American Hospital Association™
Advancing Health in America

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July 30, 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 express concern regarding recent action taken by three major drug manufacturers – Eli Lilly and Co., Merck and Sanofi – to limit the distribution of certain 340B drugs to our hospital members. Eli Lilly has filed its notice to limit the distribution of certain 340B drugs with the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA). Merck and Sanofi have directly communicated with our 340B hospital members requesting detailed information about any 340B drugs distributed through the hospital's contract pharmacy arrangements. The Merck and Sanofi communications explain the purpose of the request is to investigate possible duplicate discounts provided to state Medicaid programs.

The 340B statute is clear that manufacturers wishing to participate in the Medicaid program must enter into agreements with the Department of Health and Human Services (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."[1] Yet, Eli Lilly, Merck and Sanofi are moving forward with these actions in direct conflict with the statute and HRSA's 2010 guidance on contract pharmacy arrangements. The guidance clearly notes that: "Under 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

[1] 42 U.S.C. 256b(a)(1)

manufacturer to sell the drug at a price not to exceed the statutory 340B discount price."[2] The HRSA guidance also makes it clear that the 340B covered entity is responsible for ensuring that the entity meets all requirements of the 340B program, including efforts to ensure against duplicate discounts and diversion. Eli Lilly has issued FAQs to justify its action to deny the distribution of certain 340B drugs through a hospital's contract pharmacy by stating that contract pharmacy arrangements are not statutory.

As noted in the guidance, HRSA established and expanded to use of contract pharmacy to improve access to 340B drugs for vulnerable populations served by the 340B program. 340B hospital and community health clinics are all obligated to meet the statutory and regulatory requirements of the 340B program. Neither the 340B statute nor the HRSA guidance would allow Eli 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. Eli Lilly, Merck and Sanofi are picking and choosing those requirements with which they will adhere. They are publicly flaunting the 340B statute and HRSA 340B programmatic guidance and taking matters into their own hands to suit their best interests.

The AHA urges HRSA to address these abuses by Merck, Eli Lilly and Sanofi and request they cease this activity and work to ensure that 340B drugs are available and accessible to communities and vulnerable populations. 340B hospitals continue to struggle to meet the demands of the COVID-19 public health emergency and it is outrageous that in the middle of a pandemic, hospitals are facing added challenges to the drug supply chain brought on by the actions of these major drug manufacturers.

We look forward to continuing to work with you during this critical time to protect the health of our nation. 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/

Thomas P. Nickels
Executive Vice President

[2] https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf