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Pharma's Data Demands Stir New Fight Over Drug Discount Program

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A new legal battle is forming between health providers and pharmaceutical companies under a federal drug discount program as more manufacturers are demanding hospitals submit data every time certain medicines are dispensed to patients.

At least a dozen drugmakers, including Bristol Myers Squibb Co., AstraZeneca Plc, and Amgen Inc., recently rolled out policies that require health providers receiving hefty drug discounts under the federal 340B Drug Pricing Program to submit claims data when distributing the companies' drugs.

It's the latest endeavor from manufacturers seeking to rein in a program that has ballooned in recent years, introducing another effort to track whether discounts are going to the right patients or if hospitals are doubling up on drug price cuts. The data requirements are not new, but rather expand policies that targeted pharmacies contracting with providers to dispense drugs.

The escalation of a longstanding feud between providers and drugmakers over program transparency is raising questions over whether the data demands are legal. So far, one hospital has challenged Eli Lilly & Co. for terminating discounts after the provider refused to comply with the drugmaker's policy. Meanwhile, Novo Nordisk A/S has sent warnings to covered entities in recent weeks over noncompliance.

"These policies are illegal," Chad Golder, general counsel for the American Hospital Association, said in an interview. "For example, we think there are some real unanswered questions about whether they comply with HIPAA and whether they really are getting access to patient information."

A bipartisan group of 72 lawmakers demanded in letter on June 29 for the government to stop Lilly from conditioning access to discounts.

The 340B program requires manufacturers under Medicaid to provide up-front, steep drug discounts to qualifying healthcare providers, known as covered entities. The entities include hospitals, clinics, and community health centers designed to serve a high volume of low-income and uninsured patients.

The program has expanded significantly in the last decade. The US Health Resources & Services Administration, which oversees the program, reported $81.4 billion in drug purchases in 2024. The growth has drawn attention from the Trump administration, which released a proposed rule on July 2 to change the formula for how much hospitals can get reimbursed under the program. Hospitals, however, attribute the growth to higher drug prices that lead to steeper 340B discounts and program expansion.

"Without claims data, manufacturers are expected to provide steep 340B discounts without knowing whether the program's legal requirements are being followed," said Sarah Ryan, spokesperson for the Pharmaceutical Research and Manufacturers of America.

Valuable Data

Hospitals argue the expanded requirements violate the federal 340B statute.

The act requires manufacturers to offer drugs at or below the deeply discounted 340B ceiling price. But covered entities argue the policies introduce massive administrative burdens to track and report claims data, raising the price of the drugs beyond the statutory cap.

"It's not cheap," Golder said. "It really does raise the price that the hospital has to pay if we were to add the cost of complying."

One law firm representing hospitals asked the HHS Office of Inspector General to open an investigation into Lilly's policy, arguing the requested data creates HIPAA compliance risks by sharing protected health information with manufacturers.

"Their policies are not compliant with applicable law, and when that occurs there are of course a variety of options opposing stakeholders and the government can pursue," Todd Nova, a partner at Hall, Render, Killian, Heath & Lyman, P.C., said in an interview.

Other health attorneys signal a debate on whether certain data requirements can be used as a condition for hospitals to access discounts.

"Certain claims data is very valuable," said Mark Ogunsusi, a partner at K&L Gates LLP's Healthcare and FDA practice group. "Drug industry representatives and 340B providers both seem to question whether certain proprietary claims data can be legally required as a condition of access to discounted items."

Legal Support

Drugmakers have signaled some legal ground supports the policies.

Lilly's warning letter to hospitals pointed to decisions from the US Court of Appeals for the District of Columbia Circuit and the Third Circuit, where judges ruled the 340B statute doesn't prohibit manufacturers from imposing conditions on the distribution of discounted drugs to covered entities.

"That's really the precedent," said Christopher Schott, a partner at Latham & Watkins, who represented a manufacturer that prevailed in one of those cases. "That court case talks about exactly those questions and came out strongly in support of the manufacturer."

The industry also disagrees with hospitals' operational burden arguments, asserting that entities already collect and transmit this data to commercial insurers, Medicare, and Medicaid.

"Defenders of 340B covered entities that resist any measure of transparency argue that in-house pharmacy data collection is 'different' than the contract pharmacy data collection that the appellate courts permitted in those cases," said William Sarraille, a professor at the University of Maryland Francis King Carey School of Law. "That is, I think, a legally specious argument."

Sarraille said he expects at least 30 drugmakers to have introduced a policy by the end of next year.

Government's Silence

HRSA has taken little action in response to a series of letters from hospital groups seeking enforcement against the drugmakers.

The agency said in an email that it continues to review these policies to determine next steps and "remains committed to ensuring compliance with statutory eligibility requirements, strengthening program oversight, and enhancing enforcement to protect the integrity of the 340B program."

Still, the minimal action signals how the agency views the situation. Drugmakers are reading it as HRSA considering the legal implications of intervening.

"It's nothing but crickets from HRSA," Sarraille said. "That silence is telling — the agency has concluded that it has no authority to prevent manufacturers from introducing these policies."

For hospitals, the silence is alarming.

"Why is the government sitting on its hands," Golder said. "HHS has known this was coming since January. Tell us it's legal, tell us it's not legal. But just do something."