Hospitals Demand Congress Intervene After Lilly Terminates DSHs' 340B Discounts

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Hospitals are calling on lawmakers to force HHS to act now that Eli Lilly has cut off 340B pricing for certain disproportionate share hospitals (DSHs) not complying with the company's policy requiring them to submit claims data every time a Lilly drug is dispensed at 340B pricing. The federal government hasn't responded to stakeholders' concerns Lilly's new policy is a way to skirt its 340B program obligations, leading them to also consider legal action and call for an investigation by the HHS Office of Inspector General.

The American Hospital Association wants Congress to immediately use its oversight authority to demand HHS take a position on what hospitals consider an attempt by Lilly to hijack the 340B program through burdensome claims-data demands. The hospital group, one of many that had been pressing the government to intervene before the company terminated 340B pricing for the affected hospitals, warns the policy will drain scarce resources from 340B hospitals and threaten patients' access to lifesaving drugs.

Sources earlier this month had said drug distributors supplying 340B medicines to certain covered entities were asked to cut off access to Lilly medications for certain covered entities as soon as this week if the entities still weren't in compliance with the policy.

Without upfront discounts from Lilly, the impacted hospitals will have to purchase the company's drugs at their higher wholesale acquisition cost (WAC). Safety net hospitals and clinics say this will create additional, unnecessary operational and financial burdens.

The Health Resources and Services Administration (HRSA), which oversees the 340B program, did not respond by press time to *Inside Health Policy's* inquiry regarding the agency's next steps following Lilly's actions.

340B Health, a 340B hospital association, says Lilly's policy is a direct attack on the nation's health care safety net and that Lilly's refusal to provide 340B pricing to the impacted hospitals does not represent a legitimate offer by Lilly to sell drugs to covered entities at the 340B price.

“We believe Lilly’s actions violate the law and are an unprecedented attempt to rewrite the 340B rules without congressional approval. Congress did not give drug companies the authority to create their own reporting requirements and then deny discounts to hospitals that refuse to comply. Lilly’s policy shares many aspects of unilateral drug company rebate models that HRSA has opposed, a position two federal courts subsequently upheld,” 340B Health President and CEO Maureen Testoni said in response to Lilly’s decision Thursday (June 18).

Testoni added, “If HRSA allows this unlawful conduct to stand, many other drugmakers are poised to follow suit, dramatically increasing costs for safety-net providers and threatening health care access for millions of patients.”

Todd Nova, an attorney at the health care law firm Hall Render, tells *IHP* litigation is highly likely, and that things are likely to get worse before they get better for the hospitals impacted by the company’s decision.

Months after Lilly first launched its substantial claims data submission policy in February, and after sending warning letters to covered entities in the spring, Lilly contacted HRSA this month to let the agency know it plans to withhold 340B discounts for its medications for all covered entities that didn’t comply with its policy by June 8.

In Lilly’s June 1 letter to HRSA, the company said 2,350 covered entities -- 70% of the entities that purchase drugs from Lilly -- had begun complying with the claims data policy since the Feb. 1 start date, and the company had sent multiple rounds of letters notifying at least 1,000 remaining covered entities warning they are at risk of losing access to upfront discounts on 340B drugs if they don’t comply with the policy. Most of these entities at risk were said to be DSHs, which Lilly says are the program’s “largest and most sophisticated” participants.

Lilly’s letter also says it invited 50 of the largest “holdouts” to identify and share their concerns about the policy during in-person discussions, but meetings with 13 holdouts didn’t result in any resolution and others did not respond.

Lilly also alleged hospital associations have opposed drug company policies aimed at eliminating discount duplication and diversion in the 340B program. The company said hospital groups orchestrated a boycott against the company, with DSHs withholding data at “substantially greater rates” than community health centers, federally qualified health centers, STD clinics, and critical-access hospitals.

Hall Render, which represents 13 of the holdouts mentioned in Lilly's letter to HRSA, submitted its own letter to HRSA to rebuff the drug maker's statements.

The firm argued Lilly's claims of a coordinated boycott are unfounded, revealing that when Lilly did meet with some of the non-compliant entities, the meetings were scheduled for 15 minutes, and some lasted as few as six minutes. While Lilly promised it would provide a written analysis showcasing that it took the entities' HIPAA concerns seriously, Hall Render said, an analysis was never sent to them before the company reached out to HRSA.

Hall Render also urged HHS to open an investigation through HHS OIG, saying Lilly's letter at the time was an admission that it will soon knowingly and intentionally overcharge 340B covered entities for covered outpatient drugs, which Hall Render alleges is a violation of the 340B statute.

"An OIG investigation into Lilly would be justified both legally and financially. As the party pressing for changes, Lilly bears the burden of proving that its policy is lawful. At the very least, it should demonstrate that it applied critical thought to its plans before upending the 340B Program. It failed to do so when we asked on behalf of our clients, and it is now threatening to punish covered entities for exercising appropriate due diligence. Now, OIG should ask the same question on behalf of the American people," the Hall Render letter says.

HRSA's Office of Pharmacy Affairs responded to Hall Render requesting more clarity regarding the patient privacy concerns raised by the firm in its June 3 letter, including whether the claims data Lilly are demanding is public health information and what steps Lilly and its third-party vendor would need to take in order to protect patient privacy.

The American Society of Health-Systems Pharmacists also tells *IHP* that Lilly's policy conflicts with laws in 11 states -- Colorado, Maine, Nebraska, North Dakota, New Mexico, Rhode Island, South Dakota, Tennessee, Vermont, Washington and West Virginia -- that specifically prohibit conditioning 340B discounts on receipt of claims data. New Mexico's law only applies to 340B grantees, not participating hospitals.

Drug companies are challenging several of these laws, but with the exception of West Virginia, the courts are generally siding with the states, according to ASHP.

The consequences of Lilly's decision to pull 340B discounts from the impacted hospitals are expected to be severe. According to 340B Health, 340B hospitals provide a significant share of care to low-income

and vulnerable patients. The hospitals deliver 77% of the nation's Medicaid care and 67% of uncompensated care, and they say they usually rely on 340B savings to offset underpayments by Medicaid and Medicare as well as to subsidize rural health services, oncology programs, behavioral health and other critical programs that otherwise would be unavailable.

Stakeholders like ASHP, 340B Health and AHA are worried the effects of Lilly's decision may be exacerbated once other drug companies begin to cut off 340B pricing for covered entities that don't comply with their claims data policies. At least five other drug companies have launched or are preparing to launch their own claims data submission policies, including Exelixis, Novo Nordisk, AstraZeneca, Bristol Myers Squibb and Biogen.

ASHP and AHA have reached out to HRSA on multiple occasions, pressing the agency to shut down Lilly's policy before any entities lose access to 340B pricing. HRSA did not respond to their previous inquiries, the groups say.

"It really seems like we're in a world where there is going to be no enforcement of the rules here, and so manufacturers can just demand whatever they want, and I just haven't seen where HRSA is going to draw the line," ASHP Senior Vice President Government Relations Tom Kraus told *IHP*. -- *Gabrielle Wanneh* (gwanneh@iwpnews.com)