

HRSA Aims for Swift Dispute Resolution with new 340B ADR Final Rule

On April 18, 2024, HRSA released its **2024 340B Administrative Dispute Resolution (ADR) Final Rule (2024 ADR Final Rule)** and it is largely favorable to covered entities (CEs) with pending ADR claims against drug manufacturers. HRSA previously published an ADR final rule outlining a more formal process that was similar to litigating a case in court, but the 2024 ADR Final Rule finalized changes that significantly reduced these formalities. In addition to making the overall process less formal, HRSA also intends to move through the ADR review process quickly by implementing short timelines for responding and submitting additional information. The 2024 ADR Final Rule will become effective on June 18, 2024.

This article highlights the biggest differences between the 2020 ADR Final Rule and the 2022 proposed rule that CE's should be aware of before filing ADR claims.

No Suspension of Claims – Covered Entity Manufacturer Contract Pharmacy Claims May Proceed

Based on public comments, HRSA opted to not finalize the proposed suspension of review of ADR claims with issues that are the “same as, or similar” to an issue pending in federal court. This is a big win for CE's because many used/intend to use the ADR process to resolve manufacturers' restriction of contract pharmacies, which is an issue that is also pending in federal courts right now.

HRSA ultimately made this decision not to finalize the suspension policy because it recognized that without the ADR process, CE's have limited avenues to resolve issues within the 340B Program. Also, pausing for federal court review would leave CE's without a solution if the federal courts were split on the issues, and this would defeat the purpose of the ADR process.

Finally, HRSA's 2024 ADR Final Rule makes it very clear that the process may be used for “claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price.” This language is directly in line with drug manufacturer contract pharmacy restrictions.

HRSA Will Transfer Pending ADR Claims to Proceed Under the New 2024 ADR Final Rule.

HRSA confirmed in the 2024 ADR Final Rule that ADR claims already filed will be transferred over to the new process and considered first in the queue, so they will be prioritized. CE's that already filed an ADR claim will be allowed to supplement the claim with additional information or

revise their petition considering the new process. CEs with pending claims should expect to hear from HRSA regarding the transfer shortly after the 2024 ADR Final Rule becomes effective.

Other Updates Finalized in 2024 ADR Final Rule

1. **Elimination of Legal Proceeding Rules.** The 2024 ADR Final Rule aims to be more accessible to CEs by eliminating the use of the Federal Rules of Civil Procedure and the Federal Rules of Evidence. This will make the process more straightforward for CEs, especially smaller CEs that may not have the resources to expend on claims against manufacturers or the ability to hire attorneys to assist.
2. **Demonstration of Good Faith Effort Required for ADR Claim.** CEs are now required to demonstrate that they attempted a good faith effort to resolve the issue before submitting an ADR claim. This good faith effort was not previously required and HRSA chose to not define it but confirmed that at least one written communication with the opposing party would satisfy the requirement.
3. **Removal of \$25,000 Minimum Threshold.** HRSA finalized removing the \$25,000 minimum threshold so now covered entities can file claims of any size. HRSA did this to accommodate smaller CEs that could not meet that threshold but still have claims that are significant to them. HRSA does not expect this to be the case with the majority of the ADR claims but did not want there to be a barrier for any CE.
4. **Claim Resolution within One (1) Year.** The ADR panel is tasked with resolving claims within one year of receipt of a complete claim. The ADR panel must notify the parties to the dispute if there is a situation beyond the control of the panel that will impact its ability to issue a decision within one year.
5. **ADR Final Decisions Will be Published on HRSA's Website.** Similar to HRSA 340B audit results, HRSA will publish summaries of the final decisions on a web page within 120 days of issuance.