Insights

Shifting the 340B Model: Rebates on the Horizon

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After months of litigation and promises to issue a proposal, the Health Resources and Services Administration ("HRSA") has released long-awaited guidance on a new 340B pilot program. While the HRSA guidance provides clarity, it does not give manufacturers or 340B covered entities much to celebrate. Per the July 31 *Federal Register* notice ("Notice"), HRSA outlined a limited, voluntary program that shifts some 340B discounts from an upfront discount to a rebate program. Covered entities would purchase drugs at full price, submit data to the manufacturer within 45 days, and receive the discount through a rebate within 10 days. HRSA will accept comments through September 2, 2025, and HRSA will accept manufacturer plans by October 15, 2025. The selected plans will take effect January 1, 2026. Information about the pilot program, including the Notice, can be accessed through HRSA's website.

The 340B pilot program provides a framework for 340B rebates, but it comes with specific limits. The program is voluntary and is intended to last for a minimum of one year. It is currently limited to NDC-11 drugs included on the *CMS Medicare Drug Price Negotiation Selected Drug List*. The drug manufacturers must agree to bear all IT platform costs, provide 60 days' advance notice before implementation, and ensure covered entities continue to purchase drugs through existing distribution channels. Drug manufacturer plans must include HIPAA-compliant data protections, customer service support, and a manufacturer point of contact. Covered entities will have up to 45 days to submit claims data, which must be limited to a defined set of pharmacy claim fields, with the IT platform filtering out unnecessary data and providing real-time reconciliation. Drug manufacturers must pay rebates within 10 days of data submission.

To ensure fair treatment of covered entities, drug manufacturers may not deny rebate requests based on diversion or Medicaid duplicate discount concerns, consistent with federal law. Any denied rebate must include clear rationale and supporting documentation, such as deduplication for the Maximum Fair Price or instances where a rebate was already provided to another covered entity on the same claim. Manufacturers with concerns regarding diversion or duplicate discounts must address them directly with HRSA's Office of Pharmacy Affairs ("OPA") using established statutory mechanisms, including audits or the Administrative Dispute Resolution process. Likewise, covered entities may raise concerns with OPA regarding rebate delays, denials, or other administrative or operational issues that arise during implementation of the rebate model.

Covered entities should also keep an eye on other federal and state changes to the 340B program. The Inflation Reduction Act takes effect on January 1, 2026, which will affect drug prices and rebates. Under Indiana's new 340B reporting requirement, covered entities must report certain information by April 1, 2026. Indiana Medicaid officials are looking at ways to limit the 340B program in the state. This could include new authority that gives the FSSA Secretary authority to decide whether 340B prescription for Medicaid patients receive 340B rebates or fall under the regular Medicaid drug rebate program. Covered entities in Indiana

should follow these developments closely, as they could affect reporting and Medicaid 340B rebates.

If you or your entity has questions regarding the impact of this pilot program on your operations, or if you would like assistance with submitting a comment, please contact Brandon W. Shirley or Madison Hartman Harada.
