THE 340B COALITION

July 16, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Recent Actions by Pharmaceutical Manufacturers Eli Lilly and Merck Impacting 340B Covered Entities

Dear Secretary Azar:

On behalf of the thousands of safety-net providers enrolled in the 340B federal drug discount program, the 340B Coalition wants to bring to your attention the actions of two global pharmaceutical companies that threaten to dramatically reduce the 340B benefit that safety-net hospitals, health centers, and clinics use to serve our nation's most vulnerable citizens. We ask that the Department of Health and Human Services (HHS) use its legal authority to halt these actions and protect these vital institutions and their patients.

Background

Eli Lilly recently announced in a notice published on the Health Resources and Services Administration's Office of Pharmacy Affairs website that, effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of the drug Cialis when the 340B covered entity that purchased it elects to have it shipped to a 340B contract pharmacy.[1] Lilly has left the door open to taking similar action with other drugs. If this is allowed to stand, there would be nothing preventing Lilly from extending this policy to hundreds of very expensive drugs that qualify for 340B pricing, including critical drugs like Humalog. We believe this refusal to sell a drug at a 340B price based on where the covered entity elects to have its 340B drugs shipped violates the 340B statute's requirement that manufacturers must offer 340B prices to eligible covered entities.

By letter dated June 29, 2020, Merck asked 340B covered entities to submit contract pharmacy claims data for "commonly dispensed" Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies[2] and indicated that, without "significant cooperation" from covered entities, Merck "may take further action to address 340B Program integrity." This

[1] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

[2] Merck expressed interest in preventing duplicate discounts under Medicaid, Medicare Part D, and commercial insurance plans. Federal law prohibits Medicaid duplicate discounts but does not address duplicate discounts under Medicare Part D or commercial plans. Federal law does not confer compliance obligations on covered entities related to non-Medicaid claims.

request goes well beyond inquiries that manufacturers often engage in to address compliance concerns. Threats of "further action" absent cooperation from covered entities with such an overly broad request is not supported under the 340B statute.

In the midst of a global pandemic, with drug prices already much too high and rising, these actions cannot be allowed to stand. It is in the public interest that the Administration act swiftly and firmly to stop these actions.

A Clear Violation of Statute

Congress created the 340B drug pricing program to allow safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Covered entities use the savings created by 340B drug price discounts to support care for patients who are uninsured and underinsured without costing the American taxpayers a single dollar, as the savings come from manufacturer discounts.

340B providers are a vital part of our nation's health care safety net, as shown by their key role in our response to the COVID-19 pandemic, and their participation in 340B is central to their ability to achieve their mission. For example:

- Federally Qualified Health Centers -- whose authorizing statute explicitly requires them to provide required services such as pharmaceuticals by contractual or collaborative arrangements, if not directly[4] -- use the savings from the 340B program to underwrite the costs of providing free or heavily discounted medications to low-income uninsured and underinsured patients. These savings also support a range of other services, which vary based on the needs of each health center's community. Common examples include substance use disorder services, clinical pharmacy services, dental services, and programs to make pharmaceuticals accessible to patients who are homebound or who live in remote areas.
- Ryan White grantees use 340B savings to provide specialized and primary medical services, dental care, and other services to people living with HIV/AIDS.
- AIDS Drug Assistance Programs are fully dependent on 340B contract pharmacies for their direct purchase mechanisms and uninsured clients.
- Comprehensive hemophilia treatment centers (HTCs) use 340B program savings to maintain and expand clinical services for all bleeding disorders patients seen at their centers, including such non-reimbursable services as coordination of care, social work services, and physical therapy assessments as well as rural outreach clinics. Patients and their families rely on HTCs, which depend on 340B savings, for access to specialized, consistent, and high-quality treatment and education. With HTCs and their

[3] H.R. Rep. 102-384(II) at 12 (1992).
[4] 42 U.S.C.§ 254b(a)(1).

comprehensive care model enabled by 340B savings, patients have longer, healthier, and more productive lives.
- 340B hospitals provide 60 percent of all uncompensated care in the U.S. and 75 percent of all Medicaid hospital care.

The 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to enter into agreements with HHS that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[5] There is no provision under the statute that allows Lilly to deny 340B pricing to a covered entity, or to require that a drug purchased by a covered entity be shipped only to locations that the manufacturer has approved. Therefore, Lilly's pharmacy policy is a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

We are concerned that Merck's wide-ranging request for all contract pharmacy claims data, to address so-called "duplicate discounts" under Medicaid, Medicare Part D, and commercial plans could be extremely burdensome for covered entities to meet. We also are concerned that the data sought by Merck to prevent Medicare Part D and commercial "duplicate discounts," neither of which is prohibited under the 340B statute, will only be used to benefit the company's financial bottom line, not 340B compliance. The 340B statute does not permit pharmaceutical manufacturers to set up barriers to 340B pricing. Under federal rules, if Merck has compliance concerns regarding a particular covered entity, the company can make a good-faith inquiry targeted to that entity.[6] If the inquiry does not resolve the company's concerns, a manufacturer can request to conduct an audit of the entity.[7] We ask HHS to prohibit Merck from establishing barriers to 340B by threatening to impose "substantially more burdensome" consequences if covered entities do not voluntarily participate in the company's unnecessary and burdensome program.

A Dangerous Precedent

We are concerned that the actions of these global manufacturers, if allowed to stand, will set a dangerous and negative precedent for the 340B program and the providers and patients it serves. These policies will hurt patients with low incomes and those living in rural communities who rely on 340B covered entities for their care. The Coalition appreciates the work that President Trump and you have done to halt the rise in prescription drug prices. Taking action today to halt these ill-conceived policies will be an important part of those efforts.

[5] 42 U.S.C. § 256b(a)(1).
[6] Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406 (Dec. 12, 1996).
[7] 42 U.S.C. § 256b(a)(5)(C).

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We appreciate your consideration of our request. If you have any questions, please feel free to reach out to any of the listed 340B Coalition representatives.

Sincerely,

The 340B Coalition

cc:
Tomas J. Engels, Administrator, Health Resources and Services Administration
Rear Admiral Krista M. Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

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