



*Advancing Health in America*

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September 8, 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 again express concern with recent actions taken by several major drug manufacturers to limit the distribution of certain 340B drugs to our hospital members. While we understand that the Health Resources and Services Administration (HRSA) is further investigating these actions, we urge swift and decisive action to halt these pernicious tactics so as to prevent other manufacturers from following suit.

In our July [letter](#), we alerted you to actions taken by Eli Lilly and Merck to undermine the 340B program. Since that time, several other drug manufacturers – Sanofi, Novartis and AstraZenca – adopted similar strategies to interfere with 340B discounts for drugs distributed through contract pharmacy arrangements and/or demanding of 340B hospitals superfluous claims data requirements. These actions undermine 340B hospitals' ability to serve vulnerable communities, particularly in rural areas, where contract pharmacies help provide access to more affordable health care services.

The 340B statute is clear that manufacturers participating 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.”<sup>1</sup> There is no statutory provision that allows these manufacturers to deny 340B pricing to eligible hospitals for any drug. In addition, 340B programmatic guidance states unequivocally that, “[u]nder section 340B, if a covered

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<sup>1</sup> 42 U.S.C. 256b(a)(1)



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.<sup>2</sup> HHS, based on this alone, should act to compel drug manufacturers to halt these abusive tactics.

HRSA, in its oversight of the 340B program, found that expanding the use of contract pharmacies to improve access to 340B drugs for vulnerable communities served by the 340B program was critical, particularly in rural areas. Nearly half of all eligible 340B hospitals are in rural settings that often lack adequate access to health care services. Contract pharmacies expand access to affordable health care services for everyone in these vulnerable communities and the financial relief provided to rural hospitals from the exorbitant prices they would otherwise pay help keep them operating.

The AHA has written to each of these drug manufacturers' leadership to request they discontinue these abusive tactics. The responses received thus far cite unsubstantiated concerns about duplicate discounts between the Medicaid and 340B programs. However, even if these concerns are valid, there is no legitimate basis for these companies to limit the distribution of prescription drugs to 340B hospitals or demand superfluous paperwork.

The drug companies are attempting to exploit for their financial benefit the current COVID-19 health care crisis. As you are aware, hospitals throughout the nation are under severe stress by the need to prepare for, and/or care for, COVID-19 patients, while coping with the financial damages inflicted by the virus. Therefore, we urge you to act immediately against any drug manufacturer employing these pernicious tactics to ensure that 340B drugs are available and accessible to vulnerable communities.

We look forward to continuing to work with you during this critical time to protect our nation's health. Please contact me if you have questions, or feel free to have a member of your team contact Molly Collins, AHA's director of policy, at (202) 626-2326 or [mcollins@aha.org](mailto:mcollins@aha.org) or Aimee Kuhlman, AHA's senior associate director of federal relations, at (202) 626-2291 or [akuhlman@aha.org](mailto:akuhlman@aha.org).

Sincerely,

/s/

Richard J. Pollack  
President and Chief Executive Officer

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<sup>2</sup> <https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf> (emphasis supplied)