Published on *The National Law Review* https://natlawreview.com

340B Program Administrative Dispute Resolution Final Rule: Key Takeaways

Article By:

Abdie Santiago

Pat G. Ouellette

On April 18, 2024, the U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) released a new Final Rule for its oft-criticized 340B Administrative Dispute Resolution (ADR) Program (2024 Final Rule).

The 340B ADR process was mandated by the Affordable Care Act and enacted in 2012. The intended purpose of the ADR process was to resolve claims by 340B covered entities that manufacturers overcharged for covered outpatient drugs and, alternatively, resolve manufacturer claims against covered entities for diversion or duplicate discount violations determined during manufacturer audits. The 340B ADR process is an administrative process that provides stakeholders with an opportunity to have disputes evaluated by a third-party when covered entities and manufacturers are unable to otherwise reach a mutually acceptable resolution. The ADR program, according to the 2024 Final Rule, never quite met its intended goal as HRSA "encountered policy and operational challenges with implementation" and no claims were ever settled pursuant to the existing process.

The ADR process for the 340B Program was not finalized by HHS and HRSA until 2020 (2020 Final Rule). This initial version of the ADR process was heavily criticized as being too rigid and in 2022, HRSA went back to the drawing board with a new proposed process (2022 Proposed Rule). The 2024 Final Rule largely finalizes HRSA's proposals and makes several other changes to the ADR Process.

A More Workable ADR Process

HHS noted in the 2024 Final Rule that it "believes that for the ADR process to be workable, it needs to be accessible." HHS also stated that it "recognizes that many covered entities are small, community-based organizations with limited means. These covered entities may not have the financial resources to hire an attorney to navigate the complex … requirements and engage in a lengthy, trial-like process, as envisioned in the 2020 final rule." Indeed, the revisions to the ADR process appear to do away with the trial-like aspects of the 2020 ADR process. In the name of facilitating covered entity utilization of the new ADR process, HHS finalized the following proposals:

- removing the $25,000 minimum threshold for filing an ADR petition;
- removing reliance on the Federal Rules of Civil Procedure and Federal Rules of Evidence during the ADR process; and
- providing for the automatic transfer of claims filed under the 2020 ADR process to the new 2024 ADR process.

Along with the procedural adjustments noted above, HHS and HRSA also finalized the following key changes:

- revising the structure and expertise requirements for ADR panel members;- Panel members would not include Administrative Law Judges;
- Panel members would be screened of potential conflicts of interest and removed by the Secretary when necessary.
- - Panel members would be 340B subject matter experts from the HRSA Office of Pharmacy Affairs (OPA);
- requiring all parties to work together in good-faith dispute resolution efforts before proceeding with the ADR process;
- - According to the 2024 Final Rule, this would include at least “one instance of written documentation demonstrating that the initiating party has made attempts to contact the opposing party regarding the specific issues cited in the ADR claim.” The 2024 Final Rule further stated that good faith efforts and documentation can include evidence of communications between parties indicating attempts at providing additional clarification or explanation that may not have been readily apparent to the parties and may help mitigate some concerns.
- aligning more closely to the 340B Statute and limiting claims to disputes involving diversion, duplicate discounts, and overcharges; and
- - The 2024 Final Rule provides examples of the types of claims that could be brought in the new ADR process.
- establishing a reconsideration process for parties dissatisfied with ADR panel decisions.- The reconsideration request would need to be submitted within 30 days of receiving the final decision letter.
- - Under the new process, the panel would aim to issue a decision within 1 year of filing. No decisions were made under the 2020 ADR process.

Other notable changes to the ADR process include:

- prohibiting trade associations from filing claims on behalf of manufacturers. The law permits associations to file claims on behalf of covered entities;
- establishing deadlines and procedures for filing claims; and
- permitting claims to proceed through the 340B ADR process even if it is the same as, or similar to, a claim pending before Federal court.

The Future of 340B: New Legislative Developments

The 2024 Final Rule goes into effect on June 18, 2024. It will be interesting to monitor the utilization of the new process and if the program will better resolve disputes than the 2020 process. Outside of the ADR process, it will also be important to continue to follow new legislative developments in the 340B program. Across the country, states continue to enact 340B contract pharmacy “non-discrimination” legislation. At the federal level, although some legislative efforts have been put forth to reform the 340B program, there has not been much movement towards enactment. Some

proposals, such as the Bipartisan 340B Sustain Act, have received some media attention due to discussions at Senate committee hearings, responses to a request for information contained in the discussion draft of the bill, as well as statements made by Sen. John Thune (R-SD), a leading sponsor of the bill. Lastly, it remains to be seen whether the 340B program will be included in some way in the White House's efforts to reign in prescription drug costs. To date, the White House has not referenced the program in its press releases or roundtables discussing the topic.

National Law Review, Volume XIV, Number 137