HHS Announces New 340B Rebate Model Pilot Program



9/1/2025

On August 19, 2025, the United States Department of Health and Human Services (HHS) issued a notice announcing the launch of a voluntary 340B Rebate Model Pilot Program, marking a significant potential shift in how 340B pricing may be implemented for select drugs. Under the 340B program, drug manufacturers negotiate the prices of certain drugs with HHS, and certain covered entities, such as hospitals and federal grantees, can purchase these drugs for the negotiated discounted price. Traditionally a point-of-sale discount program, the new pilot program will allow covered entities to pay the standard acquisition cost for the drugs up front and then receive post-purchase rebates reflecting the 340B ceiling price. These rebates will be provided to the purchasers of the drugs based on reporting data that they provide to the manufacturer. The pilot program is in response to widespread stakeholder feedback, particularly from drug manufacturers, regarding challenges in implementing the Medicare Drug Price Negotiation Program (MDPNP). Many covered entity providers argue, however, that this method of offering discounts provides more opportunities for drug manufacturers to deny discounts based on data reported by the purchaser.

The pilot program is initially limited to drugs listed under the CMS Medicare Drug Price Negotiation Selected Drug List and is open to manufacturers with MDPNP agreements with HHS for the 2026 applicability year.

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