FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

# Congress of the United States
## House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

September 3, 2020

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write today to express our strong concerns about several drug manufacturers' actions that threaten to undermine the 340B Drug Pricing Program. The 340B Program is a critical tool in the fight to lower drug prices, and helps safety net health providers, including Federally Qualified Health Centers and disproportionate share hospitals, among others, to provide frontline care in the midst of the coronavirus disease of 2019 (COVID-19) pandemic. It is critical that the Administration maintains program integrity to ensure this care is not interrupted.

As you know, the 340B Program "enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services."[1] Under the Program, drug manufacturers participating in Medicaid are required to provide discounts on outpatient prescription drugs to certain safety net health providers, called "covered entities", who can then use those savings to expand and improve care for the uninsured and underinsured. In order to expand the reach of their services, many 340B covered entities have entered into arrangements with "contract pharmacies" that dispense discounted drugs on behalf of the covered entities. These arrangements can be especially helpful to patients in rural and underserved areas, where access to care is especially limited.

We are concerned that in recent weeks, several drug manufacturers have taken or threatened to take varying measures to limit the reach of the 340B Program. This has included placing arbitrary limits on the number of contract pharmacies they will serve, or, in some instances, cutting off delivery of drugs at discounted 340B prices to contract pharmacies

[1] Health Resources & Services Administration, *340B Drug Pricing Program*, (September 2020) (www.hrsa.gov/opa/index.html).

altogether.[2, 3, 4, 5] Other drug manufacturers have instituted new reporting requirements on covered entities, suggesting that should covered entities fail to comply, manufacturers may take additional steps that would be "substantially more burdensome."[6] While we recognize many manufacturers have taken issue with the expanded reach of contract pharmacies and have expressed concern about the potential for duplicate discounts, these actions are not oversight or compliance measures authorized by law, and could represent a failure of manufacturers to meet their requirements under the 340B statute.

As explained in a guidance document issued by the Health Services and Resources Administration (HRSA), the law does not limit the number of contract pharmacy arrangements a covered entity may enter into, but each covered entity maintains the responsibility to prevent diversion and duplicate discounts under such arrangements.[7] To ensure compliance, the 340B statute allows HRSA and manufacturers to audit covered entities.[8] HRSA can also enforce sanctions if covered entities are out of compliance.[9] However, there is no provision of law which allows participating manufacturers to deny service to covered entities, or choose where covered entities may dispense the drugs they purchase. Failure of manufacturers to offer drugs at the appropriate 340B price may violate the 340B statute's requirements or result in overcharges to covered entities, in contravention of the law.

We appreciate HRSA's recent acknowledgement that a manufacturer's failure to deliver drugs to covered entities' contract pharmacies at 340B prices could "significantly [limit] access to 340B discounted drugs for many underserved and vulnerable populations."[10] While we hope that drug manufacturers retreat from these announced policies so patients will not lose access to care, HHS has an obligation to ensure manufacturers comply with the law. Furthermore, Congress has provided you with tools, including manufacturer auditing rights and civil monetary

---

[2] *Eli Lilly Says it Doesn't Have to Provide 340B-priced Drugs to Contract Pharmacies*, 340B Report (July 7, 2020).

[3] *Sanofi to Require 340B Data or Cut Off Contract Pharmacies' Discounts*, Inside Health Policy (July 31, 2020).

[4] *AstraZeneca to Stop 340B Discounts Via Contract Pharmacies*, Inside Health Policy (August 18, 2020).

[5] *Eli Lilly Dramatically Escalates Efforts to Restrict Access to 340B Pricing*, 340B Report (September 1, 2020).

[6] *Eli Lilly Says it Doesn't Have to Provide 340B-priced Drugs to Contract Pharmacies*, 340B Report (July 7, 2020).

[7] 75 Fed. Reg. 10272.

[8] 42 U.S.C. § 256b.

[9] *Id.*

[10] *HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies*, Inside Health Policy(August 20, 2020).

penalties, to enforce it. Failure to enforce 340B requirements threatens to undermine program integrity. Allowing manufacturers to institute extralegal requirements on covered entities under the threat of refusing to ship drugs as required, or allowing manufacturers to pick and choose where they will comply with program requirements, could set us on a treacherous path where program participants might disregard any or all of their legal obligations.

As we confront the COVID-19 pandemic, patients are relying on 340B covered entities to go the extra mile to provide care. We look forward to working with you to ensure access to care is not threatened and all participants in the 340B program are fulfilling their obligations under the law.

Thank you for your attention to this matter. If you have questions regarding this letter, please contact Stephen Holland of the Committee Staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Anna G. Eshoo
Chairwoman
Subcommittee on Health

Diana DeGette
Chair
Subcommittee on Oversight
and Investigations