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HHS Goes Back to The Drawing Board on the 340B ADR Process

Article By:

Emily J. Cook

Cathy Ren

Citing “policy and operational challenges” with the current 340B Administrative Dispute Resolution (ADR) Process, the US Department of Health and Human Services (HHS) has issued a new Proposed Rule to modify the current ADR Process. The Proposed Rule would materially simplify and speed up the ADR Process, but leaves open questions as to the specific nature and scope of disputes that can be brought to the ADR Panel for review. Further, like the current ADR Process, the proposed process will likely only serve as the starting point of a formal litigation process to resolve disputes between 340B Covered Entities and drug manufacturers. The Proposed Rule is available here. Our prior analysis of the rule implementing the current ADR Process is available here.

IN DEPTH

According to HHS statements in the preamble to the new Proposed Rule, the proposed ADR Process would differ from the current ADR Process in several key ways:

1. Removal of the requirements to follow the Federal Rules of Evidence and Rules of Civil Procedure

2. Limiting the ADR Panel members to 340B subject matter experts from the Office of Pharmacy Affairs

3. Requiring all parties to engage in good-faith dispute resolution efforts before initiating the ADR process

4. Limiting claims to disputes involving overcharges, duplicate discounts and diversion

5. Establishing a reconsideration process for ADR Panel decisions.

In addition to these explicitly cited differences, other material differences include that the new

Proposed Rule would remove the monetary threshold on claims before the ADR Panel, would suspend claims brought to the ADR Panel if the claim involves the same or similar issues pending in Federal court, and would no longer make the ADR Panel decisions precedential.

The new Proposed Rule responds to the primary challenge to the current ADR Process, which is that it was established in a manner that allegedly violates the Administrative Procedure Act. Specifically, both 340B Covered Entities and drug manufacturers have sued HHS claiming that the final rule establishing the ADR Process did not follow proper notice and comment rulemaking and was based on a proposed rule that HHS had previously withdrawn.

The Proposed Rule also appears to address certain other criticisms that have been raised about the current ADR process. Notably, the Proposed Rule explicitly provides that claims would be suspended if they involve the same or similar issues pending in federal court. This proposed change is almost certainly a response to the filing of ADR claims by 340B Covered Entities alleging drug manufacturer overcharges stemming from restrictions placed on 340B purchasing for drugs dispensed through contract pharmacies, while the drug manufacturers have argued in federal court that those restrictions are legal. Although the ADR Panel initially accepted these disputes for review and the parties spent more than a year working through the ADR process, the claims were recently dismissed due to the ongoing litigation. Under the Proposed Rule, these claims would have been suspended upon filing for the duration of the litigation.

The Proposed Rule also appears to address concerns about the scope of claims that can be brought by drug manufacturers to the ADR Panels. The statutory scope of the ADR claims is limited to overcharge claims brought by Covered Entities against drug manufacturers and duplicate discount and diversion claims brought by drug manufacturers against Covered Entities. The ADR Process provides that drug manufacturer restrictions on the purchase of drugs at the 340B price could be filed as overcharge claims, which is not contemplated in the text of the 340B statute.

The current ADR Process also allows drug manufacturers to claim that a specific 340B Covered Entity is not eligible to participate in the 340B Program. The Proposed Rule would remove this language to simply state that the ADR Process could be used for claims of overcharging, drug diversion and duplicate discounts, without specifying the specific types of claims that Covered Entities and drug manufacturers may respectively bring.

While it is not entirely clear from the preamble text whether these changes are intended to indicate that restrictions imposed by drug manufacturers on 340B purchasing and Covered Entity eligibility are no longer within the scope of the ADR process, the preamble text indicates that HHS believes that the Proposed Rule reduces the scope of claims that can be brought to the ADR Process from the types of claims currently permitted.

Another concern that the Proposed Rule appears to attempt to address is the concern that the ADR Panel decisions would be used as a means to “back-door” rulemaking. The 340B Statute has been interpreted to prohibit HHS from using notice and comment rulemaking to establish requirements for participation in the 340B Program. Under the current rule, the ADR Panel decisions are precedential. In theory, even though the decisions of the ADR Panel are binding only on the parties to the dispute, this means that the interpretation of 340B Program requirements resulting in the decision would effectively become rules governing all participants in the 340B Program.

Because the ADR Panels have not issued any final decisions, this theory has never played out in practice. The new Proposed Rule would remove the reference to making the decisions of the ADR

Panels precedential, but it would remain a possibility that the decisions would nevertheless be relied upon in future disputes and be treated by drug manufacturers and Covered Entities as program requirements. As noted below, however, the change in the composition of the ADR Panel membership and delegation of any administrative review decisions to the Health Resources & Services Administration (HRSA) Administrator suggests that the ADR Panel decisions will hone closely to existing 340B Program guidance.

Many of the changes to the Proposed Rule would remove the structure and formality of the current process, making the ADR Process more accessible to Covered Entities and placing the entirety of the ADR Process and decision-making within the purview of HRSA. The removal of the use of the Federal Rules of Evidence and Civil Procedure would mean that the process could be navigated without requiring use of legal counsel. This change, coupled with the removal of the damages threshold, would mean that more Covered Entities are likely to file claims with the ADR Panel. These changes would be less likely to increase the volume of drug manufacturer claims, particularly because the 340B Statute requires drug manufacturers to conduct audits of Covered Entities before bringing a claim to the ADR Panel and the cost of such audits (which must be borne by the drug manufacturer) is only warranted when the expected damages are large enough to justify the audit cost.

The change in the ADR Panel composition—from requiring representatives from HRSA, the Centers for Medicare & Medicaid Services (CMS) and the HHS Office of General Counsel (OGC), to requiring that all ADR Panel members be 340B subject matter experts from within the Office of Pharmacy Affairs (OPA)—also suggests that the decisions of the ADR Panels would closely follow existing 340B Program guidance. Under the prior structure, either the CMS or the OGC representative could have determined the outcome of the ADR Panel decision in a manner that would not necessarily have followed prior 340B Program guidance.

The Proposed Rule would add an administrative appeals process that is not present in the current rule. The Proposed Rule would allow for either party to an ADR Panel to request a reconsideration of the decision by the HRSA Administrator (or their designee), as well as the option for the HRSA Administrator to initiate such a reconsideration review without a request from either party. Although the Proposed Rule includes a provision that would allow the HRSA Administrator to consult with HHS staff, as needed, during the reconsideration process, much like the change to make the ADR Panel comprised of entirely OPA staff, the proposed reconsideration process appears to retain HRSA control over the outcome of the decisions. This suggests that there would be limited opportunity for deviation from existing OPA policies in the decision process. If subject to reconsideration review, the decision of the HRSA Administrator would be the final agency action, which could then be appealed in federal court.

Consistent with the 340B Statute, the Proposed Rule would not modify certain concerns expressed by drug manufacturers that derive directly from the 340B Statute. The 340B Statute requires that drug manufacturers conduct audits of Covered Entities prior to bringing a claim to the ADR Panel. There is no statutory prior-audit requirement imposed on Covered Entity claims against drug manufacturers under the statute. In addition, the 340B Statute allows for associations and organizations representing Covered Entities to bring claims on behalf of multiple Covered Entities against a single drug manufacturer, but provides no similar option for associations or organizations of drug manufacturers. Despite statements from drug manufacturers in response to the current rule that these provisions create an inequitable structure for drug manufacturers under the ADR Process, the Proposed Rule follows the 340B statutory provisions.

SUMMARY

We have provided a chart below comparing the current ADR Process and the process under the Proposed Rule.

Issue	Current ADR Process	Proposed ADR Process
Panel Member Agencies	• Health Resources and Services Administration Centers for Medicare & Medicaid Services Office of General Counsel	• Health Resources and Services Administration, limited to 340B subject matter experts from the Office of Pharmacy Affairs
Jurisdiction Subject	• Overcharges • Diversions • Duplicate Discounts • Covered Entity Eligibility	• Overcharges • Diversion • Duplicate Discounts
Jurisdiction Amount	• $25,000	• None; but note that drug manufacturers must incur applicable audit costs before bringing a claim (similar audit costs do not apply to

Issue	Current ADR Process	Proposed ADR Process
		Covered Entities bringing an ADR claim)
Prior Resolution Efforts		
	• Manufacturers must audit Covered Entity (if manufacturer is bringing the claim)	• Parties must engage in good-faith efforts to resolve the dispute
		• Manufacturers must audit Covered Entity (if manufacturer is bringing the claim)
Joint or Consolidated Claims		
	• Covered Entities and Covered Entity associations and organizations can bring consolidated and joint claims against a single manufacturer	• Covered Entities and Covered Entity associations and organizations must request to bring consolidated and joint claims against a single manufacturer, determination is based on Covered Entity(ies) consent
	• Manufacturers must request to file consolidated claims against the same Covered Entity, determination is based on fairness and economy of resources	• Manufacturers must request to file consolidated claims against the same Covered Entity, determination is based on fairness and economy of

Issue	Current ADR Process	Proposed ADR Process
		resources
ADR Proceedings		
	• Governed by Federal Rules of Civil Procedure and Federal Rules of Evidence	• Governed by rules set forth at 42 CFR §§ 10.21-10.23
Appeals		
	• Discretionary review by HHS Secretary	• Either party may request reconsideration by the HRSA Administrator
		• Discretionary review by HHS Secretary
Final Decision		
	• ADR Panel decision is a Final Agency Action, appealable in federal court	• ADR Panel decision is a Final Agency Action, appealable in federal court
	• ADR Panel decision is binding on the parties to the decision	• ADR Panel decision is binding on the parties to the decision
	• ADR Panel decision is	

Issue	Current ADR Process	Proposed ADR Process
	precedential	

The deadline for submitting comments in response to the new Proposed Rule is January 30, 2023.

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