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Chantelle Britton
Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Rockville, Maryland 20857

Submitted electronically via regulations.gov

RE: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (HHS-2026-03042)

Dear Director Britton,

On behalf of the American Academy of Family Physicians (AAFP), which represents 124,500 family physicians and medical students across the country, we appreciate the opportunity to comment on the [Request for Information](#) from the Health Resources And Services Administration (HRSA) regarding the impact of implementing the proposed 340B Rebate Model Pilot program, published in the Federal Register on February 17, 2026.

The 340B Drug Pricing Program is essential to the health care safety net, enabling covered entities, including certain disproportionate share hospitals, community health centers (CHCs), federally qualified health centers (FQHCs), and other federally funded outpatient clinics, to expand access to affordable, life-saving medications. By providing statutory discounts at the point of purchase, the program supports continuity of care for patients with chronic disease and sustains the financial viability of safety-net providers that serve high-need, low-income communities. The proposed 340B Rebate Model Pilot would replace current up-front 340B discounts with a post-dispensing reimbursement, requiring covered entities to acquire selected drugs at full Wholesale Acquisition Cost (WAC) and seek rebates from manufacturers. The pilot would apply to the ten drugs selected for the Medicare Drug Price Negotiation Program (MDPNP) in 2026, most of which are essential medications for chronic conditions routinely managed in CHCs and primary care settings.

On behalf of family physicians who provide continuous, comprehensive care for patients across the lifespan and deliver much of the frontline care for the three in four Americans living with at least one chronic condition, **the AAFP strongly encourages HRSA to exempt Community Health Centers (CHCs) from the 340B Rebate Model Pilot program.ⁱ**

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Access to affordable medications is foundational for effective primary care. The AAFP strongly [supports](#) the availability of effective, safe and affordable medications through policies that promote competition and availability, transparency, patient-centric pricing, drug price negotiation and review. Further, the AAFP [believes](#) that formularies should be designed to reduce or eliminate out-of-pocket costs for patients with chronic conditions to improve adherence and patient outcomes.

Primary care and family physicians practicing in CHCs manage a disproportionate share of the nation's chronic disease burden, including diabetes, hypertension, cardiovascular disease, asthma, and serious mental illness; conditions that require uninterrupted, medication-based treatment. In 2024 alone, CHCs provided care to 3.5 million patients with diabetes and 6.2 million patients with hypertension.ⁱⁱ This care resulted in 72 percent of patients reaching control over their hemoglobin A1c levels, leading to an estimated \$24 billion in health care savings, and 67 percent of patients achieving hypertension control leading to an estimated \$8 billion in health care savings.ⁱⁱⁱ Yet medication adherence rates for chronic disease therapies remain approximately 50 percent nationwide, with cost-related nonadherence already common among low income and uninsured patients.^{iv} **Any model that delays or disrupts access to affordable medications at the point of care risks worsening medication adherence, increasing avoidable and costly downstream hospital and emergency department utilization, and undermining patient outcomes.**

The risks of the rebate model are most clearly illustrated by its impact on insulin access. Insulin products such as NovoLog® and Fiasp®, included in the 2026 Medicare Drug Price Negotiation list, are commonly prescribed insulin therapies in primary care. Primary care physicians provide longitudinal care for the majority of the more than 38 million Americans living with diabetes, including millions who rely on CHCs.^{v,vi} Federal requirements, including [Executive Order No. 14273](#), "Lowering Drug Prices by Once Again Putting Americans First", condition future Section 330(e) funding on CHCs providing low-income patients with access to discounted insulin at the point of care. The proposed retrospective rebate model offers no operational pathway to meet this obligation, as insulin would be dispensed at full WAC rather than the discounted 340B price. This misalignment would make insulin unaffordable at the pharmacy counter, impede compliance with federal requirements, and foreseeably lead to treatment interruptions, preventable hospitalizations, and increased morbidity and mortality among patients with insulin-dependent diabetes.

The proposed rebate model also risks destabilizing CHC pharmacy operations more broadly. CHCs rely on 340B savings to maintain integrated pharmacy services that enable patients to receive medications at the point of care. Requiring up-front WAC purchases will increase inventory costs, strain cash flow, and introduce uncertainty related to rebate timing, reconciliation, and denial. Under previously proposed versions of the rebate model, manufacturers could deny rebate claims based on ambiguous grounds, such as "duplicate rebate," without providing the data or documentation necessary for covered entities to

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understand or contest those decisions. When a rebate is denied, the CHC bears the full financial loss, having already paid WAC and dispensed the drug at a reduced price. **Financial pressures from implementing the proposed 340B rebate model will force CHCs, many of which operate with limited cash reserves, to restrict formularies, reduce services, or shift patients into fragmented pharmacy settings where cost, transportation, and care discontinuity further erode patient outcomes.** This financial harm is compounded by the fact that the 340B price is no longer reflected in the wholesaler's price catalog or the pharmacy software at the time of purchase. This forces CHCs to "estimate" rebate amounts, creating unpredictable financial losses and the potential to undercharge or overcharge patients.

The rebate model also introduces substantial and costly administrative burdens. If finalized, CHCs would be required to navigate multiple manufacturer-specific rebate processes, invest in new IT infrastructure, and dedicate staff to claims submission, reconciliation, and dispute resolution; all without assurance of timely or complete reimbursement. These burdens fall most heavily on CHCs already operating on thin margins and divert scarce resources away from direct patient care.

CHCs already operate under a comprehensive statutory and regulatory framework established by Section 330 of the Public Health Service Act ([42 U.S. Code § 254b](#)) and the 340B statute ([42 U.S.C. § 256b](#); [42 C.F.R. Part 10](#)). In alignment with Section 330 of the Public Health Service Act, CHCs implement sliding fee discount programs based on income and household size, ensure full discounts for patients at or below 100 percent of the federal poverty level, and maintain robust eligibility determination systems. These services are made possible in large part by 340B savings. Further, CHCs are subject to regular Operational Site Visits to verify compliance with Health Center Program requirements and adhere to strict 340B compliance protocols, including internal audits, staff training, and external oversight. They also report detailed 340B-related data annually through the Uniform Data System, including information on drug purchases, costs, revenues, and patient populations served. Given the compliance infrastructure and strict statutory requirements already in place for CHCs, implementing a rebate model would cause disproportionate administrative and financial burdens to CHCs and the patients they serve.

Unlike the proposed retrospective rebate model that shifts financial and administrative risk onto safety-net providers, the up-front 340B discount enables CHCs to meet legally mandated affordability requirements and prevent avoidable downstream costs; particularly hospitalizations and emergency department utilization that would otherwise be borne by Medicare, Medicaid, and federal grant programs. The savings generated through 340B participation at CHCs are not excess revenues but are tightly constrained by statute and reinvested in required patient services, including sliding-fee discounts, integrated pharmacy access, and chronic disease management. **The proposed rebate model would not meaningfully recapture spending at CHCs but displace those savings with higher federal expenditures resulting from disrupted medication access and worsening health**

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outcomes. Exempting CHCs therefore preserves the clinical and fiscal efficiencies the 340B program was designed to achieve, while allowing HRSA to evaluate rebate models without destabilizing core safety-net infrastructure.

If HRSA proceeds with a rebate-based pricing model, we recommend HRSA to develop clear, enforceable operational guardrails for the pilot program to prevent the systematic shifting of financial and administrative risk to covered entities. HRSA should require that any rebate model operate under uniform national standards that limit manufacturer discretion, ensure timely and accurate payment, and protect covered entities from financial harm. Further, it is imperative that HRSA require manufacturers to leverage their existing resources to protect the stability of the safety-net providers that the 340B program was designed to support.

We thank you for the opportunity to provide comments on this important issue. Should you have any questions, please contact Sahana Chakravarti, Regulatory Specialist, at schakravarti@aafp.org.

Sincerely,

A handwritten signature in black ink that reads "J Brull, MD". The signature is fluid and cursive.

Jen Brull, MD, FAAFP
American Academy of Family Physicians, Board Chair

ⁱ Watson KB, Wiltz JL, Nhim K, Kaufmann RB, Thomas CW, Greenlund KJ. Trends in Multiple Chronic Conditions Among US Adults, By Life Stage, Behavioral Risk Factor Surveillance System, 2013–2023. *Prev Chronic Dis* 2025;22:240539. DOI: <http://dx.doi.org/10.5888/pcd22.240539>

ⁱⁱ Parker, ED, et al., Economic Costs of Diabetes in the U.S. in 2022. *Diabetes Care* 2 January 2024; 47 (1): 26–43 <https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022>

ⁱⁱⁱ Parker, ED, et al., Economic Costs of Diabetes in the U.S. in 2022. *Diabetes Care* 2 January 2024; 47 (1): 26–43 <https://diabetesjournals.org/care/article/47/1/26/153797/Economic-Costs-of-Diabetes-in-the-U-S-in-2022>

^{iv} Pruitt, S.D., Khan, R., Chaiyakunapruk, N. *et al.* The silent epidemic of non-adherence – insights from the 2024 a:care congress. *BMC Proc* 19 (Suppl 10), 13 (2025). <https://doi.org/10.1186/s12919-025-00326-4>

^v Pilla, S. J., Segal, J. B., & Maruthur, N. M. (2019). Primary Care Provides the Majority of Outpatient Care for Patients with Diabetes in the US: NAMCS 2009-2015. *Journal of general internal medicine*, 34(7), 1089–1091. <https://doi.org/10.1007/s11606-019-04843-9>

^{vi} Holliday CS, Gabbay RA. Breaking Barriers: CDC and American Diabetes Association Unite to Combat Diabetes. *Prev Chronic Dis* 2025;22:240273. DOI: <http://dx.doi.org/10.5888/pcd22.240273>