Hospitals, Pharma Clash Over Burdens Under HHS Drug Rebate Plan

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Reporter

- Hospitals and major drugmakers are battling over the financial impact of a government pilot program that could change how medicines are discounted for low-income and uninsured patients.
- The proposed pilot program would shift how pharmaceutical manufacturers provide discounted medicines to covered entities under the federal 340B Drug Pricing Program, with covered entities buying medicines at full price and then submitting data to receive a rebate.
- The plan has raised concerns among health providers about cash flow and operational issues, while drugmakers believe it would ensure their steep drug discounts are going to eligible patients and are asking the government to expand the plan.

Hospitals and major drugmakers are battling over the financial impact of a government pilot program that could shake up how medicines are steeply discounted for low-income and uninsured patients.

Over a thousand **comments** weighed in on the US Department of Health and Human Services' **proposed pilot program** that would shift how pharmaceutical manufacturers provide discounted medicines to covered entities under the federal 340B Drug Pricing Program.

Drugmakers currently provide up-front drug discounts to covered entities, such as qualifying safety-net hospitals, clinics, and providers that treat a disproportionate number of low-income and uninsured patients. But under the pilot, covered entities would buy medicines at full price and then submit data to drugmakers to receive a rebate.

The plan would significantly change how the 340B program operates. For health providers, the proposed model raised concerns of cash flow and operational issues. The pharmaceutical industry voiced optimism that it would ensure their steep drug discounts are going to eligible patients.

The risks prompted health providers—and even a **bipartisan group of lawmakers**—to urge HHS to scrap the pilot. Drugmakers, meanwhile, are asking the government to expand the plan, as the proposal only limits participants to manufacturers with medicines selected for the **first round** of the Medicare Drug Price Negotiation Program.

The model is a "fundamental, massive shift," said Jeffrey Davis, a member at Bass, Berry & Sims PLC, specializing in 340B.

"A lot of comments really quantify the financial impact—how many millions of dollars that providers would have to float by buying these drugs at a much higher price," Davis said an interview. "But several manufacturers have taken a position that they believe in moving 340B to a rebate model."

The pilot comes as the 340B program faces scrutiny over its massive growth, which has drawn ire from drugmakers in particular. A **report** published this month by the Congressional Budget Office attributed that growth to the integration of hospitals and off-site clinics, increased facility participation after the implementation of the Affordable Care Act, and expanded use of off-site pharmacies that dispense 340B drugs.

The Health Resources and Services Administration, the agency under HHS that oversees 340B, has until Oct. 15 to approve rebate plans submitted by eligible drugmakers such as Johnson & Johnson, Boehringer Ingelheim, and Novo Nordisk A/S. Approved models are expected to go live Jan. 1, 2026, when the first round of negotiated drug prices go into effect.

Margins at Risk

For Parkland Health—a Texas-based safety-net hospital system—the pilot would pressure it to pay millions more for drugs.

Specifically for the 10 Medicare negotiated drugs selected for the rebate program, what would cost them approximately $5 million with current 340B pricing would instead result in a cost of $95 million under the rebate model, Parkland said in its **comments**.

The Craneware Group, a partner to 340B covered entities, **said** rebates would force some of the organizations they work with to pay five times higher than their current 340B acquisition costs.

“Covered entities don’t have the bandwidth to assume this additional expense that these up-front purchases are going to have,” said Felicity Homsted, chief executive officer of FQHC 340B Compliance.

Rebates would also increase the financial risks for covered entities, given they “often are dealing with pretty low profit margins to begin with,” Amanda Bogle, a health-care attorney at Sheppard Mullin, said in an interview.

“It’s going to further restrict and impede their ability to provide the additional services and care,” Bogle said.

Groups such as the **American Hospital Association**, **Ryan White Clinics for 340B Access**, and **340B Health** also shared concerns about spending additional funds to track data for rebates and footing potential legal costs associated with improper rebate delays or denials.

“It takes a lot of resources,” said Kyle Vasquez, a shareholder at Polsinelli, specializing in 340B compliance. “It’s a complicated system and process that’s ripe for errors, so it’s inevitable that this will impose a pretty significant cost on a covered entity.”

Transparent Plan

Drugmakers and other proponents of the pilot, however, argue that covered entities have the resources to implement this system.

“Covered entities already collect and transmit similar data in the normal course of business, including through electronic platforms that make the incremental burden of submitting claims data likely insignificant, and modest at most,” Sanofi SA said in its **comments**.

Novartis AG similarly **said** that retrospective cash-rebates is an approach widely used in other federal programs and for commercial payers.

“Every single provider has systems in place to automatically provide this data in a claim format, and they already do it,” said Angie Franks, chief executive officer of Kalderos, a health tech company that provides a drug discount management platform. “They have to submit claims to insurance companies to get paid.”

AstraZeneca Plc and **Novo Nordisk** also chimed in with **comments** about how the pilot ensures transparency in the program as it’s faced scrutiny in recent years over its integrity and how discounts are used. It would ensure manufacturers have the data they need to **avoid duplicate discounts** under the Medicare drug price negotiations, the drugmakers said.

While proponents are backing the government’s plan, they’re also urging HHS to expand the pilot to other manufacturers.

“It needs to be one that can be useful to all manufacturers, not just a few,” said Heath Ingram, a partner at Goodwin Procter LLP’s life sciences group.

“The concern manufacturers have is that if the 340B program continues to grow at an unchecked level, at a certain point, it’s going to negatively impact the drug manufacturers’ capacity to innovate,” Ingram said. “The model is an improved way of trying to track duplicate discounts or diversion in a complicated system where it’s hard to get access to quality data.”

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