

HHS Finalizes Rule on 340B Administrative Dispute Resolution Process

On April 18, the Department of Health and Human Services (HHS) finalized a long-delayed [rule](#) to establish a 340B Administrative Dispute Resolution (ADR) process as required under the Affordable Care Act. The rule is supposed to give 340B covered entities (CEs) better opportunities to address concerns where drug companies are not complying with certain aspects of the 340B program.

Specifically, the rule is supposed to create an administrative law dispute resolution process (rather than a trial-like process) using government officials with subject matter expertise from the Office of Pharmacy Affairs. It would allow CEs to bring forth claims when they have been overcharged by a drug company or when a drug company or its wholesaler denies access to 340B pricing. Diversions and duplicate discounts could also be examined via the ADR process.

Decisions would be required to be reached in no longer than a one-year timeframe with a reconsideration process available for either party dissatisfied with the initial decision. Parties would also have to have first worked in good faith to resolve the issue before utilizing the ADR process. Importantly, parties would not have to wait out cases where similar claims are pending in federal court before bringing them to the ADR process.

Contact WHA Vice President of Federal and State Relations [Jon Hoelter](#) with questions.

Other Articles in this Issue

- [WHA Board Meeting Highlights Advocacy Successes, Discusses Outlook for 2024](#)
- [WHA Hosts CMS and Hospital Leaders to Discuss Burden Reduction](#)
- [Aspirus Health CEO Matt Heywood Discusses Hospital Closure Impacts, Strategies for an Evolving Health Care Environment](#)
- [HHS Finalizes Rule on 340B Administrative Dispute Resolution Process](#)
- [Business Groups File Lawsuit to Block FTC Non-Compete Ban](#)
- [WHA Seeks Quality Improvement Stories for Annual Report](#)
- [Wisconsin Hospitals Participate in The Joint Commission Webinar](#)