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Ms. Carole Johnson
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 – Proposed Drug Manufacturer Rebate Models

Dear Administrator Johnson:

On behalf of its member academic health systems, the Association of American Medical Colleges (AAMC or the Association) writes to convey concerns with rebate models for the 340B Drug Pricing Program proposed by drug manufacturers. We commend the Health Resources and Services Administration (HRSA) for its commitment to preserving access to 340B discounts and for its position regarding enforcement action against drug manufacturers, including its December 13 communication to Sanofi, but we remain concerned about the growing number and expanding scope of the rebate models being proposed. We urge HRSA to continue to maintain its unequivocal stance that these rebate models contravene the 340B statute and to impose appropriate sanctions on drug manufacturers that fail to comply.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 159 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited 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 201,000 full-time faculty members, 97,000 medical students, 158,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers International broadened participation in the AAMC by 70 international academic health centers throughout five regional offices across the globe.

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, although they account for just five percent of all short-term, non-federal hospitals nationwide, AAMC members comprise 21 percent of all hospital beds, including 100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 72 percent of all burn unit beds, 61 percent of all level-one trauma centers, and 63 percent

of pediatric ICU beds.[1] 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.

Since August, four drug manufacturers have announced their intention to implement a rebate model for 340B drugs.[2] These models differ in terms of the types of covered entities and the number of drugs to which they apply, but they share the common theme of requiring hospitals to submit claims data for 340B drugs and receive the 340B price as a retrospective rebate instead of an upfront discount. As we outline in further detail in the letter, not only are these rebate models in violation of the 340B statute, but they also would result in substantial financial losses for 340B hospitals and would be operationally complex, if not impossible, to implement. Moreover, these manufacturer actions ultimately seek to upend HRSA's compliance responsibilities related to the 340B program and replace them with a patchwork of manufacturer policies addressing purported program integrity issues.

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.

Rebate Models Violate the 340B Statute and Depart from Longstanding Precedent

The rebate models require certain covered entity types to purchase covered outpatient drugs at commercial price (e.g., wholesale acquisition cost, or WAC) and then receive a rebate equal to the difference between the purchase price and the ceiling price. In unilaterally attempting to effectuate 340B prices as retrospective rebates instead of upfront discounts, drug manufacturers are violating the 340B statute's requirement that each "manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price,"[3] a point that HRSA has emphasized in its communications to manufacturers.[4] By requiring 340B hospitals to first purchase a drug at the much-higher WAC price, manufacturers would be running afoul of the 340B statute's requirement that the purchase price not exceed the ceiling price. While manufacturers assert that the 340B statute is silent as to the method of effectuating 340B prices, the statute ultimately tasks HRSA—not manufacturers—with the authority to determine whether 340B prices can be offered through retrospective rebates.[5] To date, HRSA has only authorized such an arrangement for one covered entity type—AIDS drug assistance programs. By shifting to rebate models, manufacturers are departing from over three decades of precedent, which would be disruptive for covered entities and necessitate significant operational changes for covered entities, manufacturers, and HRSA.

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[1] AAMC analysis of FY2022 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2023, and the National Cancer Institute's Office of Cancer Centers, 2022. AAMC membership data, March 2024.
[2] The four drug manufacturers are Johnson & Johnson, Eli Lilly, Sanofi, and Bristol Myers Squibb.
[3] 340B Statute. Sec. 340B(a)(1).
[4] Letter from HRSA Administrator Carole Johnson to Johnson & Johnson CEO Joaquin Duato. September 17, 2024
[5] 340B Statute. Sec. 340B(a)(1) ("taking into account any rebate or discount, as provided by the Secretary").

Rebate Models Attempt to Usurp HRSA's Oversight Responsibilities

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, the agency that HHS has tasked with 340B oversight. 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 violation of 340B program requirements is made by HRSA.[6] 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)."[7]

However, in implementing rebate models, manufacturers are requiring covered entities to submit claims data to them through their selected vendors. Manufacturers will evaluate each claim's 340B eligibility before determining whether to provide a credit equal to the difference between WAC and the ceiling price. Sanofi is going one step further and will require covered entities to submit records establishing a relationship between a patient and the covered entity that satisfies the patient definition. Manufacturers have cited supposed compliance issues on duplicate discounts as reasons for their rebate models.[8] By attempting to police the 340B program, manufacturers are creating a compliance nightmare for HRSA and covered entities and undermining program integrity efforts. The parameters of each manufacturer's rebate model differ in many aspects, including the processes for submitting data, timelines, and terms and conditions. It would be confusing for covered entities to keep track of and comply with these numerous rebate models and would ultimately run counter to ensuring program integrity. If these rebate models go into effect, HRSA would have to keep track of the various manufacturer rebate models, and because manufacturers would ultimately be deciding which drugs receive a 340B rebate, HRSA would likely see an increase in claims from covered entities of manufacturers charging above ceiling price if manufacturers do not provide rebates on some 340B drugs. If manufacturers do have legitimate concerns about program integrity, they can use existing mechanisms authorized by the 340B statute, such as manufacturer audits or the administrative dispute resolution process to address these concerns.

Rebate Models Would Devastate Financially Vulnerable Hospitals and Impede Patient Access to the Services Made Possible by 340B Savings

The proposed rebate models would devastate financially vulnerable 340B hospitals and undermine their ability to continue providing access to essential services and discounted drugs to their patients, while serving only to increase the margins of drug manufacturers. Shifting the 340B program to a rebate program would delay much needed cash flow to 340B hospitals by significantly delaying the receipt of their 340B discounts. For safety-net hospitals that often carry minimal cash on hand, the impact of the delay in realizing 340B savings would have significant negative impacts on their financial standing and downstream impacts on patient care. In addition to the delayed receipt of 340B discounts, leaving the determination of which drugs are 340B eligible to the manufacturer could result in many 340B claims being denied at the manufacturer's discretion, with no oversight or appeal mechanism available to 340B

[6] 340B Statute. Sec. 340B(a)(5)A.
[7] 340B Statute. Sec. 340B(d)(2) (emphasis added).
[8] See, e.g., Eli Lilly complaint in U.S. District Court for the District of Columbia. Case No. 1:24-cv-3220. November 11, 2024 ("Responding to that guidance, Lilly has been searching for a solution to these government-created compliance problems.").

hospitals. One AAMC member academic health system projects that the annual impact of the rebate models proposed by the four drug manufacturers would be approximately $60 million in lost (not delayed) 340B savings. This figure does not account for the impacts associated with additional compliance costs, delayed savings through a rebate model, or potential effects on the ability to use 340B discounts for Medicaid patients, as well as potential loss of sub-ceiling prices.

Reduced 340B savings would impede the ability of academic health systems to maintain the unique services they disproportionately provide, such as burn care, trauma care, and pediatric specialty care. 340B hospitals have a demonstrated commitment to serving low-income, vulnerable populations—to qualify for the program, they must meet a minimum disproportionate share hospital adjustment percentage—representing their commitment to Medicaid and low-income Medicare patients. Losses from a rebate model would compound the billions of dollars of losses hospitals have already incurred because of manufacturer restrictions on 340B drugs dispensed through contract pharmacies.[9] Destabilizing these hospitals would undermine not just 340B hospitals but would harm their low-income patients as well.

Rebate Models Would be Administratively Burdensome, If Not Impossible, to Implement

Beyond the direct financial losses that 340B hospitals would incur because of the rebate models, there would be significant operational challenges and administrative burden on hospital staff associated with complying with manufacturer rebate models and requests for claim data.

The rebate models require covered entities to turn over voluminous amounts of sensitive data to vendors such as Second Sight Solutions and Kalderos, including multiple data elements for each 340B drug claim. Collecting and transmitting this data to these vendors would require aggregating data from various pharmacy settings, particularly in large academic health systems that manage multiple in-house pharmacies, dispense 340B drugs in mixed-use settings, and have relationships with contract pharmacies. 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.

Additionally, these rebate models would require 340B hospitals to modify their existing inventory practices to maintain a separate inventory for non-340B drugs that are purchased at WAC and cannot be purchased at a lower price through a group purchasing organization (GPO) due to the GPO prohibition on 340B hospitals. 340B hospitals would have to likely utilize third-party platforms to make and track rebate requests and ultimately to match their rebate payment amounts with the 340B prices for those drugs.

Conclusion

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. To summarize, we urge HRSA to continue to enforce the 340B statute by prohibiting the adoption of rebate models by drug manufacturers. These unlawful rebate models would create compliance difficulties for HRSA and covered entities and would severely disrupt the 340B savings of academic health systems and ultimately their ability to invest these savings into the programs and specialized health care services provided uniquely by academic health systems. We would be happy

[9] 340B Health. Drugmakers Pulling $8 Billion Out of Safety-Net Hospitals. July 11, 2023. Note that this figure underestimates the true impact of these restrictions, because it was based on 21 drug manufacturers' restrictions. The number of manufacturers that have imposed limitations now stands at 37.

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