

HHS Previews Guidance Addressing Implementation of 340B Rebate System

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In the fall of 2024, several pharmaceutical companies reacted to HRSA's decision to prevent them from implementing a rebate model for their respective 340B Programs by filing lawsuits against HHS and HRSA claiming that the Department and its subagency violated their rights under the Administrative Procedure Act and took actions that conflicted with the language of section 42 U.S.C. § 256b(a)(1) of the 340B statute. HHS and HRSA reacted by filing a Cross Motion for Summary Judgment countering Plaintiffs' argument that the Pharmaceutical Pricing Agreements between HHS and pharmaceutical manufacturers should permit the use of a rebate model to structure the 340B Program.

While the Cross Motion for Summary Judgment filed by HHS and HRSA demonstrated HHS and HRSA's continued adherence to the up-front discount model, this recent Notice demonstrates that HHS acknowledges that the implications of a rebate model are not straightforward. If the payment mechanism were to change to a rebate model, 340B covered entities could face significant financial increases in purchasing costs, operational costs, and costs associated with any process whereby pharmaceutical manufacturers have oversight over payment of rebates. In addition, the Inflation Reduction Act requires that drug manufacturers will, starting on January 1, 2026, be required to provide 340B pharmacies with the lower of the maximum fair price (MFP) or the 340B ceiling price for certain drugs. The Inflation Reduction Act, however, makes clear that the 340B pharmacies cannot obtain the benefit of receiving both discounts.

Once the HHS guidance is published, all participants in the 340B Program should determine how this guidance may impact their operations. We will provide relevant updates concerning the guidance once published.

For additional information on the current state of affairs for the 340B Program, please contact [Alissa D. Fleming](#), [Greg Fliszar](#), [Katherine Denney](#), or any member of the Baker Donelson [Health Law](#) Team.