



December 9, 2020

Mr. Harry Norsworthy, RPh, ACE
Chief Executive Officer / Owner
Komplete 340B Solutions
h.norsworthy@komplete340b.com

Dear Mr. Norsworthy:

Secretary Azar asked me to thank you for your letter regarding recent actions by several drug manufacturers impacting covered entities that participate in the 340B Drug Pricing Program (340B Program).

Your letter raises concerns about specific actions that limit access to 340B drugs. For example, Eli Lilly USA (Lilly) is no longer providing 340B discounts on several of its drug products to covered entities through contract pharmacy arrangements. Several other manufacturers have also announced plans not to sell 340B drugs to contract pharmacies, while others are limiting sales by requiring specific data requirements or selling drug products only after a covered entity has demonstrated 340B compliance.

The Health Resources and Services Administration (HRSA) is continuing to review the various proposals and whether these actions by manufacturers violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B (d)(1)(B)(vi) of the PHSA. In a letter to Lilly posted on the 340B website, the U.S. Department of Health and Human Services reiterates its concern with actions such as those Lilly is taking.¹

The 340B statute does not specify the mode by which 340B drugs may be dispensed. HRSA believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies.

¹ See: <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf>

HRSA believes that manufacturers that refuse to honor contract pharmacy orders could limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Some covered entities have reached out to HRSA expressing concern that they are unable to receive the 340B ceiling price on certain drug products due to these recent actions. HRSA is working closely with each impacted covered entity and is actively investigating the matter in order to make a final determination as to any potential action. Please share my letter with your co-signers.

Sincerely,

Handwritten signature of Krista M. Pedley in black ink.

Krista M. Pedley, PharmD, MS
RADM, USPHS

Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration