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Significant changes for 340B Drug Pricing Program could mean new risks and responsibilities for provider organizations

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<https://www.chartis.com/insights/significant-changes-340b-drug-pricing-program-could-mean-new-risks-and-responsibilities>

The Buzz This Week

The 340B Drug Pricing program remains in the spotlight with recent federal and manufacturer efforts to limit scope and costs. For provider organizations, the cumulative effect is a more volatile and uncertain environment that could significantly impact their ability to provide access in rural and under-resourced communities.

Recent developments include:

- **Manufacturers' expanded claims reporting policies:** Novo Nordisk and Eli Lilly's new data collection policies require provider participants to provide claims-level data for all pharmacy and medical dispensations, including in-house and contract pharmacy dispensaries. Other drugmakers are expected to follow suit. The American Hospital Association (AHA) has petitioned the Health Resources and Services Administration (HRSA) to block these requirements, citing onerous costs and burdens for participating hospitals.
- **"Child site" advance registration requirements:** A federal court ruled HRSA's 2023 policy requiring advance registration for child site off-campus hospital facilities was unlawful. The ruling stated that HRSA could not add new eligibility conditions for 340B drug pricing, invalidating the requirement that child sites must be previously registered or included in a Medicare cost report. The federal government has 60 days from the decision to determine whether it will file an appeal.

- **Rebate model pilot program:** Following a court-ordered pause of its original 2026 rebate model pilot program, HRSA has issued a request for information to explore the possibility of reviving a rebate-based approach. Covered entities and stakeholders have until April 20 to submit final comments.
- **Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey:** The Centers for Medicare & Medicaid Services' (CMS') 2026 Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey asks covered 340B hospitals to report costs for separately payable outpatient drugs by March 31. While the survey is not mandatory, the agency has indicated that submitted data could inform future payment policy adjustments.

These recent developments signal a period of heightened scrutiny, operational complexity, and financial uncertainty for 340B covered entities.

Why It Matters

For providers that rely on 340B savings to subsidize uncompensated care, pharmacy services, and community-based programs, the cumulative impact of these recent developments is substantial. For safety net hospitals operating on narrow margins, these changes present material risks to financial viability and ability to maintain essential services.

Manufacturers' expanded claims-level data requirements are a notable shift in oversight expectations. Requiring detailed pharmacy and medical claims data as a condition of receiving 340B pricing imposes new technical and operational demands.

For many hospitals and health systems, generating, validating, and transmitting this information will require system upgrades, additional compliance staffing, and expanded coordination with pharmacy partners. These efforts may significantly increase administrative costs and ultimately reduce 340B savings.

Recent federal court rulings addressing rebate models and child-site eligibility offer temporary relief by eliminating delays and improving short-term financial planning ability. However, the federal government retains the option to appeal, and HRSA continues to explore structural reforms, including a rebate-based pricing framework. As a result, providers must operate in an environment in which core elements of the program remain unsettled.

CMS' Drug Acquisition Cost Survey adds another layer of complexity. Although the reporting burden is significant, participation may shape how the agency understands hospitals' actual drug acquisition costs and inform future reimbursement policy.

Importantly, these 340B-specific changes are unfolding within a broader and rapidly evolving pharmacy policy environment. Renewed federal emphasis on drug pricing reform (including executive actions focused on price transparency, PBM practices, and broader cost containment initiatives) signals sustained scrutiny of pharmaceutical pricing channels.

As high-cost therapies continue to drive up spending, policymakers are increasingly examining how discounts, rebates, and distribution mechanisms shape overall drug costs, drawing the 340B program into the spotlight.

In response to these developments, provider organizations should consider:

- Refreshing their 340B strategy to ensure they position their program for sustained performance and compliance in the face of change
- Strengthening pharmacy data infrastructure and reporting capabilities to support potential rebate reconciliation and enhanced manufacturer or federal reporting requirements
- Reviewing contract pharmacy agreements to ensure compliance flexibility
- Bolstering internal 340B compliance monitoring and documentation processes
- Engaging in policy advocacy and formal comment submissions
- Integrating 340B risk scenarios into long-term planning

Navigating this landscape will be critical to preserving the role of 340B savings in supporting access to care for vulnerable populations.

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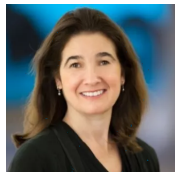
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Cynthia Bailey

Associate Vice President of Strategy



Jason Abbot, PharmD

Senior Partner