



655 K Street, NW, Suite 100  
Washington, DC 20001-2399  
T 202-828-0400  
aamc.org

*Submitted via email to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov)*

April 22, 2026

Maria G. Button  
Director, Executive Secretariat  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
5600 Fishers Lane  
Rockville, MD 20857

**Re: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-XXXX**

Dear Director Button:

The AAMC<sup>1</sup> welcomes this opportunity to comment on the Information Collection Request (ICR) titled “**340B Rebate Model Pilot Program Application, Implementation, and Evaluation**” 91 Fed. Reg. 9632 (February 26, 2026), issued by the Health Resources and Services Administration (HRSA or the Agency). HRSA issued the ICR to collect feedback from the public on its burden estimate of the costs associated with implementing a rebate model to effectuate prices in the 340B Drug Pricing Program. In a separate request for information (RFI), CMS sought feedback on implementing such a rebate model.<sup>2</sup> As the AAMC explained in its separate comments on the RFI, we strongly oppose 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.<sup>3</sup> In these comments, we focus on HRSA’s estimate of the burden associated with collecting data under a rebate model, and as we note, we believe HRSA grossly underestimates the actual burden associated with collecting data under a 340B rebate model program.

---

<sup>1</sup> 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.

<sup>2</sup> Request for Information: 340B Rebate Model Pilot Program,” 91 Fed. Reg. 7287 (February 17, 2026)

<sup>3</sup> H.R. Rep. No. 102-384(II) (1992).

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 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.<sup>4</sup> 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.

As a federal agency, HRSA is required to issue an ICR when it plans to collect information from the public under the Paperwork Reduction Act of 1995. In the ICR, HRSA estimates the annual burden hours stemming from collection of proposed rebate model plans from qualifying drug manufacturers, the ongoing collection of sales data from drug manufacturers, and the collection of data submitted by covered entities to manufacturers to request a rebate in connection with a potential 340B rebate model program. Specific to collection of data from covered entities, HRSA estimates the total annual burden per respondent would be 260 hours, which amounts to 5 hours per week. **This estimate significantly understates the actual time that 340B hospitals will spend on submitting claims data and complying with the requirements of a 340B rebate model.** AAMC member hospitals expect their staff to spend at least 25 to 40 hours a week to submit claims data to a third-party platform, which totals 1300 to 2080 hours annually per hospital and is five to eight times higher than HRSA's estimate.

HRSA states that the burden associated with a rebate model program "may not be significant" because the agency "expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities" (p. 9633). This statement could not be further from the truth. As the AAMC noted in its separate comment letter to HRSA on the 340B rebate model RFI, the administrative costs of complying with a rebate model are substantial and involve more than just submitting claims data to the portal.<sup>5</sup>

---

<sup>4</sup> 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.

<sup>5</sup> [AAMC Comment Letter to HRSA on Request for Information: 340B Rebate Model Pilot Program \(HRSA-2026-03042\)](#). Submitted April 20, 2026.

Participating in a rebate model would involve developing new 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. These types of changes alone, which go beyond the baseline task of submitting claims to a third-party portal, would require the hiring of up to six or more full-time equivalent (FTE) employees dedicated to broader rebate model compliance across the pharmacy, finance, revenue cycle, IT, and compliance functions.

In the ICR, HRSA requests comments on “the necessity and utility of the proposed information collection for the proper performance of the agency's function” and “the accuracy of the estimated burden” (p. 9633). As we note above, the agency’s burden estimates are inaccurate and do not comport with the operational realities of how 340B hospitals collect, store, and report information that would need to be submitted through a rebate platform. HRSA should work with 340B program stakeholders to more accurately understand the time and resources that would be required to comply with a 340B rebate model program. Regarding the question of the necessity and utility of the proposed information collection, the AAMC does not believe that a rebate model is necessary for the “proper performance of the agency’s function.” As the AAMC further explained in its comment letter on the RFI, rebate models are unnecessary to ensure 340B program integrity or to meet HRSA’s and the Centers for Medicare and Medicare Services’ (CMS’) goals of assisting with Maximum Fair Price (MFP) deduplication.<sup>6</sup> Instead of creating additional burden through unnecessary new processes, HRSA should continue to build on existing program integrity tools at its disposal. HRSA could work with CMS to develop more feasible alternative policies to achieve MFP deduplication, such as a prospective approach to MFP effectuation that allows for the purchase of 340B drugs and MFP-eligible drugs at upfront discounts or CMS could use a neutral third-party entity, such as the Medicare Transaction Facilitator, to assist with deduplicating MFP from 340B prices.

## **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 believe HRSA’s burden estimate grossly understates the true cost and burden of compliance with 340B rebate models and we believe that the collection of claims data through a 340B rebate model is unnecessary to further HRSA’s program integrity goals. 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](mailto:szaman@aamc.org)).

---

<sup>6</sup> Ibid.

Director Button  
April 27, 2026  
Page 4

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