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December 7, 2020

Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Engels,

I write with deep concern over continued efforts by a number of pharmaceutical manufacturers restricting access to discounted drugs – including life-sustaining pharmaceuticals, such as those that treat respiratory diseases like asthma and COPD – through the 340B Drug Pricing Program for providers that utilize contract pharmacies. Therefore, as the agency that oversees the 340B Drug Pricing Program, the Health Resources and Services Administration (HRSA) must intervene immediately to stop these illegal and deeply troubling restrictions and barriers to discounted drugs being put in place by pharmaceutical manufacturers.

As you know, the 340B Program requires drug manufacturers that receive reimbursements through Medicaid to provide drugs at a discount to eligible public and nonprofit health care organizations, including Federally Qualified Health Centers (FQHCs), FQHC Look-Alikes, hospitals – which encompass disproportionate share hospitals, rural hospitals, and children’s hospitals – Ryan White HIV/AIDS clinics, and other safety net providers.¹ These health care providers then use 340B savings to provide discounted drugs to patients, especially those who are low-income or uninsured, and expand access to essential patient care.² In 1996, HRSA released guidance indicating that the 340B statute allows the above-mentioned 340B entities to contract with a pharmacy (known as a “contract pharmacy”) to dispense 340B drugs.³ In 2010, HRSA released additional guidance specifying how covered 340B health care providers

¹ 42 U.S.C. § 256b(a)(1).

² National Association of Community Health Centers, Inc., *Health Centers and the 340B Drug Discount Pricing Program: Increasing Access to Essential Medications and Services to Communities in Need [Fact Sheet]* (June 2014), http://www.nachc.org/wp-content/uploads/2016/02/340B_FS_2014.pdf

³ Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996).

can use multiple contract pharmacies to support care for vulnerable populations, especially those in underserved areas.⁴

Despite the fact that the 340B statute requires pharmaceutical manufacturers to sell drugs at 340B prices including drugs dispensed through contract pharmacies and despite the longstanding history of 340B covered entities providing access to these critical drugs through the contract pharmacy model – multiple drug manufacturers have recently begun denying 340B pricing to covered entities for drugs dispensed through contract pharmacies. Just this week, Novo Nordisk announced that will no longer distribute certain 340B drugs to hospital contract pharmacies.⁵

Such refusals to provide 340B pricing for use in contract pharmacies are likely a violation of the law. The 340B statute requires drug companies that participate in Medicaid to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price of such drug is made available to any purchaser at any price”⁶ and HRSA’s 2010 guidance makes clear that “[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price.”⁷

By improperly limiting access to 340B drugs, manufacturers will sever a lifeline to treatment for those who are overwhelmingly underserved, low-income, and vulnerable. Your agency has agreed, stating, “Manufacturers that refuse to honor contract pharmacy orders may be significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations. Many of these populations may reside in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions.”

Further, these moves by pharmaceutical companies are especially troubling during the COVID-19 pandemic. Your agency has agreed. In a recent letter, HRSA’s General Counsel, Robert F. Charrow, wrote that these pricing changes are, “at the very least, insensitive to the recent state of the economy” given that “the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19.” Mr. Charrow, writing for HRSA, further wrote, “During this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance.”⁸ One provider in Connecticut even noted that some of the most impacted drugs include Bevespi, Daliresp, Symbicort, and Pulmicort – drugs that treat respiratory diseases such as asthma and COPD – during a global COVID-19 pandemic that preys on individuals with pre-existing respiratory conditions.

⁴ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

⁵ 340B Report, *BREAKING: Novo Nordisk Will Cease 340B Pricing for Hospital Contract Pharmacies on Jan. 1* (Dec. 1, 2020): <https://340breport.substack.com/p/breaking-novo-nordisk-will-cease>

⁶ 42 U.S.C. 256b(a)(1).

⁷ 75 Fed. Reg. at 10278.

⁸ Robert P. Charrow to Anat Hakim, Sep. 21, 2020: <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf>

It is clear that HRSA agrees it is now more important than ever that 340B providers are able to flexibly provide treatment and care to the individuals they serve without undue burdens. However, the pharmaceutical industry's recent actions are particularly troubling and detrimental to the goals of the 340B Program. It is essential that HRSA take clear, concrete actions to put a stop to these illegal actions by the pharmaceutical industry that cause lower income patients significant harm, and to protect health care providers and the patients that they serve.

Sincerely,

A handwritten signature in blue ink, reading "Richard Blumenthal". The signature is written in a cursive style with a prominent flourish at the end.

RICHARD BLUMENTHAL
United States Senate