AMERICA'S ESSENTIAL HOSPITALS

August 28, 2020

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Ref: Pharmaceutical Company Actions Undermining 340B Drug Pricing Program

Dear Secretary Azar,

America's Essential Hospitals appreciates the actions of the Trump administration to mitigate the COVID-19 pandemic. We are encouraged that the Department of Health and Human Services (HHS) has provided flexibility throughout the pandemic that has been critical to providers on the front lines responding to the pandemic in their communities. In particular, the Health Resources & Services Administration (HRSA) issued guidance during this public health emergency to enable 340B Drug Pricing Program providers to continue to stretch their scarce resources and offer access to their vulnerable populations. Unfortunately, recent actions from multiple drug manufacturers threaten to undermine the progress the administration has made on reducing provider burden and tackling rising drug prices. We urge HHS to intervene to prevent these drug manufacturer actions from restricting access to lifesaving drugs.

Our more than 300 member hospitals serve a disproportionate share of low-income patients; as such, almost all qualify to participate in the 340B program. Essential hospitals, at the center of the nation's safety net, face the COVID-19 pandemic with short supplies of available resources. Costs associated with COVID-19 continue to rise while revenues decrease. Savings from the 340B program are more critical than ever to ensure our member hospitals can reach more patients and continue to offer vital services, safeguarding access to affordable health care for vulnerable individuals. Recent actions by five of the largest drug manufacturers threaten to undermine the ability of 340B hospitals to access affordable, lifesaving drugs for their patients. These actions are contrary to the 340B statute, add unnecessary burden on hospitals that already are stretched thin during an unprecedented pandemic, and impede vulnerable populations' access to affordable drugs.

To date, Eli Lilly and AstraZeneca have sent letters informing covered entities that the companies will cease shipping 340B-priced drugs to the recipients' contract pharmacies. While Eli Lilly's current actions are limited to one drug, AstraZeneca's action spans the scope of all contract pharmacy drugs. Three other manufacturers have taken a different approach. Merck, Sanofi, and Novartis have imposed arbitrary and ill-timed reporting requirements on 340B hospitals, requesting data on all contract pharmacy claims on a biweekly basis. The requested claims include Medicaid, Medicare Part D, and commercial claims. These manufacturers have threatened to take punitive measures if covered entities refuse to comply with these frivolous

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: info@essentialhospitals.org

inquiries, including ceasing to ship 340B drugs to their contract pharmacies. These actions are problematic for many reasons.

First, these actions are a clear violation of drug manufacturers' statutory obligation to provide 340B discounts to covered entities. Under statute, drug manufacturers must provide 340B discounts to covered entities if they opt to have their drugs covered by the Medicaid prescription drug rebate program. The 340B statute is unequivocal in its requirement that these manufacturers provide 340B drugs to covered entities "at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[1] HRSA realized the importance of contract pharmacies in allowing for these arrangements in its previous guidance, and the manufacturers' actions flout this guidance, as well.

Second, the steps taken by the manufacturers will severely restrict access to affordable, lifesaving drugs for the most vulnerable populations, which depend on these drugs for treatment of acute and chronic conditions. Hospitals in the 340B program use HRSA-approved contract pharmacy arrangements to ensure they can expand access as widely as possible so patients can fill their prescriptions where it is most convenient for them. This is particularly true in the case of health systems that do not have expansive in-house pharmacy networks or that have patients facing barriers to access making it impractical to come to the hospital to replenish their supplies of needed medications. These patients include individuals living in rural areas and those facing various social risk factors, such as lack of transportation. If the manufacturers follow through with their threats to not honor 340B pricing at contract pharmacies, patients who have come to rely on contract pharmacies in their neighborhoods would be left without their usual source of discounted prescription drugs. Instead, they would have to purchase these drugs either at higher prices or at other pharmacies less accessible to them.

Third, the manufacturer actions are not based in any sound policy rationale. The manufacturers requesting contract pharmacy claims data cite concerns about duplicate discounts. However, the statutory prohibition on duplicate discounts only applies to the Medicaid context. Covered entities, in conjunction with state Medicaid programs, already take thorough steps in accordance with guidance from HRSA and the Centers for Medicare & Medicaid Services to avoid duplicate discounts. This includes appending claims modifiers to Medicaid claims, using the Medicaid exclusion file, and other actions. There is no reason related to 340B program integrity for manufacturers to seek to avoid duplicate discounts in the Medicare or commercial contexts, as there is no such thing as a duplicate discount in those contexts.

Finally, the requests place undue administrative burden on hospitals that works against this administration's efforts to reduce provider burden. The onerous manufacturer requests will further burden hospitals that already comply with numerous governmental and private stakeholder data reporting requests. Producing the claims data that manufacturers request on a biweekly basis will require dedicated staff time, if not the hiring of new staff dedicated to these requests. Considering the burden associated with complying with these inquiries, a pandemic is not the time to impose new data collection requests on 340B hospitals. These hospitals are singularly focused on responding to and recovering from COVID-19 and directing their staff toward these efforts.

For these reasons, we urge the agency to intervene to prevent manufacturers from undermining the 340B program and violating their statutory obligations. By putting a stop to these unjustified

[1] Public Health Service Act, section 340B(a)(1).

and burdensome actions, HHS will lift an unnecessary burden from hospitals and ensure continued access to affordable drugs, a key priority of this administration.

****

America's Essential Hospitals appreciates your consideration of this letter. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO