United States Senate

September 27, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write to ask that you and the Department of Health and Human Services (HHS) and its Office of the Inspector General (OIG) take immediate action to stop a series of alarming and escalating actions taken by several of the largest U.S. drug manufacturers and other stakeholders against our safety-net providers who participate in the 340B drug pricing program. These actions are causing significant harm to safety-net providers participating in the 340B program and the millions of West Virginians and Hoosiers who rely on 340B covered entities for their care.

There are 37 hospitals in the state of West Virginia and 58 hospitals in the state of Indiana that participate and rely on the 340B Program. For example, hospitals like West Virginia University Health System and Indiana University Health use their 340B savings to support patient care for vulnerable individuals, through critical programs such as bedside pharmacy discharge delivery and counseling. 340B also allows the health system to maintain a mobile lung cancer screening unit, as well as diabetes support groups. For some rural hospitals, 340B helps keep their doors open.

First, as you are aware, in summer 2020, nine drug companies started unlawfully denying 340B discounts to hospitals, health centers, and clinics that contract with community pharmacies to dispense drugs to their patients. Since this time, there has been overwhelming bipartisan opposition to these actions, and last year, HHS issued a strongly written advisory opinion (AO) concluding that these actions violate the 340B statute. The restrictions imposed by drug companies on 340B discounts are causing alarming financial losses for safety-net hospitals, health centers, and other 340B providers as more companies impose such limits and increasingly target discounts on costly specialty drugs, HHS OIG needs to fully enforce the law against all drug manufacturers who unlawfully overcharge safety net health care providers.

We appreciate efforts HHS has taken thus far, including the Health Resources and Services Administration (HRSA) sending enforcement letters to nine drug manufacturers and referring the actions of seven companies to the HHS OIG to evaluate whether to impose penalties.[1] The OIG is authorized to impose certain penalties against manufacturers that knowingly and intentionally overcharge 340B hospitals and health centers.[2] We urge the OIG to conclude its review as soon as possible and take any necessary action against manufacturers that are in violation of federal law.

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[1] HRSA Correspondence to Stakeholders, Updated HRSA Letters to United Therapeutics Corporation, Sanofi, Novo Nordisk, Novartis Pharmaceuticals Corporation, Eli Lilly and Company, and AstraZeneca Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, September 22, 2021, https://www.hrsa.gov/opa/program-integrity/index.html; HRSA Correspondence to Stakeholders, Updated HRSA Letter to Boehringer Ingelheim Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, March 29, 2022, https://www.hrsa.gov/opa/program-integrity/index.html.

[2] 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. §10.11(a).

We also urge HHS to review further enforcement actions against the remaining nine drug companies that have implemented restrictive policies, but have not yet been notified they are violating federal law nor been subsequently referred to the OIG. It is critical that both HHS and OIG enforce the law and penalize manufacturers who are overcharging 340B providers and dissuade more manufacturers from implementing similar policies.

Since these denials began in the summer of 2020, Congress has written multiple bipartisan letters strongly opposing these actions, including letters to HHS calling for swift enforcement actions against manufacturers that overcharge covered entities participating in 340B. However, despite calls for enforcement and the actions HHS has already undertaken, the problem has gotten worse.

While we wait for the OIG to assess further action, more drug manufacturers have implemented policies restricting access to 340B pricing. A survey conducted in March 2022 showed that the estimated annualized impact of manufacturer overcharges has more than doubled since 2021.[3] These actions are unlawfully denying hospitals' drug savings they rely on to serve patients living with low incomes. The longer they are allowed to continue, the more harm this causes providers' ability to care for patients most in need.

Thank you for your consideration in promptly addressing these critical and time sensitive issues. We look forward to working with you to protect and preserve the 340B program and the many patients who rely on it for quality care in West Virginia, Indiana, and the rest of the country.

Sincerely,

Joe Manchin III
United States Senator

Mike Braun
United States Senator

CC: Christi A. Grimm
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[3] 340B Health, Contract Pharmacy Restrictions Represent Growing Threat to 340B Hospitals and Patients: Survey Results, https://www.340bhealth.org/files/Contract_Pharmacy_Survey_Report_FINAL_05-05-2022.pdf.