American Hospital Association™
Advancing Health in America

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October 16, 2020

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

Dear Secretary Azar:

On behalf of the American Hospital Association's (AHA) nearly 2,000 340B member hospitals, we are writing to follow up on our previous correspondence on the serious situation Eli Lilly, AstraZeneca and Sanofi are creating for the nation's most vulnerable communities by refusing to comply with the requirements of the 340B program to sell to contract pharmacies at the discounts required by section 340B of the Public Health Service Act.

Despite correspondence to the drug manufacturers from AHA, 340B Health and others affected by this conduct followed by a letter from the Department of Health and Human Services' (HHS) General Counsel to Eli Lilly expressing "significant" concerns, Eli Lilly, Astra Zeneca and Sanofi have yet to halt their conduct, which is plainly illegal. Therefore, we request that HHS immediately direct all three companies to cease charging hospitals and covered entities more than the 340B ceiling price for drugs being dispensed by a contract pharmacy and pursuant to 42 U.S.C. § 256b(d)(1)(B)(ii) to issue refunds for each overcharge instance. We also request that the matter be referred to the HHS Office of Inspector General for assessment of civil money penalties pursuant to 42 C.F.R. § 10.11 and 42 C.F.R. Part 1003.[1]

Eli Lilly signaled its intent to flaunt the law in May 2020, when the Health Resources and Services Administration (HRSA) posted a notice from Eli Lilly, which states that, effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of its drug Cialis® when the 340B covered entity purchasing the drug elects

[1] HRSA's civil money penalty regulations recognize that the penalties are in addition to repayment for overcharging as required by 42 U.S.C. § 256b(d)(1)(B)(ii). 42 C.F.R. § 10.11(a).

to have it shipped to a 340B contract pharmacy. *See Limited Distribution Plan Notice for Cialis*® on HRSA's website. On Sept. 1, 2020, Lilly extended this policy to all of its drugs, effective Oct. 1, 2020, and AstraZeneca and Sanofi quickly followed suit implementing similar policies withdrawing 340B pricing for their drugs when the covered entity elects to have the purchased drug shipped to a contract pharmacy.

These manufacturers' failure to sell their drugs to covered entities for delivery to patients through contract pharmacies at the 340B ceiling price is contrary to section 340B of the Public Health Service Act, 21 U.S.C. § 256b. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) these manufacturers have entered with HRSA under the statute, the manufacturers must charge covered entities no more than the 340B ceiling price for any covered outpatient drug. Failure to do so violates the 340B statute and the PPA.

As we further explain below, the plain meaning of the 340B statute requires all manufacturers to sell their drugs to covered entities at the 340B ceiling price, regardless of whether the drug is furnished at the entity's pharmacy or at a pharmacy that has entered into a contract with the covered entity to furnish 340B drugs to the covered entity's patients. HRSA has issued guidance on contract pharmacies that provides the correct interpretation of the statute. The statute does bind HHS and HRSA, and even without the guidance the statute would prohibit the manufacturers' conduct.

Under the 340B program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid, are required to enter into a PPA with the HHS Secretary pursuant to which they must offer 340B providers outpatient drugs at or below the ceiling price. Nothing in the statute limits how covered entities are permitted to get those drugs to their patients if the covered entity is complying with the statutory requirements, including the prohibition on drug diversion and duplicate discounting.

In 1996, HRSA issued "final guidelines" which recalled that since the beginning of the program, HHS has recognized that covered entities are permitted to use contract pharmacies to dispense 340B drugs as long as they comply with the prohibition on drug diversion. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) ("As early as 1993, several covered entity groups ... came forward to assist the Department in developing a workable mechanism to use outside pharmacies...")

The 1996 guidelines formalized a mechanism that covered entities could use to contract with a pharmacy to provide services to the covered entity's patients. 61 Fed. Reg. 43549. Although those guidelines provided only for the use of a single contract pharmacy, the limitation was driven by HRSA's desire to provide a mechanism that it thought would eliminate the risk of potential drug diversion rather than with a determination that HRSA believed it was not permitted. *Id.* In fact, HRSA agreed with comments that "[a]s a matter of State law, entities possess[ed] the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients" and that "even in the absence of Federal guidelines, covered entities have the right to

contract with retail pharmacies for the purpose of dispensing 340B drugs." HRSA also agreed that "[b]y issuing the guidelines, [the Office of Drug Policy, a Division of HRSA, was] not seeking to create a new right but rather [was] simply recognizing an existing right that covered entities enjoy under State law." *Id*. Finally, HRSA stated that "[u]nder section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. *Id.* at 43555 (emphasis added).[2]

In 2001, HRSA stated that certain covered entities could use more than one contract pharmacy, 75 Fed. Reg at 10273. And in 2007, HRSA proposed guidelines formally recognizing this mechanism. 72 Fed. Reg. 1540 (Jan 12, 2007). When those guidelines were finalized in 2010 (75 Fed. Reg. 10272), HRSA again recognized 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." Id.* (emphasis added). Until now, Lilly and all other manufacturers have followed HRSA's interpretation of the statute. The refusal to follow the law is harming vulnerable communities and health care providers that the HHS General Counsel noted are already "struggling financially."

We are asking for a meeting with you and your staff to discuss what steps HHS intends to take to address this situation. We believe we can work together with you to halt this illegal conduct.

Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, director of policy, at 202-626-2326 or mcollins@aha.org or Aimee Kuhlman, senior associate director of federal relations, at 202-626-2291 or akuhlmanl@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer

[2] In response to comments arguing that the statute does not permit the use of contract pharmacy arrangements, HRSA noted that "[t]he statute is silent as to permissible drug distribution programs and that "[t]here is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." According to HRSA, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified groups of 340B covered entities." *Id.* at 43549.