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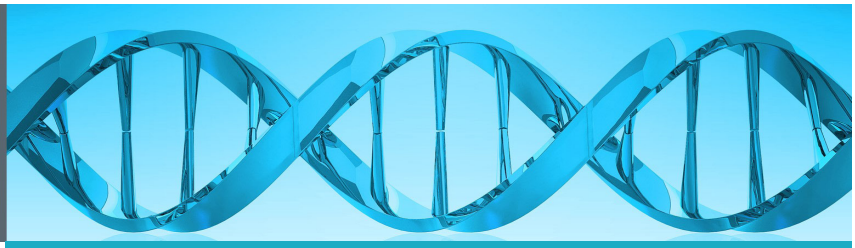

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New 340B Dispute Resolution Process: Will It Level the Playing Field?

In this Issue:

On August 12, HRSA published a formal proposed rule regarding a 340B Drug Pricing Program administrative dispute resolution (ADR) process. The rule can be found here. HRSA's use of the administrative rulemaking process is a rare occasion given its perceived limited rulemaking authority granted by Congress. It is critical that stakeholders review HRSA's proposal to consider how it would impact current and future 340B-related disputes, and to determine if the proposed rule goes far enough to level the 340B pricing playing field.

The proposed ADR rule implements a law which requires the Secretary of Health and Human Services (HHS) to establish and implement a binding ADR process for certain disputes arising under the 340B program. When finalized, this proposed rule appears to replace the 340B Program's guidelines on the informal—and seldom used—dispute resolution process. We encourage covered entities, manufacturers and other stakeholders to carefully review the ADR proposal and submit comments on or before October 11, 2016.

The following are key highlights from HRSA's proposal:

- **The ADR process is limited to three subject matters,** including covered entity allegations that a manufacturer charged prices that exceed the 340B ceiling price and manufacturer allegations that a covered entity either diverted 340B-priced drugs to non-patients or created a duplicate discount. Notably, group purchasing organization prohibition and orphan drug matters are beyond the scope of ADR process

- **Decisions of the 340B ADR Panel would be binding,** unless overturned by a court of competent jurisdiction
- **Covered entities may have the right to file civil actions challenging ADR decisions**
- **HRSA proposed a 3-year time bar** that would bar claims that exceed 3 years from the date of the drug sale, payment, or other event that form the basis for the allegations at issue
- **Multiple covered entities may consolidate claims** against the same manufacturer for the same drug(s) in one administrative proceeding. Consolidated claims are also permitted on behalf of covered entities by associations or organizations representing their interest
- **Covered entities may obtain additional information from manufacturers via the ADR process** but the proposal does not go as far as imposing sanctions on manufacturers that fail to respond to such requests
- Comments are due on or before October 11, 2016

ADR Panel Composition and Purpose

The rule proposes to create a decision-making body, referred to as the 340B ADR Panel, to resolve claims between covered entities and manufacturers regarding overcharges, diversion, and duplicate discounts. The ADR Panel will include three voting members and one ex-officio, non-voting member. The voting members will be selected from a roster of eligible individuals, comprised of Federal employees with demonstrated expertise or familiarity with the 340B program. The ex-officio member will be selected from the staff of the Office of Pharmacy Affairs (OPA). For each claim, the Healthcare Systems Bureau (HSB) will review the qualifications of the individuals on the 340B ADR Panel roster and select those with expertise or familiarity with the appropriate aspects of the 340B program. Individuals serving on the Panel may be removed for cause, such as where there is a conflict of interest.

The 340B ADR Panel is not intended to replace good faith efforts to resolve disputes, but rather act as a last resort should good faith efforts fail. The decisions of the Panel will be binding on all parties involved, unless invalidated by an order of a court of competent jurisdiction.

Something that should not be overlooked is the concept that a final decision by the ADR Panel may be considered a final agency decision that would permit judicial review through the Administrative Procedure Act. This could give covered entities access to courts that is otherwise foreclosed by Supreme Court precedent denying covered entities a private right of action under the 340B statute. That said, the action would likely be against HHS regarding its ADR decision which would be subject to high level of deference by the court. In any event, this is still a small step in the right direction for covered entities.

Initiating the ADR Process

The party filing the claim must include documentation sufficient to support its claim. It is unclear in the proposed rule what burden must be met by the filing party in order to proceed to the ADR process. Manufacturer claims alleging diversion or duplicate discounts are eligible for the ADR process only after the manufacturer has conducted an audit of the covered entity. Manufacturers are required to demonstrate to HRSA that they have reasonable cause to believe a covered entity violated the 340B program rules and regulations before HRSA will permit a manufacturer to audit a covered entity. If approved by HRSA, a manufacturer is required to use an independent public accounting firm to conduct the audit and shall bear the expense of the audit.

This process appears to remain intact in the ADR proposal as HRSA proposes to require manufacturers to submit a copy of the final audit report with its claim to initiate the ADR process. Once a claim is submitted, the 340B ADR Panel will consider all documentation submitted by the parties and may request additional information or clarification. The Panel may also consult subject matter experts from OPA. Finally, the Panel's decision must reflect a majority of the membership but need not be unanimous.

Consolidation of Claims and Data Requests

Pursuant to statutory requirements, the proposed rule permits the consolidation of multiple claims against the same entity brought by covered entities or manufacturers. Associations or organizations representing covered entities may also assert claims on behalf of their members. Note that such organizational representation is not permitted for manufacturers.

Covered entities may obtain information from manufacturers and relevant third parties through the 340B ADR process. This is significant because covered entities do not have the authority to audit manufacturers; however, the proposed rule does not appear to provide any kind of enforcement mechanism against a manufacturer who refuses to provide information requested through the ADR process. Instead, the proposal indicates that the ADR panel will render a decision based only on the original documents that the covered entity submitted. This could be problematic should the covered entity need critical documentation from the manufacturer to provide final support of its claims. For example, manufacturers may have pricing or purchasing data for historical time periods that covered entities do not have access to.

3-Year Time Limitation

The rule proposes a claim filing deadline of three years from the date of the sale or payment at issue. This timeframe is meant to be consistent with the record retention expectations for the 340B program.

Agency Decision-Making Process

Once the 340B ADR Panel has reviewed the claim and all supporting documentation provided by all parties involved, it will prepare a draft agency decision letter detailing the Panel's findings and conclusions regarding the alleged violation(s). As proposed, the Panel will issue a draft decision that will be sent to all parties for review and comment. The Panel will review and consider all comments prior to issuing a final agency decision letter. Once finalized, the agency decision letter will be submitted to HSB to take further enforcement action or apply sanctions, as appropriate. Such sanctions may include repayment of diverted drugs or a refund of an overcharge.

As proposed, HRSA may also make general information about the underlying dispute and its findings public via publication on its website. This will ensure transparency, but may also have a chilling effect on parties considering bringing a claim. Proposing that HRSA clarify exactly what it intends to include in a website publication may help to minimize that effect. As a result, we encourage covered entities to comment on this issue, and also encourage HHS to amend the sanctions discussion to confirm that HRSA will have leeway to impose additional sanctions that it develops pursuant to other administrative action, including, but not limited to, sanctions contemplated under its proposed ceiling price regulations for knowingly overcharging covered entities.

HRSA Seeks Comments

HRSA is soliciting comments in the following areas:

- The size and composition of the Panel, including whether the membership should be consistent or vary with complexity of the case and whether the OPA member should have voting rights
- The three-year limitation on claims submission
- The feasibility of producing specific documentation to support covered entity claims of overcharging
- The grounds under which consolidation of manufacturer claims against covered entities would be consistent with fairness and economy of resources
- How manufacturers requesting a consolidated claim against a covered entity can satisfy the audit requirement
- Whether the draft agency decision letter, comment period, and final agency decision letter process will facilitate or hinder the fair, efficient, and timely resolution of claims

Anticipating that the 340B Program will continue to undergo changes implemented in future guidance (e.g., updated patient definition, ceiling price sanctions, etc.), the ADR Process must be fluid to account for changes on the horizon. We encourage stakeholders to review the proposed rule and offer comments in areas that you believe require further clarity to protect the interests of your organization and to protect the integrity of the 340B program overall. Our 340B team members are happy to assist with the development of comments and answer any questions that you may have.

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For More Information

For questions regarding this information, please contact one of the authors below, a member of Polsinelli's Health Care practice, or your Polsinelli attorney.

Mary Beth Blake
816.360.4284
mblake@polsinelli.com

Lauren Z. Groebe
816.572.4588
lgroebe@polsinelli.com

Travis F. Jackson
310.203.5343
tjackson@polsinelli.com

Emily Shaw
816.218.1291
eshaw@polsinelli.com

Kyle A. Vasquez
312.463.63384
kvasquez@polsinelli.com

To contact a member of our Health Care team, click here or visit our website at www.polsinelli.com > Services > Health Care Services > Related Professionals.

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