

PUBLICATION

Judge Blocks Implementation of 340B Drug Rebate Pilot

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A federal judge temporarily blocked the Health Resources and Services Administration (HRSA) from implementing its 340B Rebate Pilot Program (Rebate Program or Program) that was set to take effect on January 1, 2026. Judge Lance E. Walker of the U.S. District Court for the District of Maine issued the order on December 29, 2025. The American Hospital Association, the Maine Hospital Association, and four health systems filed suit against HRSA on December 1, 2025, seeking to block the Rebate Program claiming it violated the Administrative Procedures Act (APA).

The plaintiffs were able to show irreparable harm based on the economic impact of paying full price for the drugs at the point of sale as well as the reporting costs of complying with the data requirements of the Program and tracking the rebates. Judge Walker ruled that HRSA failed to provide an adequate administrative record explaining its decision to implement the Program.

In rendering his decision, Judge Walker noted that the Rebate Program was a significant departure from more than 30 years of upfront drug discounts and stated that HRSA's implementation of the Rebate Program "has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities." He further explained that the "Defendants cannot fly the plane before they build it" and that the Rebate Program cannot "take flight on January 1, 2026."¹

This decision is a win for all providers participating in the 340B program, although it may be temporary.

Shortly after the opinion was filed, the Department of Health and Human Services (HHS) appealed the decision, seeking a stay of the order. Both Judge Walker and the First Circuit denied the motion for an immediate stay on December 30 and 31, respectively, but the First Circuit ordered an immediate briefing that was due on December 31 and stated that it plans to render a decision on the broader stay request "as soon as practicable." Consequently, it is imperative that all 340B stakeholders continue to follow fast-paced developments on this decision and the Rebate Program in general.

Further, Judge Walker did note that HRSA "is empowered by statute to achieve the de-duplication [of drug discounts] objective through a rebate model." Judge Walker's analysis focuses instead on how HRSA did not presently meet APA requirements to implement the Program.² Thus, it is possible that HRSA may try to roll out the Rebate Program again after building a more robust administrative record explaining its rationale for drastically changing the 30-year-old 340B program.

For additional information on the current state of affairs for the 340B Program, please contact [Greg Fliszar](#), [Alissa D. Fleming](#), [Katherine Denney](#), or any member of the Baker Donelson [Health Law](#) Team.

¹Am. Hosp. Ass'n et al. v. Kennedy et al., No. 2:25-cv-00600, at 2 and 21 (D. Me. Dec. 29, 2025).

²*Id.* at 2.

