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Submitted electronically to Thomas.Engels@hrsa.hhs.gov

February 4, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: 340B Drug Pricing Program – Claims-Level Data Submission for In-House Pharmacies

Dear Administrator Engels:

On behalf of its member academic health systems and teaching hospitals, the AAMC[1] writes you to urge the Health Resources and Services Administration (HRSA) to prohibit drug manufacturers from pursuing unilateral policies that impose onerous claims data reporting requirements on 340B Drug Pricing Program covered entities. We call on HRSA to clearly communicate to drug manufacturers that their actions run afoul of the 340B statute and to use the enforcement mechanisms at the agency's disposal to follow through if manufacturers fail to comply.

The 340B program is critical to academic health systems and the patients and communities they serve. 340B hospitals are a vital part of the nation's health care safety-net, ensuring access to cutting-edge technology, research, and health expertise for their patients. Over 90 percent of AAMC-member short-term non-federal hospitals are 340B eligible and provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, pediatric specialty care, and treatment for rare and complex conditions. For example, AAMC members comprise 100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 75 percent of all burn unit beds, 59

[1] The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, clinical care, biomedical research, and community collaborations. Its members are all 162 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 Canadian medical schools accredited by the Committee on Accreditation of Canadian Medical Schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

percent of all level-one trauma centers, and 64 percent of pediatric ICU beds.[2] AAMC member institutions share a common mission to care for the underserved and train the nation's future health care workforce, making life-saving health care services available to all patients, regardless of their ability to pay. This commitment to high-quality care, regardless of a patient's insurance coverage or socioeconomic status, can create significant financial challenges. Savings from the 340B program help our members to navigate these challenges, supporting their ability to maintain, improve, and expand access to care for their patients.

On January 15, drug manufacturer Eli Lilly and Company (Lilly) informed covered entities that beginning February 1, they must submit claims-level data for all 340B drugs, including drugs dispensed at in-house pharmacies, making Lilly the second drug manufacturer to impose such a requirement.[3] This new requirement compounds the other operationally complex, costly, and legally tenuous policies that the drug manufacturer has imposed over the past six years. Since December 2021, Lilly has required covered entities to submit claims data for 340B-priced drugs dispensed at contract pharmacies affiliated with the covered entity, but it has not extended this requirement to in-house pharmacies until now. Lilly was also the first drug manufacturer to restrict covered entities' ability to purchase 340B-priced drugs when dispensed at contract pharmacies. The new claims-level data reporting requirement for in-house pharmacies marks a significant expansion of Lilly's policy. The notice sent to covered entities notes that "failure to provide timely, complete, and accurate data . . . may result in loss of access to pricing until such time as the outstanding data is provided." Effectively, Lilly has threatened that it could delay or withhold 340B pricing to covered entities at their in-house pharmacies—a clear overreach and violation of the statute's directive that a "manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."[4]

To justify its new reporting requirement, Lilly cites the purported need to use the claims data for program integrity and to ensure duplicate discounts are not occurring—that is, a drug is not receiving both a 340B discount and a rebate through the Medicaid Drug Rebate Program. Collecting this data is unnecessary and is burdensome, as HRSA and state Medicaid agencies have longstanding, tested policies in place to ensure compliance with the statutory prohibition on duplicate discounts. As drug manufacturers have done in other contexts, the unilateral action seeks to upend HRSA's compliance responsibilities related to the 340B program and replace them with the manufacturer's own policies addressing purported program integrity issues. In enacting the 340B statute, Congress delegated responsibility for overseeing and enforcing the 340B program solely to the Department of Health and Human Services (HHS) through HRSA. For example, the 340B statute provides HHS with audit authority, as well as discretion to establish a mechanism for avoiding duplicate discounts. While manufacturers are permitted under the statute to audit covered entities, the ultimate decision to sanction a covered entity for

[2] AAMC analysis of FY2023 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2024, and the National Cancer Institute's Office of Cancer Centers, 2024. AAMC membership data, December 2024.
[3] Exelixis Letter to 340B Covered Entities. September 3, 2025.
[4] 340B Statute. Sec. 340B(a)(1).

violation of 340B program requirements is made by HRSA.[5] The statute further provides that "the *Secretary* shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5)."[6] Therefore, it is unnecessary for manufacturers usurp this authority by implementing their own piecemeal approaches to preventing duplicate discounts or ensuring program integrity.

The claims-level data collection request requires 340B providers to turn over voluminous amounts of sensitive pharmacy and medical claims data to a third-party vendor (Second Sight Solutions through the 340B ESP platform), including multiple data elements for each 340B drug claim. Manufacturers have provided no assurances about maintaining the privacy and security of these claims data. On the contrary, 340B hospitals have reported that the terms and conditions of the contracts they are compelled to sign are non-negotiable and contain terms unfavorable to hospitals.

We are concerned that, like previous actions by drug manufacturers, if HRSA does not put an end to this overreach, other drug manufacturers will soon follow suit. To preserve the vital function of these academic health systems and 340B program intent, we urge HRSA to continue to monitor, enforce, and ensure compliance with the 340B program through clear directives to manufacturers, and, if necessary, enforcement action. Should these manufacturers fail to comply, we encourage HRSA to use the enforcement tools within its purview, such as referring manufacturers to the Office of Inspector General for charging above ceiling price.

Thank you for HRSA's continued support of the 340B program and for ensuring program integrity for all 340B stakeholders. Through robust internal controls, 340B hospitals are invested in and share HRSA's goal of ensuring program integrity. We would be happy to work with HRSA on any of the issues discussed or other topics related to the 340B program. If you have questions regarding our comments, please feel free to contact my colleague Shahid Zaman (szaman@aamc.org).

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer
Chantelle Britton, Director, HRSA Office of Pharmacy Affairs
Rear Admiral Krista M. Pedley, Director, HRSA Office of Special Health Initiatives

[5] 340B Statute. Sec. 340B(a)(5)A.
[6] 340B Statute. Sec. 340B(d)(2) (emphasis added).