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Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence avenue, SW
Washington, DC 20201

Re: 340B Drug Pricing Program – Proposed Drug Manufacturer Rebate Models

Dear Secretary Kennedy:

On behalf of its member academic health systems and teaching hospitals, 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 Department of Health and Human Services (HHS) for its commitment to preserving access to 340B discounts through its statutory enforcement authority, as well as its opposition to unilateral rebate models in litigation initiated by five manufacturers challenging HHS' position. Because HHS noted in a May 2 court filing that it will be issuing guidance within 30 days, we write to express our concerns with allowing for the inclusion of rebate models in any upcoming guidance related to the 340B program. We urge HHS to continue to maintain its unequivocal stance that these rebate models contravene the 340B statute and to foreclose the possibility of such rebate models being used by manufacturers, either independently or as any part of a solution for deduplicating maximum fair price (MFP) under the Inflation Reduction Act (IRA) from 340B discounts. Separately, we look forward to working with the agency on how to ensure 340B program integrity and to develop efficient mechanisms to de-duplicate 340B prices from MFP under the IRA.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, biomedical research, and community collaborations. Its members are all 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 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 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.

The 340B program is critical to the patients and communities that academic health systems and teaching hospitals 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, 75 percent of all burn unit beds, 59 percent of all level-one trauma centers, and 64 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 financial means, 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. These savings are critical in allowing 340B hospitals to improve the health of their communities, whether through medication management, providing charity care, offering access to healthy food, and expanding care through mobile clinics and community health programs.

Since last August, five drug manufacturers and one vendor marketing a rebate platform 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 the HHS' 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 HHS to avoid the use of 340B rebate models and to continue to monitor, enforce, and ensure compliance with the 340B program through clear directives to manufacturers, and, if necessary, enforcement action. Below, we outline the legal, financial, and operational challenges implicated by these proposed 340B rebate models.

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 HHS 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 HHS—not manufacturers—with the

[1] 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.
[2] The five drug manufacturers are Johnson & Johnson, Eli Lilly, Sanofi, Bristol Myers Squibb, and Novartis.
[3] 340B Statute. Sec. 340B(a)(1).
[4] Letter from HRSA Administrator Carole Johnson to Johnson & Johnson CEO Joaquin Duato. September 17, 2024

authority to determine whether 340B prices can be offered through retrospective rebates.[5] To date, HHS has only authorized such an arrangement for one covered entity type—AIDS drug assistance programs. By allowing the use of rebate models, HHS would be departing from over three decades of precedent, which would be disruptive for covered entities and necessitate significant and costly operational changes for covered entities, manufacturers, and HHS.

Rebate Models Attempt to Usurp HHS' Oversight Responsibilities

In enacting the 340B statute, Congress delegated responsibility for overseeing and enforcing the 340B program solely to HHS through the Health Resources and Services Administration (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 HHS.[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] Allowing manufacturers to assume oversight responsibilities of the 340B program would result in a compliance nightmare for HHS and covered entities, ultimately 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, HHS would have to keep track of the various manufacturer rebate models, and because manufacturers would ultimately be deciding which drugs receive a 340B rebate, HHS 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 Providers 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

[5] 340B Statute. Sec. 340B(a)(1) ("taking into account any rebate or discount, as provided by the Secretary").
[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.").

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 hospitals. One AAMC member academic health system projects that the annual impact of the first four drug manufacturers to propose rebate models 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. The projection is staggering for that one system and would be similarly impactful to other academic health systems and teaching hospitals that participate in the 340B program.

Reduced 340B savings would impede the ability of academic health systems and teaching hospitals 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 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

[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.

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 HHS' 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 HHS' goal of ensuring program integrity. To summarize, we urge HHS 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 HHS and covered entities and would severely disrupt the 340B savings of academic health systems and teaching hospitals and ultimately their ability to invest these savings into the programs and specialized health care services they uniquely provide. Ultimately and of most concern, the patients in these health systems' communities would be harmed by the inability to continue these programs and specialized services. We would be happy to work with HHS 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,

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Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer
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