

Final 340B Administrative Dispute Resolution Rule Is Unlawful and Unconstitutional

Summary of Legal Challenge – January 2021

Background:

- When Congress created the 340B program in 1992, it established careful limits to ensure that the steep discounts manufacturers provide on medicines extend only to the covered entities specified in the 340B statute who treat eligible “patients.” The 340B law includes three crucial safeguards to protect against abuse and ensure the program serves its intended purpose: 1) prohibition on duplicate discounts; 2) prohibition on diversion of 340B medicines; and 3) authorization of manufacturer and federal agency audits of covered entities’ compliance with 340B program requirements.
- The 340B law’s “duplicate discount” ban prohibits covered entities from purchasing a medicine that generates a Medicaid rebate claim at a 340B discount. The 340B statute also prohibits “diversion” which refers to when a covered entity resells or otherwise transfers a 340B purchased medicine to a person who is not a 340B “patient” of the entity.
- Over the last nearly 30 years, there have been multiple reports of program violations of these statutory prohibitions. As recently as December 2020, a Government Accountability Office report found that for Health Resources and Services Administration (HRSA) audits in FY 2012-2019 there were [more than 1,500 findings of noncompliance by covered entities](#) with 340B requirements.
- In 2010 Congress amended the 340B statute as part of the Affordable Care Act and directed the U.S. Department of Health and Human Services (HHS) to establish an Administrative Dispute Resolution (ADR) process to resolve disputes over covered entity violations of duplicate discounting and diversion, as well as claims by covered entities that they have been overcharged.
- In the fall of 2020, HHS notified the Office of Management and Budget that it would soon finalize a previously-abandoned 2016 proposed rule establishing an ADR process. On November 24, 2020, [PhRMA filed a petition](#) to express its deep concern with this approach and requested that HHS instead reopen the record so that HHS could consider these issues in light of new evidence of increased diversion and duplicate discounts, including in multiple government reports. HRSA did not address PhRMA’s petition.
- After failing for a decade to establish this process, on December 14, 2020, HHS revived the 4-year-old proposed rule and rushed out the *340B Drug Pricing Program: Administrative Dispute Resolution Regulation Final Rule* (ADR Final Rule) in an attempt to end lawsuits over its failure to comply with the statute, ignoring stakeholder concerns with the 2016 proposed rule, including the petition PhRMA filed last year.

PhRMA Asserts the ADR Final Rule is Unlawful and Unconstitutional:

PhRMA's complaint includes three causes of action and is seeking declaratory and injunctive relief to set aside, vacate and remand the ADR Final Rule.

1. **The ADR Rule is Arbitrary and Capricious in Violation of the Administrative Procedure Act.** By rushing out a previously withdrawn proposed rule and finalizing it on a stale record, the agency failed to appropriately consider comments and changed circumstances. Instead, the ADR Final Rule creates a biased process that improperly hampers the ability of manufacturers to address violations of program requirements by covered entities. Specifically:
 - a. HRSA failed to adequately address comments regarding the audit guidelines, which govern the audit prerequisite for manufacturers to initiate ADR claims and present a blocked gateway to manufacturers trying to use the ADR process to seek relief from covered entity violations (diversion and duplicate discounts); and
 - b. HRSA failed to consider the changed program environment and the evidence in PhRMA's petition filed in November 2020.
2. **The Manufacturer Audit Guidelines Are Contrary to Law.** The audit guidelines exceed the limited grant of authority in the statute that authorizes HHS to create "procedures ... relating to the number, duration, and scope of audits" conducted by manufacturers.
 - a. First, the audit guidelines impermissibly require manufacturers to establish "reasonable cause" to HRSA that a covered entity has violated the prohibitions on diversion or duplicate discounts before they can even commence an audit, a requirement that is not a "procedure[] ... relating to the number, duration, [or] scope" of audits.
 - b. Second, the guidelines' requirement that manufacturers employ third parties to conduct audits conflicts with the plain language of the statute, which directs covered entities to "permit the Secretary and *the manufacturer*" to audit the covered entities' records.
3. **The ADR Rule is in Violation of the Appointments Clause of the U.S. Constitution.** Under the final ADR rule, ADR Board members are "principal officers" of the United States because they independently determine how to conduct proceedings and make final precedential determinations for HHS that are not subject to any further executive branch review. Because ADR Board Members function as principal officers under the ADR Rule even though they are not appointed by the President with the Senate's advice and consent, the ADR Rule violates the Appointments Clause of Article II of the U.S. Constitution.