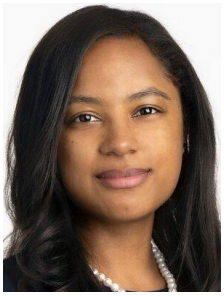
Court's HRSA Policy Reversal Leaves 340B Rules Murky

By **Martha Cramer** (April 24, 2026)



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On March 31, the U.S. District Court for the District of Columbia released its opinion in Premier Inc. v. U.S. Department of Health and Human Services.

The court vacated the Health Resources and Services Administration's 2013 guidance that limited when certain hospitals covered by Section 340B, namely disproportionate share hospitals, could use group purchasing organizations to acquire outpatient drugs under virtual or replenishment inventory models.[1]

The court set aside HRSA's 2013 GPO policy as arbitrary and capricious.

Although the court did not endorse the GPO replenishment model as lawful, it cast doubt on HRSA's authority to restrict such purchasing arrangements until there is at least further explanation or rulemaking.

This decision also follows a series of recent court rulings that have scrutinized and, in some instances, limited HRSA's ability to impose binding requirements on 340B-covered entities, particularly where agency positions are articulated through subregulatory guidance rather than notice-and-comment rulemaking or are not supported by a reasoned explanation grounded in statutory text.

In the absence of congressional action, the 340B program is expected to be fraught with unresolved questions, with compliance expectations emerging from litigation, enforcement activity and manufacturer practices, rather than clear, prospective regulatory rules.

Background on the 340B GPO Prohibition

Under Section 340B, DSH hospitals may participate in the 340B program only if they "do[] not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."[2]

For decades, hospitals subject to this GPO prohibition relied on a variety of inventory management approaches — including a virtual inventory model or replenishment model —

to manage mixed inpatient, outpatient and 340B drug use without maintaining strictly separate inventories in order to comply with the statute.

In February 2013, HRSA first directed, via subregulatory guidance, that hospitals subject to the GPO prohibition violate the statute if they acquire covered outpatient drugs through a GPO, even if the drugs are later reclassified or replenished with 340B-priced product through accounting mechanisms. HRSA asserted that such violations could not be cured, and could result in termination from the 340B program and repayment obligations.

In July 2023, Premier, a healthcare improvement company that operates a GPO providing services to 340B hospitals, asked HRSA for an exemption from the 2013 guidance, which HRSA rejected.

Premier then sued, alleging that HRSA's policy was contrary to the text and purpose of Section 340B, arbitrary and capricious under the Administrative Procedure Act, and issued in excess of HRSA's limited statutory authority.

Premier argued that, under a replenishment model, drugs purchased for initial neutral inventory are not covered outpatient drugs at the time of purchase, and therefore fall outside the scope of the GPO prohibition, and that HRSA failed to provide a reasoned explanation for adopting a contrary position.

The Court's Decision

The court concluded that the 2013 GPO policy is arbitrary and capricious under the APA, and therefore must be vacated.

The court emphasized that HRSA failed to explain its position that use of a GPO-based replenishment model violated the statute, in view of the statutory text, prior agency guidance, or the overall structure of the 340B program.

The court also highlighted HRSA's failure to grapple with its own prior practice. Before 2013, HRSA and its contractors had tolerated or implicitly permitted replenishment models that relied on GPO-purchased initial neutral inventory. Yet, the 2013 guidance neither acknowledged nor explained this apparent shift in position, a deficiency the court found incompatible with reasoned agency decision-making.

Importantly, the court did not decide whether the 340B statute affirmatively permits

hospitals subject to the GPO prohibition to use GPOs for initial neutral inventory purchases. Instead, the court held only that HRSA's contrary interpretation lacked an adequate explanation.

Because the court invalidated the guidance as arbitrary and capricious, the court did not reach Premier's additional arguments that HRSA's guidance lacked statutory authority and constituted an unlawful legislative rule.

An Unresolved Question Under the GPO Prohibition

The court's analysis also surfaces a threshold statutory issue that HRSA has historically treated as settled: When does a drug become a covered outpatient drug for purposes of the GPO prohibition?

Premier's replenishment theory turns on the timing of that designation, arguing that drugs purchased as initial neutral inventory through a GPO do not acquire 340B status until later matched to outpatient utilization through dispensing and replenishment.

By faulting HRSA for failing to engage with that logic, the court signaled that future agency interpretations may need to address not only how drugs are purchased, but when statutory restrictions attach.

That question has implications beyond the GPO context, and may shape how courts evaluate other HRSA positions that turn on inventory classification, drug status and timing under the 340B statute.

Practical Implications for Covered Entities

HRSA still has the option to appeal, but as it stands, the effect of the court's decision is to remove the 2013 HRSA guidance as a valid enforcement predicate. However, the ruling does not greenlight GPO-funded initial inventory purchases, and providers should not assume that pre-2013 purchasing practices are now automatically permissible.

Further, even if HRSA does not appeal, the agency may seek to adopt new guidance or take other action to articulate a revised interpretation of the GPO prohibition that addresses the deficiencies identified by the court.

Audit and compliance exposure therefore is uncertain. DSH hospitals remain subject to the

statutory GPO prohibition, annual 340B certifications and HRSA audit authority. And HRSA may be able to articulate an APA-sustainable interpretation of the statute or seek to rely on existing statutory standards in audits or corrective action plans.

Finally, the court's decision, if not altered in any appeal, may be relevant for DSH hospitals addressing repayment demands, adverse audit findings or eligibility determinations that were premised on the 2013 guidance's interpretation of initial inventory purchases.

A Shifting 340B Landscape

Premier reflects a broader pattern of judicial scrutiny of HRSA's use of subregulatory guidance to impose binding requirements under the 340B program. Recent decisions have constrained HRSA's enforcement authority by limiting reliance on interpretations that lack a reasoned administrative explanation or clear statutory grounding.

At the same time, limits on HRSA's authority have not produced regulatory stability. After courts rejected the agency's initial effort to implement a 340B rebate model pilot program, HRSA shifted to gathering stakeholder input through a request for information, signaling continued interest in revisiting how the program operates.

Against this backdrop, manufacturers have imposed additional operational and data-submission requirements as conditions of access to 340B pricing, prompting objections from hospitals and trade groups. HRSA has taken only limited formal action in response, despite the practical impact on covered entities.

Viewed in this broader context, Premier underscores the ongoing uncertainty surrounding the administration of the 340B program. While recent decisions — including Premier — have limited HRSA's ability to enforce long-standing interpretations through subregulatory guidance, they have not resolved core statutory questions about purchasing models, inventory classification or program oversight.

Instead, the combined effect has been to shift those unresolved questions into the courts, where agency interpretations now face closer scrutiny but regulated entities lack clear, affirmative rules to rely on.

The result is a 340B landscape shaped less by published guidance than by vacated policies, evolving manufacturer practices and open statutory questions that remain unaddressed by Congress.

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[1] Premier, Inc. v. HHS, No. 1:24-cv-03116 (D.D.C. Mar. 31, 2026).

[2] 42 U.S.C. § 256b(a)(4)(L)(iii).