Illinois Health and Hospital Association

340B Fact Sheet

April 2024

340B Drug Pricing Program; Administrative Dispute Resolution Regulation (RIN 0906-AB28)

On April 19, 2024, the U.S. Dept. of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) published a final rule modifying the 340B Program's administrative dispute resolution (ADR) process.

The Affordable Care Act required the HHS Secretary to promulgate regulations establishing and implementing a binding 340B ADR process to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers, and (2) claims by manufacturers that a covered entity has violated the prohibition on diversion or duplicate discounts. For manufacturers to bring forth a claim under the ADR process, they must first conduct an audit of the covered entity as authorized by section 340B(a)(5)(C) of the Public Health Services (PHS) Act. Covered entities and manufacturers are still encouraged to attempt to resolve disputes in good faith, but should such efforts fail this administrative process is meant to provide stakeholders the opportunity to have disputes evaluated in a timely, consistent, and fair and equitable manner.

The 2024 final rule modifies HHS' 2020 ADR final rule which was effective Jan. 13, 2021, but encountered policy and operational challenges when implemented. The 2024 final rule is intended to:

1. Establish a more accessible ADR process that reflects an administrative process rather than a trial-like proceeding;
2. Revise the structure of the 340B ADR Panel that resolves disputes so that it is comprised of 340B Program subject-matter experts;
3. Ensure that covered entities and manufacturers have attempted to resolve the dispute in good faith before proceeding through the ADR process;
4. More closely align the ADR process with statute to address disputes specific to diversion, duplicate discounts, and overcharges; and
5. Include a reconsideration process for parties that are dissatisfied with the 340B ADR Panel's decision.

A table outlining the changes between the 2020 and 2024 final rules is below. The 2024 final rule is effective June 18, 2024.

ISSUE	CURRENT ADR RULE	FINAL RULE
Panel Members	Equal number of Representatives from HRSA, the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of General Counsel.	Representatives limited to HRSA 340B subject matter experts from the Office of Pharmacy Affairs (OPA). ADR panel members must undergo an additional screening for conflicts of interest, and the HHS Secretary may remove any ADR panel member for any reason, even after assigned to a claim.
Jurisdiction Subject	Overcharges, including restrictions on access to the 340B price; diversion; duplicate discounts; and covered entity eligibility.	Overcharges, including restrictions on access to the 340B price; diversion, including covered entity eligibility where relevant to the diversion allegations; and duplicate discounts, including Medicaid managed care. Additionally, claims in these categories can go through the ADR process even if there are issues related to the claims pending before federal courts.
Jurisdiction Amount	$25,000	None, but drug manufacturers must audit (and incur related costs) a covered entity before bringing a claim to the ADR process. There are not similar audit requirements and costs for covered entities bringing an ADR claim.
Prior Resolution Efforts	Manufacturers must audit covered entity (if manufacturer is bringing the claim)	Covered entities and manufacturers must engage in good-faith efforts to resolve the dispute before bringing a claim to the ADR process. Additionally, manufacturers must audit covered entities before bringing a claim to the ADR process.
Joint or Consolidated Claims	Manufacturers must request to file consolidated claims against the same covered entity; determination is based on fairness and economy of resources; associations or organizations are not permitted to represent manufacturers in their claims. Covered entities may consent to jointly filing overcharge claims against the same manufacturer of the same drug if each has a permitted claim. Covered entities may also consent to	Manufacturers must request to file consolidated claims against the same covered entity; determination is based on fairness and economy of resources; associations or organizations are not permitted to represent manufacturers in their claims. Covered entities may consent to jointly filing overcharge claims. Covered entities may also consent to representation by an association or organization if the joint claim asserts overcharging by a single manufacturer for the same drug(s) and the claim includes a letter attesting to the agreement to participate by each

	representation by an association or organization.	covered entity and the point of contact for each covered entity.
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 reviews by the HHS Secretary are still allowed, and both the covered entity and the manufacturer must be informed of their reconsideration rights at the time a Panel decision is made.
Final Decision	The ADR Panel decision is binding on the disputing parties, and the ADR Panel decision is precedential.	The ADR Panel decision is a final agency action, appealable in federal court. The ADR panel decision and HRSA administrator reconsideration decision are both subject to review and reversal by the HHS Secretary. The ADR Panel decision is binding on the disputing parties; the ADR Panel has one year to resolve claims brought to them unless there are extenuating circumstances; the ADR Panel must notify disputing parties if the decision will take longer than one year.

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