LEGAL UPDATES

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D.C. District Court Vacates HRSA's 340B Child Site Registration Requirement

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On March 3, 2026, the U.S. District Court for the District of Columbia issued a significant decision for hospitals participating in the federal 340B Drug Pricing Program. In *Albany Med Health System v. Health Resources and Services Administration*, the court vacated HRSA's policy requiring hospital "child sites" to appear on a hospital's Medicare cost report and be registered in HRSA's Office of Pharmacy Affairs Information System (OPAIS) before becoming eligible to purchase and use 340B-priced drugs. The court held that this registration requirement is contrary to the text of the 340B statute and exceeds HRSA's statutory authority.

Background

Section 340B of the Public Health Service Act requires participating drug manufacturers to provide discounted outpatient drugs to specified "covered entities," including certain safety-net hospitals. For decades, HRSA required off-campus outpatient facilities—commonly referred to as "child sites"—to satisfy two conditions before accessing 340B pricing: (1) inclusion on the hospital's most recently filed Medicare cost report and (2) registration and listing in OPAIS.

During the COVID-19 public health emergency, HRSA issued guidance allowing hospitals to use 340B drugs at new child sites before those sites were formally registered. In October 2023, HRSA announced that it was ending that flexibility and reverting to its pre-pandemic registration policy. More than 40 hospitals and health systems challenged that action under the Administrative Procedure Act.

The Court's Decision

The court granted summary judgment to the hospital plaintiffs and vacated HRSA's reinstated registration requirement. Applying independent statutory interpretation principles following the Supreme Court's decision in *Loper Bright*, the court concluded that the 340B statute does not authorize HRSA to impose registration or agency approval as a condition of eligibility for hospital child sites.

Key points from the court's analysis include the duplicate discount prohibition, avoiding diversion, and compliance with audit authority. The statute does not require hospitals or their child sites to obtain prior HRSA approval or registration before accessing 340B pricing.

Congressional intent. Congress expressly required agency certification for certain non-hospital covered entities but did not impose similar certification or registration requirements on hospitals. The court viewed this distinction as strong evidence that Congress did not intend HRSA to add such prerequisites for hospital child sites.

Limits on HRSA authority. The court emphasized that HRSA lacks general rulemaking authority under the 340B statute. While HRSA may require hospitals to identify child sites and may maintain OPAIS as an identification and transparency tool, it may not delay a statutorily eligible site's access to 340B pricing pending registration or verification.

As relief, the court vacated HRSA's October 2023 Notice and declared that the Notice unlawfully required a hospital child site to be listed on a Medicare cost report and registered in OPAIS before it may use 340B-priced drugs.

Practical Implications for Hospitals

The decision has significant implications for hospital covered entities:

Earlier access to 340B pricing. Hospitals may use 340B drugs at qualifying child sites without waiting months for cost-report inclusion or OPAIS registration, reducing delays and associated drug acquisition costs.

Continued compliance obligations. The ruling does not eliminate HRSA's oversight role. Hospitals must still comply with all statutory 340B requirements, including patient eligibility, diversion prohibitions, duplicate discount restrictions, and audit readiness.

Registration remains relevant but not determinative. Hospitals should continue to register child sites and maintain accurate OPAIS listings for transparency and compliance purposes, even though registration is no longer a prerequisite to eligibility.

Potential enforcement and audits. As HRSA's front-end eligibility reviews are curtailed, manufacturers are likely to rely more heavily on audits, contract pharmacy restrictions, and other enforcement mechanisms to address 340B program integrity.

It remains to be seen if HRSA will appeal the court's decision.

Contact us

If you have questions regarding 340B Program guidance or how this decision affects hospitals participating in the federal 340B Drug Pricing Program, please contact Rob Hess, Renee Zerbonia, or your Husch Blackwell attorney.