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April 20, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Attention: HHS Docket No. HRSA–2026–03042
5600 Fishers Lane
Rockville, MD 20857

Re: Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042)

Dear Administrator Engels:

The AAMC¹ welcomes this opportunity to comment on the request for information (RFI) titled “**Request for Information: 340B Rebate Model Pilot Program**,” 91 Fed. Reg. 7287 (February 17, 2026), issued by the Health Resources and Services Administration (HRSA or the Agency). HRSA issued the RFI to collect feedback from the public on whether to implement a rebate model to effectuate prices in the 340B Drug Pricing Program, as well as the costs and implementation considerations related to a 340B rebate model. As we explain further in the comments below, the AAMC strongly opposes the adoption of a rebate model for the 340B program, as such a fundamental restructuring of the program’s design would jeopardize the ability of academic health systems nationwide to fulfill the 340B program’s core purpose of stretching their scarce resources to reach more eligible patients and provide more comprehensive services.²

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. Nearly 90 percent of AAMC-member short-term non-federal hospitals are 340B eligible and provide highly

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 163 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.

² H.R. Rep. No. 102-384(II) (1992).

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 member hospitals comprise 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.³ 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. 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, or expanding care through mobile clinics and community health programs.

The AAMC commends HRSA for seeking detailed feedback from 340B program stakeholders on the potential implementation of a 340B rebate model. We continue to maintain our unequivocal opposition to the use of rebate models in the 340B program, which represent a stark departure from over three decades of precedent and are unnecessary to ensure 340B program integrity. The association appreciates the opportunity to comment on this RFI to demonstrate the prohibitive costs associated with participating in rebate models, the significant operational changes rebate models would necessitate, and the availability of more practical solutions to addressing the issues drug manufacturers have cited as their rationale for using rebate models. The following summary reflects the AAMC's comments in response to HRSA's RFI:

- ***HRSA Should Not Implement a Rebate Model.*** Rebate models mark a stark departure from over 34 years of 340B program precedent, are unnecessary to meet HRSA's stated goals, and would set a dangerous precedent for future expansion. To receive meaningful feedback on the costs of a rebate model, HRSA must first outline the parameters of such a rebate model.
- ***Payment Timing and Potential Cash Flow Impacts for Covered Entities.*** Rebate models would significantly delay the ability of 340B hospitals to receive critical savings, having significant negative impacts on their financial standing and downstream impacts on patient care.
- ***Costs to Covered Entities.*** Rebate models would be operationally burdensome and impose substantial administrative costs on 340B hospitals resulting from staffing changes, information technology (IT) system updates, new third-party vendor contracts, and other implementation costs.
- ***Rebate Denials.*** While the AAMC is strongly opposed to the implementation of a rebate model, if HRSA were to nonetheless proceed with implementation of a rebate model

³ 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.

program, the program should be narrowly crafted and limited in scope with a robust dispute and appeals process.

- **Data Collection by Covered Entities.** The agency should take all appropriate steps to streamline and simplify the method and amount of data covered entities need to report to effectuate a rebate model.
- **Required Reporting.** If HRSA pursues a rebate model, it should collect data from manufacturers on rebates paid and denied, which will allow the agency to hold manufacturers accountable for honoring their obligation to provide 340B prices to covered entities and to provide rebates as expeditiously as possible.
- **340B Program Integrity and Other Potential Benefits of a Rebate Pilot.** The AAMC does not believe rebate models are necessary to ensure 340B program integrity. Instead of creating additional burden through unnecessary new processes, HRSA should continue to build on existing program integrity tools at its disposal.

HRSA SHOULD NOT IMPLEMENT A 340B REBATE MODEL PROGRAM

Rebate Models are an Unnecessary Departure from 34 Years of 340B Program Precedent

For over thirty years, 340B discounts have been offered by manufacturers to all but one covered entity type through upfront pricing.⁴ In August 2024, five drug manufacturers and one vendor marketing a rebate platform announced their intention to implement a rebate model for 340B drugs, shifting away from the longstanding upfront pricing structure of the 340B program.⁵ After a federal district court held that the 340B statute prohibits drug manufacturers from unilaterally effectuating 340B prices through a rebate instead of as upfront discounts without first receiving HRSA approval,⁶ HRSA issued a notice seeking drug manufacturer applications to participate in a 340B Rebate Model Pilot Program to begin on January 1, 2026.⁷ The pilot program, which in 2026 was to be limited to the 10 drugs in the Medicare Drug Price Negotiation Program (MDPNP), never went into effect due to a federal district court injunction prohibiting its implementation.⁸ HRSA is issuing this new RFI to solicit feedback in advance of implementing a new rebate model program. The information HRSA requests feedback on includes the costs associated with rebate models, delayed saving resulting from rebate models, denied rebate claims, and ideas for additional guardrails in future rebate models. HRSA does not specifically propose a rebate model or outline the parameters of a potential new rebate model. However, in both the RFI and in HRSA's separate information collection request,⁹ HRSA indicates the basic structure of any new rebate model program would require hospitals to submit

⁴ 340B-eligible Aids Drug Assistance Programs (ADAPs) collect rebates to receive 340B discounts instead of receiving upfront discounts.

⁵ The five drug manufacturers are Johnson & Johnson, Eli Lilly, Sanofi, Bristol Myers Squibb, and Novartis.

⁶ *Eli Lilly & Co v. Kennedy*, 2025 WL 1423630, (D.D.C. May 15, 2025)

⁷ 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program. 90 FR 36163. August 1, 2025.

⁸ *American Hospital Association v. Robert F. Kennedy, Jr.*, No. 2:25-cv-00600. December 29, 2025.

⁹ 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW. 91 FR 9632 (February 26, 2026).

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 throughout this letter, such models would result in substantial financial losses for safety-net teaching hospitals, ultimately affecting patient care and access. Moreover, a rebate model would be operationally complex, if not impossible, to implement, especially within the short timeframe outlined.

To preserve the vital function of academic health systems and 340B program intent, **we urge HRSA to maintain the ability of covered entities to purchase 340B drugs at upfront discounted prices. Further, we ask that HRSA explore other, less disruptive ways to realize the goal of deduplicating 340B and maximum fair price (MFP) under the Inflation Reduction Act (IRA).**¹⁰

To Collect Meaningful Feedback, HRSA Must Provide Sufficient Information About the Scope of a Potential Rebate Model

In the RFI, HRSA seeks detailed information about the impact of a potential rebate model pilot program and asks for the inclusion of “facts, research, and evidence” as well as “data collection instruments, data sets, and detailed findings” (p. 7288). The topics on which HRSA seeks feedback include the administrative costs of a potential rebate model program, staffing impacts, systems and infrastructure costs, and cash flow impacts. Yet, HRSA does not provide any details about how a potential rebate model would be structured, such as which manufacturers would participate, which drugs would be covered, whether the model would be limited to certain payers or include all payers, which third-party platform would be used to collect claims data, and who would be responsible for bearing the costs of implementation. While we acknowledge that this is an RFI and not a proposed rule, HRSA should have provided some parameters of a potential rebate model that 340B program stakeholders could use in assessing impact and providing feedback. Without this information, it is impossible to accurately provide the information HRSA is looking for and HRSA is bound to have substantial variation in the responses it receives, as they would be based on different assumptions about the scope of a rebate model. The costs and delayed savings associated with a rebate model that applies to a limited subset of drugs (such as the ten drugs included in the MDPNP in 2026) would differ substantially from the costs and delayed savings associated with a rebate model that includes all 340B drugs. While HRSA does not explicitly state this, it is our assumption that a rebate model would be similar in scope to the 340B Rebate Model Pilot Program that was to begin on January 1, 2026—that is, limited to the ten drugs eligible for drug price negotiation through the MDPNP in 2026 and possibly expanded to include other negotiation eligible drugs in subsequent years. Therefore, our specific responses on costs related to participating in a rebate model are based on this assumption, unless otherwise stated.

¹⁰ [Letter from HRSA Administrator Carole Johnson to Johnson & Johnson CEO Joaquin Duato](#), September 17, 2024

A 340B Rebate Program Sets a Dangerous Precedent for Future Expansion of Rebate Models

In the RFI, HRSA does not specifically propose a new rebate model program, but we assume that HRSA would use the feedback provided in response to this RFI to launch a new program that would be limited to drug manufacturers with MDPNP agreements in a given year. While the AAMC appreciates HRSA's approach of issuing a limited rebate model, **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.** Left unchecked, a rebate model would result in unfettered discretion in the hands of drug manufacturers, handing over HRSA's traditional compliance responsibilities to drug manufacturers and undermining covered entities' ability to receive 340B savings. 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.

HRSA Can Pursue Better Alternatives for Ensuring 340B Program Integrity and Achieving MFP Effectuation Under the IRA That Do Not Conflict with the Operation of the 340B Program

In the RFI, HRSA indicates the primary purpose of the pilot program is to allow manufacturers to comply with provisions of the IRA that require manufacturers to provide the lower of the 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,¹¹ 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 subsequently receive a refund or rebate equal to the difference between WAC and the MFP. When 340B price is lower than the MFP for a specific drug, the manufacturer would provide a larger rebate that equals the difference between the WAC and 340B price. 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 (MTF), 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

¹¹ [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.

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).

Alternatively, if CMS chooses not to adopt a prospective model, CMS could use a neutral third-party entity, such as the MTF, to assist with deduplicating MFP from 340B prices. Pharmacies could submit necessary and limited claims data to the MTF, instead of directly to drug manufacturers, to determine whether a drug is a 340B drug or should instead receive the MFP. Because the MTF is an already established entity that facilitates the provision of MFP rebates, it could easily be structured to serve the purpose of deduplicating MFP from 340B price. Another option CMS could consider is to leverage the Medicare Part D Claims Data 340B Repository that it established in the calendar year 2026 Physician Fee Schedule final rule¹² for voluntary submissions by covered entities in 2026 to remove 340B units from Part D rebate calculations. This mechanism relates to another provision of the IRA, which is that drug manufacturers provide inflationary rebates to Medicare when their drug prices rise faster than the rate of inflation but that they do not provide an inflationary rebate on 340B drugs. The Part D repository is set up to receive data elements from covered entities that identify drugs as 340B drugs, and therefore, could also be expanded in use to serve the purpose of deduplicating MFP and 340B price.

Although CMS is responsible for IRA implementation, HRSA serves an important role in ensuring that CMS' preferred implementation approaches do not interfere with the operation of the 340B program. **By coordinating with CMS to adopt one of the above alternatives to manufacturers' chosen retrospective approaches, HRSA can ensure it is furthering the joint goals of IRA implementation and preserving the structure of the 340B program as an upfront discount program.**

PAYMENT TIMING AND POTENTIAL CASH FLOW IMPACTS FOR COVERED ENTITIES

HRSA requests feedback on whether payment timing under a potential rebate model would affect cash flow, including whether rebate models would pose financial risk to 340B covered entities (p. 7289-90). As we explain in further detail, the cash flow delays associated with the use of rebate models to effectuate 340B drug pricing could devastate financially vulnerable 340B hospitals and the programs their patients and communities rely on. A shift from an upfront discount to 340B rebate models would alter the way that 340B covered entities have realized the benefit of discounted drugs for over 30 years. Instead of purchasing 340B drugs upfront at discounted prices and being able to benefit from these savings immediately, hospitals under a rebate model would have to wait potentially months between when a drug is purchased and when a manufacturer provides a rebate on that drug. While under HRSA's previously finalized 340B Rebate Model Pilot Program manufacturers had ten days from receipt of a claim to pay a rebate,

¹² 90 FR 49266. November 5, 2025.

the actual lag time between when a drug is purchased and when the 340B rebate is received would be much longer due to drug procurement processes and the many intervening steps that would take place between when a drug is purchased and dispensed and when a rebate is ultimately received. We anticipate that beyond this typical timeline, there would be additional delays in hospitals receiving rebate payments due to claims disputes, errors, and denials.

Rebate models undermine the ability of academic health systems and teaching hospitals 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 if a new rebate model requires rebates be disbursed within 10 calendar days of data submission, some covered entities may be challenged or unable to acquire 340B drugs without upfront discount pricing and still maintain their other services offered. On average, the delayed or deferred savings resulting from effectuating 340B pricing through a rebate amounts to tens of millions of dollars annually for academic health systems and teaching hospitals.¹³ The deferred savings are a result of the hospitals having to purchase drugs at WAC and wait for a manufacturer rebate, as opposed to purchasing the drug at the discounted price upfront. Effectively, the hospital ends up floating tens of millions of dollars to the manufacturer in the meantime, depriving the hospital of critical cash reserves while the hospital awaits a rebate. If rebate models were to be expanded to additional drugs in 2027 and beyond, the deferred savings amount would grow significantly. Expanding drugs covered by the rebate model to include the 15 drugs eligible for drug price negotiation in 2027 would nearly double the deferred savings impact compared with the 10 included drugs in 2026.

For safety-net hospitals that often carry minimal cash on hand, the impact of the delay in realizing 340B savings would further limit their cash reserves, having significant negative impacts on their financial standing and downstream impacts on patient care. Delays in realizing 340B savings impacting hospitals drug purchasing power is just one part of the financial impact that 340B hospitals will experience due to rebate models. The delayed savings will also result in the loss of interest on deferred savings, which one academic health system estimated at a 4 percent loss on their affected 340B drugs. In addition, hospitals would lose sub-ceiling discounts due to loss of 340B discount pricing. Furthermore, we expect that a percentage of 340B claim rebates would not be paid in error, would be contested, or would be denied by manufacturers altogether. One AAMC member institution estimates that these confounding factors—loss of interest, loss of subceiling discounts, rebate denials, and wastage loss—would amount to over \$6 million in annual permanent losses, not including any administrative implementation costs. This is one example—for some institutions with an even larger 340B footprint, these losses could be even greater.

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,

¹³ Data collected from AAMC member institutions. The deferred savings were calculated as WAC minus ceiling price for the drugs expected to be included in a rebate model program.

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. Financial losses resulting from rebate models would further reduce slim (often negative) financial margins, thus impacting clinical programs, coordination of care services, capital investments, and the community benefit programs offered by these safety-net hospitals. The reduction in cash on hand and the additional upfront compliance costs could also impact hospitals' bond ratings and their ability to secure loans. Ultimately, any reduction in services would affect patient access. Direct patient impacts that could result from rebate models include reduced specialty drug inventory, delays in therapy initiation, reduced contract pharmacy access, and decreased patient support programs, particularly affecting rural and underserved populations.

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,¹⁴ in addition to other 340B-related pressures such as new claims-level data reporting requirements imposed by three drug manufacturers on in-house pharmacy claims.¹⁵ 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 2034.¹⁶ Cuts to federal spending are expected to further strain already scarce 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.

Delayed Savings and Wholesaler Payment Terms

HRSA asks about payment timing under current wholesaler contracts and how that timing would interact with rebate models. While the exact terms are specific to the agreement between a particular wholesaler and hospital, and they often vary for specific classes of drugs, hospitals would not be receiving their 340B rebate under a rebate model before their payment is due to their wholesalers. Therefore, under their wholesaler contracts as currently structured, hospitals would purchase the 340B drug, pay the wholesaler at the higher, non-340B WAC (which is list price), and then receive the 340B rebate (calculated as the difference between WAC and 340B ceiling price) at some point weeks or months later, or not at all if denied by the manufacturer.

¹⁴ 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.

¹⁵ As of the date of this letter, three drug manufacturers—Exelixis, Eli Lilly and Company, and Novo Nordisk have begun requiring 340B covered entities to submit claims-level data on in-house pharmacy drugs.

¹⁶ 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)

COSTS TO COVERED ENTITIES

Current Administrative Costs under the Upfront 340B Discount

HRSA requests feedback on the compliance costs that 340B covered entities currently incur as part of their participation in the 340B program. We do not have specific data to share on this question because we believe current 340B compliance costs are irrelevant to the question of the additional costs that would be imposed by rebate models. 340B hospitals, who are good stewards of the program dedicated to program integrity, invest substantial resources into 340B compliance. This is an expected and ongoing commitment that 340B hospitals make as part of their participation in the 340B program. These investments assure that the covered entity is complying with the statutory requirements of the 340B program, such as ensuring drugs are dispensed to patients of the covered entity, tracking claims, working with contract pharmacy partners and third party vendors, and avoiding duplicate discounts. 340B hospitals maintain staff from multiple functional areas across the entity that help with these responsibilities, including legal, compliance, pharmacy, finance and reimbursement, and revenue cycle staff. In addition to maintaining robust records, they are responsible for conducting internal audits and record reviews, as well as responding to HRSA and manufacturer audits. As large health systems with multifaceted 340B programs that include contract pharmacy arrangements, multiple in-house pharmacies, and offsite clinics, the costs of compliance are higher. These are costs that 340B covered entities take into account in determining the value of 340B participation. In addition to these costs related to compliance with statutory requirements, covered entities' costs of participation have increased in recent years due to unilateral reporting requirements imposed by manufacturers, such as contract pharmacy claims and recent requirements by three manufacturers that covered entities report in-house claims data. Additional, unforeseen costs, such as those imposed by 340B rebate models, could potentially change this calculation.

Administrative Costs Under a Potential 340B Rebate Model Pilot Program

Participating in 340B rebate models would impose significant costs on 340B hospitals. 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.

Based on feedback we received from AAMC member health systems, the direct administrative costs associated with shifting from an upfront discount program to a retrospective rebate model fall into the following categories:

- Startup costs related to preparing for rebate workflow development, claims submission, and reconciliation, as well as annual, ongoing costs related to rebate claim submission and reconciliation.

- Startup and ongoing, annual costs of IT-related changes, such as upgrading existing systems or purchasing and installing new systems that have the functionalities needed to comply with a rebate model.
- Startup and ongoing, annual costs related to revising existing third-party vendor contracts (such as third-party administrators) or contracting with new vendors to assist with rebate model compliance.
- Costs related to providing education and training to existing hospital staff on new rebate model requirements, as well as costs related to adjusting existing staff workflows and realigning staff responsibilities.
- Initial and annual costs related to hiring and training new staff responsible for supporting rebate model compliance.

Depending on the specific hospital, our member hospitals reported that total annual administrative costs ranged from \$100,000 to more than \$600,000, encompassing both IT and staffing-related changes. The types of changes contributing to these costs include developing processes and systems to submit and track claims, as well as subsequently reconcile those claims; developing a process for appealing or disputing claims; investing in compliance and audit process changes to prepare for increased audits related to rebate models; staff training and education; and annual vendor fees. Academic health systems have reported that a rebate model would involve extracting data, such as from a third-party administrator and reconciling it with data accepted into the Beacon platform. Staff time related to submitting and reconciling claims and managing disputes and discrepancies is estimated to require 25 to 40 hours per week.

Under a 340B rebate program, 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, impartial system to collect required data, rather than utilizing a patchwork of IT systems from each individual, approved drug manufacturer.

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 previously finalized 340B Rebate Model Pilot Program, the agency required 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. 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.

HRSA asks how the administrative and operational costs of a rebate model could be offset (p. 7289). In HRSA's 2026 Rebate Model Pilot Program, plans were required to include assurances that all costs for data submission are the responsibility of the manufacturer and no additional administrative costs are passed to covered entities. We stress that in any rebate model, manufacturers should be the sole party 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 equivalent (FTE) employee costs required to have the additional staff collect, organize, and submit the required data. Lastly, any rebate model program should include details on how covered entities may be reimbursed for these costs. The agency should include requirements around reimbursement for these administrative costs beyond just attestations from drug manufacturers.

Staffing Impacts Under a Potential 340B Rebate Model Pilot Program

HRSA requests information on whether a potential rebate model pilot program would require additional FTE employees or cause current medical provider FTEs to reallocate work hours from medical care to perform administrative functions (p. 7289). Given the operational complexity associated with participating in rebate models and the compliance concerns implicated by this new process of effectuating the 340B prices, 340B hospitals would have to hire additional staff and realign existing staff to ensure they are ready for a rebate model. These additional staff would be needed for maintaining records of 340B claims subject to the rebate model, submitting claims, reconciling claims, disputing denied claims, responding to expanded audits resulting from the rebate model, and updating IT systems to streamline rebate model compliance.

Based on feedback provided by AAMC member hospitals, depending on the institution-specific circumstances and their current staffing levels, a hospital would need to hire from one to more than six FTEs spanning not just the pharmacy department but including legal, compliance, revenue cycle, and finance roles as well. The types of roles that hospitals have already filled or expect to fill to comply with rebate model requirements are: full-time coordinators or analysts, pharmacy 340B insight analysts, pharmacy informaticists, legal/compliance, supply chain compliance analyst, rebate operations analysts, reconciliation/finance analysts, denial and dispute specialists, IT/data integration analysts, and compliance/audit support. These would be permanent positions. Many hospitals also reported that they would have to realign existing staff time to prioritize rebate model compliance, with one hospital citing approximately 12,240 hours of staff time annually resulting from six new FTEs across pharmacy, finance, revenue cycle, and compliance teams.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Model Pilot Program

Rebate models would require costly upgrades to existing systems, procurement of new systems, and in most cases, contracting with external vendors to help with claims submission, tracking, reconciliation, and disputes. For large academic health systems and teaching hospitals, participating in rebate models entails added complexity of submitting and tracking claims due to the sheer volume of claims and the different settings in which 340B drugs are dispensed. As

340B hospitals, they often have multiple in-house pharmacies and contract pharmacy arrangements, as well as administering drugs in mixed-use settings such as in offsite clinics. 340B hospitals would not be able to rely on their existing systems to submit and track claims in these varied settings, instead having to upgrade systems or utilize third-party vendors. Expected IT system build-outs include claims mapping, interfaces, and secure data transmission of claims information to manufacturers. Finance and accounting systems would also need to be redesigned to allow for receivables tracking and reconciliation processes. Other specific examples of system changes that a rebate model would necessitate include modifications to split-billing and third-party administrator contracts, implementation of rebate submission platforms or clearinghouse interfaces, and additional vendor support for data integration and reconciliation. Due to the additional compliance concerns implicated by rebate models, hospitals would also need to implement expanded audit and risk management controls.

If a rebate model program were to be designed similar to HRSA's 340B Rebate Model Pilot Program that was set to take effect on January 1, each participating drug manufacturer would be free to operate its own drug rebate model independently, using its own choice of third-party vendor. As a result, covered entities would be required to maintain multiple different IT platforms and data submission processes to fulfill manufacturers' requirements for the 340B rebate models. 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. 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.

Other Anticipated Costs or Impacts of a Potential 340B Rebate Model Pilot Program

HRSA seeks feedback on other costs of a rebate model pilot program. In addition to delayed savings, forgone savings, and administrative costs, hospitals will see potentially delayed reimbursement and administrative costs stemming from compliance with state Medicaid billing requirements. Since manufacturers first began proposing their individual rebate models in 2024, hospitals have been contending with the question of how 340B rebate models would interact with state Medicaid billing requirements. Specifically, when providing a 340B drug to a Medicaid beneficiary, states require covered entities to bill Medicaid for these drugs at actual acquisition cost (AAC). Typically, the AAC for a 340B drug is the 340B ceiling price, which is the amount that a covered entity bills the state Medicaid agency. Under a rebate model, if 340B hospitals initially purchase drugs at WAC instead of 340B ceiling price, it is unclear if they would bill Medicaid at the WAC (which is the initial acquisition cost to the hospital) or the post-rebate 340B ceiling price. In a since-removed FAQ related to the 340B Rebate Model Pilot Program, HRSA instructed covered entities to "work with state Medicaid agencies to determine best practices for billing," also noting that manufacturers "have committed to supplying a 340B

ceiling price file” that could be used determine the post-rebate ceiling price that could be used for Medicaid billing.¹⁷ However, hospitals have informed us that they have received insufficient direction from state Medicaid agencies on how to bill Medicaid for drugs covered under the rebate model. Assuming that hospitals are to bill Medicaid at the post-rebate price, hospitals have to wait until they receive the rebate before they can bill Medicaid. This would result in added burden for the hospital and would complicate Medicaid billing, resulting in delays in Medicaid reimbursement.

REBATE DENIALS

HRSA seeks feedback on specific guardrails that should be built into a 340B rebate model pilot program to ensure that denials are limited to appropriate circumstances. Further, HRSA asks about standard process elements required for rebate denials and the timeline for adjudicating improper denials (p. 7290). The agency provides an example of limiting denials to instances when a 340B rebate was provided to another covered entity on the same claim. In other parts of the RFI, HRSA alludes to using rebate models to avoid duplicate discounts not just in the context of the MFP under the IRA but also in other CMS programs such as Medicaid.

The AAMC rejects the notion that there is a need for a manufacturer-driven solution to address purported issues around program integrity. Therefore, as we expressed above, we caution HRSA against adopting a rebate model. In the context of Medicaid, which is the only context in which duplicate discounts are explicitly prohibited by the 340B statute,¹⁸ HRSA has worked with CMS and state Medicaid agencies to develop mechanisms to prevent duplicate discounts. Most states allow 340B covered entities to decide whether to carve in their 340B drugs (provide 340B discounts to their Medicaid patients) or carve out (forgo a 340B discount and instead allow the state to receive the Medicaid rebate on that drug). Covered entities that choose to carve in 340B drugs for their Medicaid fee-for-service population must list their National Provider Identifier (NPI) number on the Medicaid exclusion file, which indicates to the state Medicaid agency that it should exclude drugs dispensed by that hospital from receiving a Medicaid rebate. Other states use billing modifiers to identify 340B drugs, while some states (most notably, Oregon) use a retrospective approach to identify claims that should be excluded from receiving Medicaid rebates. HRSA does not allow covered entities to dispense 340B drugs in the contract pharmacy setting in Medicaid FFS unless the covered entity, the contract pharmacy, and state create a plan to prevent duplicate discounts and submit this plan to HRSA.¹⁹ On top of these approaches to prevent duplicate discounts, the 340B statute authorizes HRSA to sanction 340B hospitals if they violate statutory provisions, including the prohibition on duplicate discounts, through repayment of overpayments and potential removal from the program for systematic and egregious violations. Because there are rigorous prevention and enforcement mechanisms in place regarding Medicaid and 340B duplicate discounts, it is unnecessary for the rebate models to be extended to preventing duplicate discounts in this context.

¹⁷ HRSA, [340B Rebate Model Pilot Program \(Archived Webpage\)](#). December 17, 2025.

¹⁸ 340B Statute. Sec. 340B(a)(5)A.

¹⁹ Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services , 75 Fed. Reg. at 10278.

If HRSA were to nonetheless proceed with implementation of a rebate model program, the program should be narrowly crafted and limited in scope. Under a rebate model program, the only acceptable reason for denying a 340B rebate should be in achieving MFP deduplication—that is, if a pharmacy already received a MFP rebate for a drug included in the MDPNP and the MFP is lower than the 340B ceiling price, then the covered entity would not receive a 340B rebate.

In addition to limiting the reasons for which rebates can be denied, HRSA must provide protections including a robust, impartial dispute and appeal process for covered entities. In addition to the delayed receipt of 340B discounts, a rebate model 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 recommends that HRSA outline a robust appeals process and additional details on how the agency plans to conduct oversight of a pilot program to ensure that manufacturers are remitting 340B rebates on time and not denying 340B rebates. **A process to dispute denied claims should also include the ability to dispute denials in bulk, instead of individually.** Disputing rebate denials individually is a manual and labor-intensive process. Allowing 340B covered entities to submit bulk disputes would streamline this process and be a more efficient use of limited staff time and resources.

The decision to pay or deny a 340B rebate, and the ability to analyze covered entity claims, would fall with drug manufacturers and the third-party platforms they choose to use for the rebate models. 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.²⁰ 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).”²¹ 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.

In HRSA’s previously finalized 340B Rebate Model Pilot Program, there was no formal mechanism offered for 340B covered entities to appeal or file a complaint if manufacturers improperly denied rebates. The only process HRSA made available to covered entities was for them to try to resolve any issues directly with manufacturers, and if they were unable to receive a favorable resolution, to send an email to a designated HRSA inbox. Unfortunately, relying on manufacturers to resolve issues in good faith is not a transparent or reliable method of ensuring

²⁰ 340B Statute, Sec. 340B(a)(5)A.

²¹ 340B Statute, Sec. 340B(d)(2) (emphasis added).

program integrity. In their experiences using manufacturer-chosen claims submissions platforms, covered entities have reported issues communicating with these third-party vendors and receiving an explanation for improperly denied claims. AAMC members have reported that 340B ESP, which is a platform drug manufacturers use to collect contract pharmacy claims data from covered entities, has often denied payment for claims, incorrectly alleging that submitted claims for payment were inaccurate or incomplete. When these hospitals have attempted to resolve these issues with 340B ESP, they have encountered delays in communication and insufficient explanations as to the reasons for the denials. The Beacon platform, which is the platform manufacturers are expected to use for rebate models, is operated by the same parent company as 340B ESP and early indications suggest that Beacon is not ready to operationalize a rebate model. These concerns highlight the need not only for a neutral third-party vendor (rather than one chosen by and closely affiliated with drug manufacturers) but also a formal appeals process.

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. 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 the requirements of a HRSA-approved rebate model program.

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.²² 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.

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 integrity, they can use existing mechanisms authorized by the 340B statute, such as manufacturer

²² Gluck, Adam. Sanofi, [Sanofi Tackles 340B Abuse with Innovative Credit Model](#) (November 22, 2024)

audits or the administrative dispute resolution process to address these concerns rather than fundamentally altering the 340B program.

DATA COLLECTION BY COVERED ENTITIES

HRSA asks about specific pharmacy and medical claims elements that should be collected as part of a rebate model, whether these data elements are currently available or readily available, the sources of these data, whether the data are already being furnished to third parties, and guardrails to mitigate privacy and security concerns (p. 7290).

In implementing rebate models, manufacturers are likely to require covered entities to submit claims data to them through their selected vendors, such as the Beacon platform associated with Second Sight Solutions or the Kalderos Truzo platform. HRSA must engage in oversight of these vendors and their contracts with drug manufacturers to ensure data protections. Based on past experience with third-party vendors and more recent experiences with the Beacon platform, 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. Hospitals are typically required to sign these contracts without the ability to meaningfully revise the contracts to protect their patients' sensitive data. 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.

HRSA should limit the data elements covered entities must submit to receive a rebate. In the previously finalized Rebate Model Pilot Program, HRSA had approved 12 pharmacy claims data elements and 14 medical claims data elements that would have to be completed for every claim. Manufacturers could achieve their goal of deduplicating claims using just prescription number and 340B ID. **Medical claims in particular pose additional challenges and should be excluded from a rebate model.**

Medical claims submission introduces unique challenges, particularly due to the timeframe for submitting medical claims, which are physician administered drugs, as well as the complexity of medical claims. Often, the information to submit a claim is not available for weeks or months later and the claim contains multiple claim lines representing potentially multiple drugs and services. And, payers such as Medicare, allow up to a year to submit claims data for payment, meaning hospitals are accustomed to these timelines to gather the data necessary to submit medical claims. The quantity of medication administered to the patient field, which presumably requires the quantity of billable units, poses unique challenges and requires crosslinking to national drug code (NDC). Often, the unit of measure required by the manufacturer differs from the unit of measure captured by the hospital in its IT systems. The data that are required for the medical claims elements are housed in the hospital's electronic health record (EHR) system and are not always tracked at the NDC level, because the hospital's EHR often has its own classification system to group similar drugs. Multiple drugs, such as different brands of a given drug, can be grouped into one classification in the EHR, although they each have unique NDCs.

Extracting the information in the EHR and attempting to match it to an NDC is a manual and time-intensive process.

Further, under CMS' CY 2026 PFS final Rule, CMS finalized a voluntary claims data repository inclusive of five data elements to identify a claim as being 340B or not. Under this proposal, only the NDC, 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.²³ Based on this, we urge HRSA to reconsider whether all 12 (or 14 for medical claims) of the required data elements are necessary for identifying claims as eligible for 340B pricing under these rebate models. 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 a rebate model.**

REQUIRED REPORTING

HRSA solicits feedback on data manufacturers should share with HRSA, and which of this data HRSA should make public, to ensure manufacturers are complying with a rebate model program. If HRSA pursues a rebate model, its robust oversight of the program will be imperative to hold manufacturers accountable for honoring their obligation to provide 340B prices to covered entities and to provide rebates as expeditiously as possible. Transparency will be critical in evaluating the impact of rebate models on access to 340B pricing. Therefore, if HRSA were to implement a rebate model, it should require manufacturers to provide data on the time it takes to process claims, the percentage of submitted claims successfully processed, the percentage of disputed claims, the percentage of submitted claims that are denied, the percentage of disputed claims that are denied, and the basis for denial of claims. Manufacturers should provide this information to HRSA both at the claim and provider level and also in aggregated format. For public reporting purposes, HRSA could publish aggregated information and information broken down by covered entity type and by drug.

340B PROGRAM INTEGRITY AND OTHER POTENTIAL BENEFITS OF A REBATE PILOT

HRSA solicits feedback on the benefits of a rebate model and how it would affect the integrity of the 340B program. The AAMC does not believe rebate models are necessary to ensure 340B program integrity. As we have cited throughout the letter, the costs of 340B rebate models to covered entities outweigh any marginal benefit, particularly given the availability of less disruptive alternatives. To date, there have not been documented, widespread program integrity issues that require a fundamental restructuring of the 340B program. To the extent that there are specific, targeted instances of noncompliance with the 340B statute, HRSA currently has the enforcement tools at its disposal.

²³ 90 FR 32643

Under the 340B statute, covered entities are responsible for complying with two program integrity requirements: first, the prohibition on Medicaid duplicate discounts; and second, the prohibition on diversion, meaning 340B drugs should only be dispensed or administered to patients of the covered entities. HRSA, state Medicaid agencies, covered entities, and manufacturers have rigorous controls in place to ensure 340B hospitals are operating within the confines of the 340B statute. As part of regular program integrity efforts, HRSA conducts annual audits of covered entities and publishes its audit findings. In addition, 340B hospitals maintain robust internal controls, such as conducting internal audits, maintaining patient records to support the patient definition, and collaborating with state Medicaid agencies to identify Medicaid claims. HRSA should continue to build on these processes instead of introducing new rebate models that are unnecessary to 340B's core program integrity goals.

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 robust program safeguards. To summarize, we urge HRSA to continue to preserve the benefit of the 340B program to covered entities by allowing 340B to continue to operate as an upfront discount program instead of through retrospective rebates. 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 rebate 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' 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 Shahid Zaman (szaman@aamc.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Jaffery', with a stylized flourish at the end.

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

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