

Insights

Lawsuit Injects Even More Uncertainty Over the Fate of the 340B Program

December 2, 2025

By: Brandon W. Shirley

A recent lawsuit challenging the Health Resources and Services Administration's ("HRSA") 340B Rebate pilot program is giving 340B covered entities even more uncertainty as they plan for January 1, 2026. The lawsuit, filed in a federal district court in Maine, is asking the federal court to immediately enjoin the rebate program from taking effect on January 1, 2026. The plaintiffs are the American Hospital Association and four hospitals in Maine, New York, North Dakota, and Arkansas, representing thousands of hospitals who they argue will be forced into a rebate system that requires them to forego 340B discounts. Covered entities should watch this case very carefully over the coming weeks as it could have a significant impact on 340B drug reimbursement procedures beginning January 1, 2026.

For more than 30 years, drugmakers have been required to give up-front 340B discounts on covered outpatient drugs. In response to several drugmakers' attempts to change this upfront discount to a rebate model, HRSA announced a 340B rebate program that would require covered entities to purchase drugs at full price and then seek reimbursement from drug makers via a rebate, to be paid within 7-10 days. These rebates were limited to the 10 drugs identified for negotiated discounts under the Inflation Reduction Act ("IRA") beginning on January 1, 2026.

The lawsuit alleges that the rebate model creates three kinds of harm: (1) heavy administration burden; (2) cash-flow strain from paying full price for 340B drugs upfront; and (3) technology, privacy, and dispute risks. The lawsuit alleges that the rebate pilot program was improperly implemented. HRSA reversed 30 years of policy without a reasoned explanation, ignored thousands of comments raising concerns with the proposal, failed to seriously account for costs and benefits, overreached by requiring participation in the rebate program, and overlooked obvious alternatives to prevent duplicate discounts under Medicare's negotiated prices.

The lawsuit is one of several that are working their way through federal courts and that each have the potential to significantly impact the 340B program. Plaintiff manufacturers are challenging HRSA's authority to limit a 340B rebate program to the 10 drugs identified for IRA discounts and CMS's ability to negotiate and establish IRA discounts. At least one federal court is also still considering whether HRSA can require drug makers to allow 340B drugs to be dispensed through an unlimited number of contract pharmacies.

If you have any questions about your organization 340B compliance, please contact Brandon W. Shirley.

Disclaimer: The contents of this article should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents are intended for general informational purposes only, and you are urged to consult with counsel concerning your situation and specific legal questions you may have.