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Insights

The 340B Rebate Model Halted on the Eleventh Hour

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340B Covered Entities are breathing a sigh of relief in light of a court ruling that halted the 340B rebate model from taking effect at the beginning of the year. On December 29, 2025, the U.S. District Court for the District of Maine issued a ruling preventing the Health Resources and Services Administration ("HRSA") from implementing the 340B Rebate Model Pilot Program ("Rebate Pilot Program"). The Rebate Pilot Program would have required 340B Covered Entities to purchase 340B drugs at full price and later obtain the discount through post-purchase rebates. The ruling halts the Rebate Pilot Program before its planned January 1, 2026, effective date and preserves existing 340B pricing practices while the litigation proceeds. Given the attention this program has received, it is expected that HRSA and other interested parties will seek emergency relief from this order.

HRSA announced the Rebate Pilot Program in mid-2025 as a limited initiative intended to address perceived "de-duplication" concerns arising when both 340B discounts and Inflation Reduction Act Medicaid Maximum Fair Price ("MFP") rebates apply to the same drug. Under the Rebate Pilot Program, participating manufacturers would have been permitted to charge 340B Covered Entities wholesale prices and later issue rebates reflecting the 340B discount. Between late October and mid-November 2025, HRSA approved applications from nine manufacturers covering ten drugs, with most approvals set to take effect January 1, 2026.

In granting the injunction, the court concluded that the plaintiffs were likely to succeed on their claim that HRSA fell short of meeting the requirements to fully and legally support the Rebate Pilot Program. The court also found that 340B Covered Entities would suffer irreparable harm absent an injunction and that maintaining the status quo serves the public interest. The court enjoined the Rebate Pilot Program in its entirety, setting aside the approvals that would have allowed the rebate model to proceed.

Absent a subsequent court order, existing upfront 340B discount practices will remain in place for the affected drugs, and 340B Covered Entities are not required to modify purchasing, billing, or cash-management workflows at this time. Manufacturers are likewise prohibited from transitioning the approved products to rebate-based 340B pricing under the current program framework. While the court acknowledged that Congress permits HRSA to use either rebates or upfront discounts to implement 340B pricing, it emphasized that any such shift must be supported by a robust, contemporaneous administrative record that accounts for reliance interests and operational costs. HRSA may seek appellate review, request a stay, or attempt to redesign and re-approve a rebate model consistent with federal law.

Contact Brandon Shirley at bshirley@kdlegal.com if you have any questions about your 340B program or legal considerations moving forward.

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