340B Program regulatory regime to much more rigorous scrutiny, where it has been subject to significant challenge. In this regard, while the ADR rule itself is on much more solid footing,[11] HRSA's interpretations of key pricing, diversion, and duplicate discount provisions may be subject to more intense review in this more formal process.

Given the stakes, covered entities and manufacturers should follow the progress of the Proposed Rule closely and may wish to comment in advance of the October 11 deadline.

Notes:

[1] *340B Drug Pricing Program: Administrative Dispute Resolution*, 81 Fed. Reg. 53,381 (hereinafter, Proposed Rule) (August 12, 2016).

[2] 42 U.S.C. § 256b(d)(3) (2014).

[3] *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406 (Final Notice) (December 12, 1996).

[4] *340B Drug Pricing Program Administrative Dispute Resolution Process*, 75 Fed. Reg. 57,233 (September 20, 2010).

[5] *See* Proposed Rule, 81 Fed. Reg. at 53,382.

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[6] Note this is in contrast to the Omnibus Guidance proposing a five-year record retention period for manufacturers and covered entities to maintain auditable records. *See 340B Drug Pricing Program Omnibus Guidance*, 80 Fed. Reg. 52,300, 52,309 (August 28, 2015).

[7] *See* Proposed Rule, 81 Fed. Reg. at 53,387.

[8] *See id.* at 53,383–85.

[9] *See id.* at 53,383.

[10] *See Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 45 (D.D.C. 2014) (hereinafter, *PhRMA v. HHS*) (where the D.C. District Court has held that HRSA's rulemaking authority was specifically limited by Congress and does not extend to orphan drug rulemaking).

[11] Under the Public Health Service Act, Congress specifically authorized HRSA to establish an administrative dispute resolution process, as was recognized in *PhRMA v. HHS*. *See* 42 U.S.C. § 256b(d)(3)(A) (2014).

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