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Electronically submitted via www.regulations.gov

September 8, 2025

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 Program Notice: Application Process for the 340B Rebate Model Pilot Program**

Dear Administrator Engels:

The AAMC welcomes this opportunity to comment on the announcement entitled "**340B Program Notice: Application Process for the 340B Rebate Model Pilot Program**," 90 Fed. Reg. 38165 (August 7, 2025), issued by the Health Resources and Services Administration (HRSA or the Agency).

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 160 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. The 340B Drug Pricing Program is critical to AAMC member institutions and the patients and communities they care for. Academic medical centers (AMCs) are a vital part of the nation's health care safety-net, ensuring access to cutting-edge technology, research, and health expertise for the most medically and socially complex patients.

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 for their plans to implement rebate models without HRSA approval, but we remain concerned about the prospect of introducing rebate models into the 340B Drug Pricing Program through this pilot program. For over thirty years, 340B discounts have been offered by

manufacturers to nearly all covered entity types through upfront pricing.[1] Since last August, five drug manufacturers and one vendor marketing a rebate platform announced their intention to implement a rebate model for 340B drugs, shifting away from upfront pricing.[2] While HRSA is issuing this announcement as a solution to streamline, add guardrails, and limit the use of rebate models, the pilot model shares 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. Outlined in further detail throughout this letter, such models would result in substantial financial losses for 340B hospitals and would be operationally complex, if not impossible, to implement, especially, within the short timeframe outlined. **For these reasons, we urge HRSA to continue to maintain its unequivocal stance that these rebate models contravene the 340B statute.[3]**

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.[4] 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.

To preserve the vital function of academic health systems and 340B program intent, we urge HRSA 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 financial, enforcement, and operational challenges implicated by the voluntary 340B rebate model pilot program.

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[1] 340B-eligible Aids Drug Assistance Programs (ADAPs) collect rebates to receive 340B discounts instead of receiving upfront discounts.
[2] The five drug manufacturers are Johnson & Johnson, Eli Lilly, Sanofi, Bristol Myers Squibb, and Novartis.
[3] Letter from HRSA Administrator Carole Johnson to Johnson & Johnson CEO Joaquin Duato. September 17, 2024
[4] 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.

Announcement of Voluntary 340B Rebate Model Pilot Sets a Dangerous Precedent for Future Expansion of Rebate Models

HRSA's announcement outlines the agency's voluntary 340B rebate model pilot program and the application process for manufacturers to seek approval from the agency to implement such rebate models. This pilot program allows for a minimum one-year test of rebate models limited only to drug manufacturers with Medicare Drug Price Negotiation Program Agreements for 2026 and will only apply to eligible drugs. (P. 38165). Eligible drugs will include only those on the Medicare Drug Price Negotiation Selected Drug List for 2026.[5] The AAMC appreciates HRSA's conservative approach to issuing a limited pilot model. **However, we believe the introduction of rebate models even in a narrow scope sets a dangerous precedent, opening the door for more harmful expansion of such models in the future**. The implementation of rebate models would unilaterally effectuate 340B prices as retrospective rebates instead of upfront discounts, departing from over thirty years of precedent. A change of this magnitude creates unnecessary disruption for covered entities and necessitates significant and costly operational changes for covered entities, manufacturers, and U.S. Department of Health and Human Services (HHS). The structural changes imposed by the use of rebate models in the 340B program fundamentally alter covered entities' financial planning, cash flow management, and operational risk.

Further, HRSA frames the announcement as a voluntary pilot program; however, the program appears to be voluntary only for drug manufacturers, not covered entities who would bear the greatest burden and risk of such a consequential shift in the effectuation of 340B drug pricing. The use of the term 'voluntary' has created confusion for covered entities and should be clarified to allow for voluntary participation by covered entities, allowing them to opt in or out of the pilot program. Covered entities' concerns, which we outline through these comments, should be addressed prior to requiring covered entity participation or expansion of the pilot models.

HRSA Should Work with CMS to Ensure MFP Effectuation Under the IRA Does Not Conflict with the Operation of the 340B Program

In the notice, HRSA indicates the primary purpose of the pilot program is to allow manufacturers to comply with provisions of the Inflation Reduction Act (IRA) that require manufacturers to provide the lower of the Maximum Fair Price (MFP) or the 340B ceiling price to covered entities. HRSA specifically states that manufacturers should not deny 340B rebates on other compliance grounds, such as alleged duplicate discounts or diversion by the covered entity. (P. 36165), A 340B rebate model is purportedly necessary because of the approach the Centers for Medicare & Medicaid Services (CMS) has taken in its IRA guidance,[6] which is to allow manufacturers to develop their own retrospective approaches to honoring MFP, effectively requiring pharmacies to purchase drugs at wholesale acquisition cost (WAC) and then

[5] https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices
[6] CMS Final Guidance on Manufacturer Effectuation of MFP in 2026 and 2027, October 2, 2024; CMS Draft Guidance on the Medicare Drug Price Negotiation Program in 2026, 2027, and 2028, May 12, 2025.

subsequently receive a refund or rebate equal to the difference between WAC and the MFP. Instead of allowing MFP to be effectuated retrospectively, CMS could require manufacturers to provide the MFP prospectively (at the point of sale). Under a prospective approach, non-340B pharmacies would purchase drugs at MFP up front, while 340B covered entity pharmacies would be able to purchase 340B drugs with upfront discounts. In instances where the MFP is lower than the 340B price, the covered entity would submit data elements to the Medicare Transaction Facilitator, which would then credit the covered entity the difference between the MFP and the 340B price. Requiring a prospective approach for MFP effectuation would allow 340B discounts to continue to be offered as upfront discounts, as they have for over 30 years, and negate the need for retrospective 340B rebates. While IRA implementation is not directly under HRSA's purview, we believe that HRSA can collaborate with CMS to ensure that CMS' implementation of the IRA does not have unintended consequences on the 340B program, such as leading to 340B rebate models that would be burdensome for covered entities and for HRSA to oversee (as we explain in more depth below).

The Cost of Rebate Models In the 340B Program Impact Patient Care

The use of rebate models to effectuate 340B drug pricing has the ability to devastate financially vulnerable 340B hospitals and the programs their patients and communities rely on. It would undermine their ability to provide access to essential services to their patients, while serving only to increase the margins of drug manufacturers. Shifting the 340B program to a rebate program would delay needed cash flow to 340B hospitals by significantly delaying the receipt of their 340B discounts. Even with HRSA's pilot model requiring rebates be disbursed within 10 calendar days of data submission, some covered entities may be challenged or unable to acquire 340B drugs without upfront pricing and still maintain their other services offered. (P.38166). 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. Delays in realizing 304B savings impacting hospitals drug purchasing power are just one part of the equation. The rebate models outlined do not fully account for the additional financial impacts associated with added compliance costs or the potential effects on the ability to use 340B discounts for Medicaid patients, as well as potential loss of sub-ceiling prices. There is additional complexity and impact for rebate models that include not only drugs dispensed on the retail side, included on pharmacy benefit claims, but also if the models extend to drugs dispensed on the hospital side, included on medical billing claims.

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 that hospitals have already incurred because of

manufacturer restrictions on 340B drugs dispensed through contract pharmacies.[7] These losses are exacerbated by the enactment of the One Big Beautiful Bill Act, which included a historic $1 trillion cut from federal spending on Medicaid and the Health Insurance Marketplaces over the next decade, increasing the number of uninsured by over 10 million in 2034.[8] Cuts to federal spending are expected to further strain already scare resources for safety-net hospitals committed to serving Medicaid and low-income Medicare patients. Adding an additional layer of fiscal uncertainty would destabilize these hospitals, undermining not just 340B hospitals but harming their patients as well.

HRSA Must Detail its Role in Oversight and Enforcement of the 340B Program, Provide Protections Including a Complaint and Dispute Process for Covered Entities

In addition to the delayed receipt of 340B discounts, the pilot program would leave the determination of which drugs are 340B eligible up to the manufacturer. This shift could result in many 340B claims being denied at the manufacturer's discretion, with no oversight or appeal mechanism available to 340B hospitals. The AAMC is deeply concerned with the absence of information on how HRSA plans to conduct oversight of the pilot program.

In enacting the 340B statute, Congress delegated responsibility for overseeing and enforcing the 340B program solely to HRSA, which resides under HHS. 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.[9] 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)."[10] 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 and circumventing statutory authority.

Within the guidance, there is no apparent mechanism on how 340B covered entities may appeal or file a complaint if manufacturers improperly deny rebates. It is unclear how HRSA plans to enforce compliance with the 340B statute or the criteria the agency has outlined in the rebate model pilot guidance. The move towards drug manufacturer operated rebate models will ultimately allow manufacturers to assume greater oversight responsibilities of the 340B program by leaving determination of which drugs are 340B eligible to the manufacturers. HRSA does

[7] 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.

[8] Congressional Budget Office, Estimated Budgetary Effects of Public Law 119-21, to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14, Relative to CBO's January 2025 Baseline (July 21, 2025)

[9] 340B Statute. Sec. 340B(a)(5)A.

[10] 340B Statute. Sec. 340B(d)(2) (emphasis added).

specify plans should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts and should provide rationale and specific documentation for reasons claims are denied. However, without explicit instruction on how HRSA intends to oversee these rebate models or allow covered entities to appeal such denials, there is little to ensure drug manufacturers compliance with this provision. The AAMC is further concerned with the absence of discussion around how rebate models may interact with state laws and drug manufacturers' efforts to advance contract pharmacy restrictions. This may allow drug manufacturers to use 340B rebate models to enforce compliance with their contract pharmacy restriction policies. This could be the case even in states with contract pharmacy protections where the courts have ruled state laws protecting contract pharmacy arrangements are allowed and are not pre-empted by federal law.[11]

As currently outlined, manufacturers will be the ones to evaluate each claim's 340B eligibility before determining whether to provide a credit equal to the difference between the WAC and the ceiling price. Shifting this responsibility also opens up the possibility that drug manufacturers could conduct their own patient definition reconciliation with little to no transparency, removing covered entities and HRSA from such efforts. Some drug manufacturers have already expressed an interest in this kind of reconciliation effort by utilizing rebate models to require covered entities to submit records establishing a relationship between a patient and the covered entity that satisfies the manufacturer's own version of a patient definition, which differs from HRSA's longstanding patient definition.[12] Leaving oversight of the rebate models to the drug manufacturers could result in many 340B claims being denied at the manufacturer's discretion, with no oversight or appeal mechanism available to 340B hospitals, leaving 340B hospitals, who serve some of the most vulnerable patients, at even greater financial risk. Manufacturers affinity towards rebate models 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.

Further, in implementing rebate models, manufacturers may require covered entities to submit claims data to them through their selected vendors, such as Second Sight Solutions and Kalderos. HRSA must engage in oversight of these vendors and their contracts with drug manufacturers to ensure data protections and to prohibit contingent pay agreements, such as those that provide a kickback for denied rebate requests. We are concerned the terms and conditions of the contracts 340B hospitals will be compelled to sign will be non-negotiable and contain terms unfavorable to hospitals. Many of the vendors operating in this space have worked hand in hand with drug manufacturers for years to craft these proposed rebate models, drawing questions and concerns from other stakeholders.

Even without an explicit dispute process for these models, we expect 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

[11] Pharmaceutical Research and Manufacturers of America v. McClain, No. 22-3675 (8th Cir. 2024)
[12] Gluck, Adam. Sanofi, Sanofi Tackles 340B Abuse with Innovative Credit Model (November 22, 2024)

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 rather than fundamentally altering the 340B Drug Pricing Program.

To preserve the vital function of these academic health systems and 340B program intent, we urge HRSA not to move forward with this pilot program and instead 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.

HRSA Should Not Move Forward with the Voluntary 340B Rebate Model Pilot, at Minimum the Implementation Timeline Must Be Delayed

For drug manufacturer's applications to be considered for approval by HRSA, applications must be submitted by September 15, 2025, for approval by October 15, 2025, to be effective for a start date of January 1, 2026. (P.38166). Under this timeline, applications would be due only seven days after the comment deadline. This does not give the agency sufficient time to meaningfully consider feedback on the rebate models from the wide variety of 340B stakeholders and to make revisions to the pilot program. Giving notice of less than three months before implementation of such significant operational changes is not sufficient for covered entities to implement the infrastructure and staff needed to support the data submissions required to run these models and report the requested data. Further, covered entities will have even less time than manufacturers to implement new IT platforms, policies, and processes as they will need to wait for further instructions from drug manufacturers following approval of their rebate model applications. The initial implementation timeline should be flexible to allow for covered entities to work out any roadblocks to submit accurate and complete data. **HRSA should not move forward with the use of rebate models in the 340B Program due to the factors discussed throughout these comments, including the administrative complexity. However, should the agency continue to pursue this pilot program the agency must push back the application deadline and effective date to give covered entities and manufacturers ample time to implement.**

Additionally, HRSA limits the word count for drug manufacturers applications to just 1,000 words. (P. 38166). The AAMC is concerned this is not enough space to accommodate a reasonable and robust application inclusive of enough details for HRSA to evaluate applications effectively to ensure drug manufacturers are meeting HRSA's proposed criteria. The limited detail that would be allowed in an application with a 1,000-word limit may also result in confusion around the implementation and expectations of covered entities. HRSA should also ensure it has oversight of the materials and instructions drug manufacturers provide to covered entities on how to implement and operate these rebate models and data submission processes. There is no doubt this level of instruction would require more than 1,000 words. It is our impression the restriction on word count may also be attributed to the tight timeline HRSA has proposed for implementation. The need for robust and adequately detailed applications lends itself to needing a longer timeframe to implement. Given the significance of this change in the

340B program, HRSA should be cognizant of the time needed to implement these changes correctly, with ample time to review, rather than rushing through the process, encountering errors or unaddressed issues, and having to remedy at a later date.

Rebate Models Would be Administratively Burdensome and Costly to Implement

Beyond the direct financial losses that 340B hospitals would incur because of the rebate models, additional resources would need to be allocated to address the significant operational challenges and administrative burden associated with rebate models. Hospitals would need additional IT infrastructure and staff to submit the claims data needed to produce these rebates.

Under HRSA's pilot program each drug manufacturer approved would operate its drug rebate model independently. As a result, covered entities would be required to maintain multiple different IT platforms and data submission processes to fulfill manufacturer's requirements for the 340B rebate models under this pilot. Collecting and transmitting this data to each of these platforms 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. Under the criteria for approval in the pilot program, plans would be required to include assurances all costs for data submission are the responsibility of the manufacturer and no additional administrative costs are passed to covered entities. (P. 38166). However, HRSA does not detail what is included in their definition of all costs. Under this criteria, we believe that drug manufacturers would need to be responsible for the costs of not only acquiring and implementing the IT programs and infrastructure needed for data submission but would also need to bear the full time employee (FTE) costs required to have the additional staff collect, organize, and submit the required data. As an example of the additional administrative work needed under these rebate models, 340B hospitals would need 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. As the program is operated currently, this is not required since discounts are applied seamlessly at the point of sale. **We ask that HRSA clarify that the drug manufacturers would be responsible for these additional FTE costs under their definition of all costs related to data submission.** Lastly, while the agency does require assurances all costs for data submission are the responsibility of the manufacturer, the pilot model lacks details on how covered entities may be reimbursed for these costs. This would create another instance within the pilot program where safety-net providers would be required to float costs with minimal or no understanding of when they will be made whole. The agency should include requirements around reimbursement for these administrative costs beyond just attestations from drug manufacturers.

Under this pilot model, the parameters of each manufacturer's rebate model may differ in many aspects, including the processes for submitting data and terms and conditions. It is also highly likely that each manufacturer will utilize a different vendor, format, or portal for tracking and submitting requests for rebates. It will be confusing and costly 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 will need to keep track of the various manufacturer rebate models and ensure compliance with the pilot model criteria. To streamline this work, we suggest HRSA maintain a centralized system to collect required data, rather than utilizing a patchwork of IT systems from each individual, approved drug manufacturer. At the very least, HRSA should evaluate and approve third party vendors for compliance with the pilot model criteria prior to approving a manufacturers application. This would provide the agency greater oversight of the program.

Beyond the infrastructure required to effectuate these models, there is a voluminous amount of sensitive data required to implement rebate models, inclusive of multiple data elements for each 340B drug claim. Under HRSA's pilot program, the agency would require covered entities to submit eleven different data elements per claim in order for drug manufacturers to determine if a claim would qualify for a 340B discount. (P. 38167). Multiplied by the hundreds of thousands of drug claims covered entities may be expected to submit, the volume of data needed to effectuate rebates would require covered entities to account for a formidable number of units of data.

Further, under CMS' CY 2026 Physician Fee Scheduled Proposed Rule, CMS is proposing a voluntary claims data repository inclusive of five data elements to identify a claim as being 340B or not. Under this proposal, only the National Drug Code (NCD), date of service, prescription or service reference number, fill number, and the dispensing pharmacy NPI would be needed to determine if a claim was 340B eligible or not.[13] Based on this, we urge HRSA to reconsider whether all eleven of the required data elements are necessary for identifying claims as eligible for 340B pricing under these rebate models. Both of these proposals did not include a requirement to report purchasing data. We agree with the HRSA and CMS' decision to exclude a requirement to report this type of data and encourage the agencies to continue to exclude purchasing data from data collection efforts. In order to streamline data collection, we ask HRSA to consider aligning the data elements required with those under the voluntary claims data repository. **To the extent possible, the agency should take all appropriate steps to streamline and simplify the method and amount of data covered entities need to report to effectuate the pilot rebate models.**

Conclusion

Thank you for HRSA's continued support of the 340B program and for ensuring program integrity for all 340B stakeholders. 340B hospitals remain invested in and share HRSA's goal of ensuring program integrity through adopting substantial program safeguards. To summarize, we urge HRSA to continue to enforce the 340B statute by prohibiting the adoption of rebate models by drug manufacturers. The use of rebate models would create compliance difficulties for HRSA and covered entities and would severely disrupt the flow of 340B savings to academic health systems and teaching hospitals. Ultimately, these rebated models would harm the ability of these providers to invest 340B savings into the programs and specialized health care services they uniquely provide to vulnerable patients. Of most concern, the patients in these health systems'

[13] 90 FR 32643

communities would be harmed by the inability to continue these programs and specialized services. 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 Katie Gaynor (kgaynor@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