

Insights

First Circuit Blocks 340B Rebate Pilot Program; Upfront Discounts Remain in Effect

January 8, 2026

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On January 7, 2026, the First Circuit Court of Appeals denied the federal government's emergency motion to stay a district court injunction blocking implementation of HRSA's 340B Rebate Model Pilot Program, leaving the longstanding system of upfront 340B discounts in place while the litigation proceeds. In *American Hospital Association v. HHS*, a unanimous panel concluded that the government failed to show a likelihood of success on the merits or irreparable harm, meaning HRSA remains barred from implementing the 340B Rebate Pilot Program, under which participating manufacturers would have charged wholesale prices up front and later issued rebates to reach the 340B ceiling price. The First Circuit has ordered the parties to propose an expedited briefing schedule by January 12, 2026, signaling a potentially swift resolution on the merits.

Court's Key Findings

- **Likelihood of success on the merits.** Both the district court and the First Circuit found HRSA's administrative record insufficient, emphasizing the lack of evidence that HHS adequately considered hospitals' significant reliance interests developed over decades of upfront 340B discounts or the substantial new operational and financial burdens the Rebate Model would impose. The First Circuit agreed that the agency's post-hoc declaration could not cure these deficiencies.
- **Irreparable harm and balance of equities.** The courts found that many safety-net hospitals operate with fewer than eleven days of cash on hand and could face hundreds of millions of dollars in annual losses under the Rebate Model, potentially leading to service reductions or closures. By contrast, the First Circuit emphasized that the injunction preserves a decades-long status quo and that the government failed to demonstrate irreparable harm from delaying the 340B Pilot Program.
- **Alternative avenues for manufacturers.** The First Circuit noted that manufacturers retain other mechanisms to address duplicative discount concerns, undercutting claims that the injunction causes immediate or irreparable harm.

As a result of this decision, the Rebate Model Pilot cannot be implemented unless the injunction is lifted. The status quo of upfront 340B discounts will remain in effect during the appeal. 340B Covered Entities may continue existing 340B purchasing and compliance practices without implementing 340B rebate-processing systems.



Contact Brandon W. Shirley if you have any questions about your 340B program or legal considerations moving forward.

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