

340B ADR Final Rule Factsheet

Wins, Revisions and Rejections in the Final Rule

This factsheet compares the final rules established by the **Department of Health and Human Services (HHS)** for the *340B Drug Pricing Program's Administrative Dispute Resolution (ADR)* process with the proposals and recommendations submitted by the **National Association of Community Health Centers (NACHC)**.

Overall:

NACHC supported several proposals that were implemented in the final 340B ADR rule, promoting a more accessible and user-friendly process. However, some recommendations, such as a definition of “overcharge” and eliminating the “good faith effort” requirement, were not adopted by HHS.

NACHC Supported Proposals Included in Final Rule (WINS):

- ❖ **More Accessible ADR Process:** HHS implemented a *more accessible* ADR process with provisions for easier participation by stakeholders without extensive legal expertise or high costs.
- ❖ **Less Formal Process:** The final rule *avoids* relying heavily on formal court rules, creating a less complex process than the one initially proposed in 2020.
- ❖ **Removal of Minimum Claim Threshold:** The requirement for a minimum dispute value of \$25,000 was *eliminated*, allowing claims for smaller amounts to proceed through ADR.
- ❖ **Reconsideration Process:** HHS established a process for parties to *appeal decisions* made by the ADR Panel which will be made of 340B subject matter experts from the HRSA Office of Pharmacy Affairs.
- ❖ **Combined Claims by Associations:** While many opposed requiring individual member signatures for claims submitted by associations, the final rule *allows* associations to submit an attestation confirming member agreement instead. The NPRM proposal was taken and finalized as proposed.

NACHC's Ongoing Policy Positions

- ❖ **Definition of "Overcharge":** Recommendation to define "overcharge" for the ADR process, including refusal to sell at 340B prices or with unreasonable conditions, was **not adopted by HHS**. The ADR Panel will rely on existing regulations and guidance.
- ❖ **ADR Process During Litigation:** Recommendation to eliminate the suspension of ADR during similar court cases wasn't implemented entirely. *However with the removal of provision § 10.23(a) in the NPRM, the final rule allows claims to proceed through ADR even if a similar issue is pending in federal court,*
- ❖ **"Good Faith Effort" Requirement:** HHS maintained the requirement for parties to make a good-faith effort to resolve disputes before initiating the ADR process. The final rule aligns more closely with the 1996 ADR process guidelines in this aspect.

The 2024 ADR Final Rule streamlines dispute resolution for the 340B program. It created a dedicated 340B ADR Panel composed of OPA 340B subject matter experts to review claims. This panel system allows for appeals of decisions. Additionally, the rule clarifies eligible dispute types (overcharges, duplicate discounts, diversion) and establishes clear timelines for claim filing, evidence submission, and responses. Existing claims will be smoothly transitioned into the new system.