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Samantha Miller
Director of Division of Oversight, Reporting, and Regulatory Compliance
Office of Planning Analysis and Evaluation
Health Resources and Services Administration
5600 Fishers Lane, Room 13N82
Rockville, MD 20857

RE: Comments of Positive Impact Health Centers, Inc. in Response to: "340B Rebate Model Pilot Program Application, Implementation, and Evaluation" Information Collection Request Federal Register Notice

Dear Director Miller:

Positive Impact Health Centers, Inc. (PIHC) submits these comments to the Health Resources and Services Administration (HRSA) in response to the Information Collection Request (ICR) Federal Register Notice ("FRN") dated February 26, 2026, regarding the proposed 340B Rebate Model Pilot Program Application, Implementation, and Evaluation. PIHC respectfully urges HRSA to withdraw the proposed rebate model ICR and instead work with the Centers for Medicare & Medicaid Services (CMS) to develop a neutral clearinghouse as the appropriate mechanism for preventing 340B and Maximum Fair Price (MFP) duplicate discounts.

PIHC is a Ryan White HIV/AIDS Program grantee headquartered in Atlanta, Georgia, with clinical operations in DeKalb, Gwinnett, Cobb, and Clayton Counties—all designated Tier 1 Ending the HIV Epidemic (EHE) jurisdictions. Georgia consistently ranks among the top five states for new HIV diagnoses, and the Atlanta metropolitan area bears a disproportionate share of that burden. PIHC serves approximately 10,000 individuals annually, primarily people living with HIV (PLHIV), individuals engaged in pre-exposure prophylaxis (PrEP) services, and patients requiring sexually transmitted infection (STI) prevention and treatment. The vast majority of PIHC's patients are low-income, uninsured or underinsured, and medically underserved. PIHC's mission—ensuring people living with HIV have a life worth loving—depends on the 340B program's upfront discount structure as a foundational operating assumption.

PIHC has participated in the 340B program as a covered entity for nearly a decade, building pharmacy infrastructure, staffing models, and patient programs around the certainty of upfront pricing. PIHC previously submitted detailed comments in response to HRSA's Request for Information regarding the same proposed rebate model (Docket No. HRSA-2026-03042),

documenting the specific harms such a model would cause to PIHC's patients and operations, and incorporates those comments by reference here. The ICR FRN compounds those concerns: it reveals that HRSA has not only persisted in pursuing a rebate model despite substantial opposition in the RFI record but has done so with a burden estimate that is wholly inadequate and a process that fails to account for the real-world administrative and financial consequences its proposal would impose.

I. THE ICR BURDEN ESTIMATE IS INADEQUATE AND DOES NOT REFLECT PIHC'S OPERATIONAL REALITY

HRSA estimates that each covered entity would spend an average of 260 hours per year—approximately five hours per week—complying with Rebate Model Pilot requirements. HRSA grounds this figure in the assumption that the data a rebate model would require is substantially similar to information covered entities already collect and share with manufacturers under existing contract pharmacy policies and Medicare Drug Price Negotiation Program claims processes. That assumption is wrong, and the 260-hour estimate reflects a fundamental misunderstanding of what a rebate model would actually require of organizations like PIHC.

PIHC manages its 340B compliance program in-house, without reliance on for-profit third-party administrators. Our compliance infrastructure was designed specifically for an upfront discount model. The data and workflows supporting that model are not transferable to a rebate framework—they are structurally incompatible with one. A rebate model would require PIHC to build, from the ground up, entirely new systems and processes for: tracking each covered drug purchase at WAC pricing; submitting claims to individual manufacturer platforms with differing requirements and portals; tracking denial rates, disputing rejections, and managing appeals across multiple manufacturers simultaneously; reconciling rebate receipts against claims submitted; and maintaining audit-ready documentation for each manufacturer's distinct audit standards—none of which PIHC currently does, because none of it exists under the current upfront discount model.

HRSA's comparison to data already shared under contract pharmacy policies or Medicare Drug Price Negotiation Program claims is inapt. Those frameworks apply to a narrow subset of claims under specific, pre-existing compliance structures. A rebate model applied broadly would require PIHC to perform these functions across its entire covered drug portfolio, on an ongoing monthly basis, with no guarantee that manufacturer rebate payments will be timely, accurate, or complete. The 260-hour estimate does not account for the substantial time required to build the systems to support these functions in the first place—a one-time implementation burden that alone would far exceed HRSA's annual estimate.

HRSA's estimate also does not account for the financial cost of the working capital gap a rebate model would create. The interval between WAC payment and rebate receipt is not simply an

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administrative inconvenience—it is a financing obligation. PIHC's 340B savings are not held in reserve; they are fully committed to patient services on a rolling basis. A rebate model would require PIHC to finance the difference between WAC and ceiling pricing for 60 to 90 days or longer per transaction cycle—across the full scope of the covered drug portfolio—without any certainty that rebate payments will be made on time or without dispute. That financing cost is real and material, and HRSA has not included it in its burden calculation at all.

PIHC's real-world experience and internal modeling further demonstrate that HRSA's burden estimate is materially understated. PIHC estimates approximately $2 million in annual incremental costs associated with implementing a rebate model. PIHC currently operates its 340B compliance program entirely in-house, without reliance on third-party administrators, does not participate in contract pharmacy data-sharing arrangements, and carves out Medicaid and Maximum Fair Price (MFP) drugs. As a result, PIHC has no existing infrastructure for ongoing external data sharing, and all current program operations are built on a tightly controlled, closed-network model driven by real-time patient eligibility under an upfront discount framework.

Transitioning to a rebate model would require PIHC to dismantle this efficient and compliant structure and replace it with entirely new systems and workflows. PIHC currently processes over 100,000 340B claims annually. Under a rebate model, each of these claims would require heightened review for data accuracy, submission, reconciliation, rebate tracking, and—critically—denial management and appeals. Of the estimated $2 million annual impact, approximately $100,000 represents one-time implementation costs, $800,000 reflects ongoing financing costs associated with reliance on PIHC's line of credit to cover increased drug acquisition costs, and the remainder is attributable to ongoing staffing and compliance expenses. PIHC anticipates the need to hire at least six additional full-time equivalents (FTEs) to support implementation and ongoing compliance, including:

- 1.5 FTE for 340B compliance data systems engineering
- 1.0 FTE for 340B compliance legal counsel
- 3.0 FTEs for pharmacy claims billing, reconciliation, and appeals
- 0.5 FTE for administrative support

These staffing requirements alone far exceed HRSA's estimate of five hours per week and reflect the operational reality of managing a manufacturer-driven rebate system at scale.

In addition to administrative costs, the rebate model would fundamentally alter PIHC's financial structure. PIHC estimates its annual cost of goods sold (COGS) would increase by approximately 40%, resulting in an additional monthly cash flow exposure approaching $5 million. This exposure is not theoretical; PIHC's recent experience with the Medicare Transaction Facilitator (MTF) provides a direct analogue. Over the first three months of MTF implementation, PIHC has received only approximately 60% of expected reimbursement, effectively requiring the organization to "float" the remaining 40% of drug acquisition costs. During this same period, PIHC has been forced to appeal approximately 40% of submitted claims. When extrapolated

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across PIHC's full 340B volume under a rebate model, this would equate to roughly 40,000 appealed claims annually, an administrative burden that is operationally untenable and entirely unaccounted for in HRSA's estimate.

II. THE PROPOSED COLLECTION IS UNNECESSARY BECAUSE THE REBATE MODEL ITSELF IS UNNECESSARY

The ICR FRN proceeds from the premise that a rebate model is an appropriate policy mechanism for preventing 340B-MFP duplicate discounts. That premise is wrong, and no amount of data collection will make the underlying policy sound. PIHC submitted detailed comments on this question in response to the RFI and incorporates those arguments by reference here. A rebate model is not merely operationally burdensome—it is legally questionable, structurally harmful to safety-net providers, and wholly unnecessary given the availability of a more effective alternative.

The Rebate Model Inverts Congressional Intent

The 340B statute instructs that the amount covered entities pay for covered outpatient drugs shall not exceed the 340B ceiling price at the point of sale. A rebate model, by design, requires covered entities to pay above that ceiling price and then seek reimbursement—a structure Congress explicitly declined to adopt when it created the program in 1992, notwithstanding that the Medicaid Drug Rebate Program had been established just two years earlier. HRSA does not have statutory authority to restructure the 340B program as a rebate model through administrative action, and nothing in the ICR process grants it that authority. Collecting information to operationalize an unlawful policy direction does not make the policy lawful.

A Rebate Model Would Cause Concrete, Immediate Harm to PIHC and Its Patients

As documented in PIHC's prior RFI comments, the harm a rebate model would cause is not speculative. Under a rebate model, PIHC would be required to absorb WAC pricing across its covered drug portfolio while awaiting uncertain reimbursement. That cash flow disruption would threaten PIHC's ability to fund the wraparound services—case management, medication adherence programs, behavioral health, transportation, and housing referrals—that make HIV treatment adherence possible for a patient population navigating compounding barriers to care. For people living with HIV, disruptions to antiretroviral therapy access, even brief ones, can cause viral rebound and drug resistance. Those clinical consequences carry public health costs that extend well beyond the individual patient and ultimately shift financial burden onto Medicaid, Medicare, Ryan White, and Georgia's publicly funded healthcare infrastructure.

PIHC relies on contract pharmacy partners to extend medication access to patients who cannot reach our clinic locations due to geography, transportation barriers, or work and caregiving schedules. These partnerships are operationally viable today because the upfront discount model creates predictable, manageable financial terms for all parties. A rebate model would impose

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significant new administrative complexity and financial uncertainty on those partners—complexity they did not bargain for and that many smaller or community-based contract pharmacies are not equipped to absorb. If contract pharmacy partners reduce or discontinue participation in response to a rebate model's burdens, PIHC's patients lose access to the dispensing locations they rely on. For a patient population that already navigates compounding barriers to consistent care, any contraction in the pharmacy access network is not a logistical inconvenience—it is a clinical setback with direct public health consequences for communities across the Atlanta metropolitan area.

The rebate model's administrative burdens would compound these financial harms. PIHC would be forced to redirect clinical and compliance staff hours toward rebate processing, claims disputes, and manufacturer platform management—functions that do not exist today and that would consume resources currently deployed in patient care. These are not theoretical tradeoffs. They would translate directly into reduced service capacity for approximately 10,000 patients in Georgia's highest-burden HIV communities, undermining the federal government's own Ending the HIV Epidemic objectives in the very jurisdictions where progress is most critical.

A Federally Sanctioned Rebate Model Would Empower Manufacturers at the Expense of Safety-Net Providers

PIHC is also deeply concerned that a federally endorsed rebate model—even a narrowly constructed pilot—would provide manufacturers with a structural template for further restricting covered entities' access to 340B pricing. Manufacturers have for years sought to shrink the 340B program through contract pharmacy restrictions and unilateral rebate schemes. Federal endorsement of that model would lend those efforts a legitimacy they do not deserve and shift authority over whether a covered entity purchase qualifies for the statutory ceiling price—a determination Congress never delegated to manufacturers—into manufacturers' hands.

The data sharing requirements a rebate model would impose compound this concern. Requiring PIHC to transmit claims-level, prescription-level, and potentially patient-linked data to manufacturers and their designated vendors—as a condition of receiving the pricing Congress already mandated—constitutes an unjustified transfer of proprietary and sensitive information to entities with a demonstrated financial interest in using that data adversarially. The parallel to pharmacy benefit manager (PBM) conduct is instructive and not hypothetical: for years, PBMs have used knowledge of covered entities' 340B participation to impose discriminatory reimbursement rates that systematically erode 340B savings. Georgia recognized the severity of this problem and enacted legislation prohibiting discriminatory PBM reimbursement practices—a law that passed with bipartisan support precisely because the harm to safety-net providers and their patients was documented and undeniable.

A federal rebate model that compels covered entities to share detailed claims data with manufacturers creates an identical vector for harm, now in the hands of entities with even greater

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financial leverage. For PIHC's patients specifically, the stakes are higher still: HIV-status confidentiality is both a legal protection under Georgia law and a practical prerequisite for care engagement, and any data sharing arrangement that places patient-linked HIV pharmacy records in the hands of commercial entities risks deterring the very patients most in need of consistent treatment from seeking or maintaining care.

III. HRSA SHOULD PURSUE THE NEUTRAL CLEARINGHOUSE ALTERNATIVE

PIHC does not dispute that preventing 340B-MFP duplicate discounts is a legitimate program integrity objective. What PIHC disputes is that a rebate model is the right mechanism to achieve it—particularly when a less disruptive, more reliable, and operationally superior alternative exists. It bears noting, moreover, that the scale of the problem a rebate model purports to solve does not justify the disruption it would cause. Duplicate discounts under the current upfront model are not a systemic crisis—they are a narrow, identifiable compliance issue arising at the intersection of 340B pricing and the Medicare Drug Price Negotiation Program, affecting a limited subset of covered drugs. Existing mechanisms already prevent 340B-Medicaid duplicate discounts without a rebate model, demonstrating that the program integrity objective can be achieved through targeted, less burdensome means. The rebate model is, in PIHC's view, a solution in search of a problem—one whose costs to patients, providers, and the public health infrastructure of communities like ours are wholly disproportionate to the compliance gap it is designed to close.

A neutral 340B clearinghouse, administered by the federal government or a government-designated contractor, would allow covered entities, third-party administrators, and contract pharmacies to submit 340B claims data retrospectively. The clearinghouse would identify and exclude 340B claims from the information provided to manufacturers for MFP rebate purposes, ensuring manufacturers pay rebates only on non-340B claims without requiring any covered entity to finance the WAC-to-ceiling-price gap in the interim. This model preserves the upfront discount structure Congress intended, eliminates the adversarial manufacturer-administered rebate process, and achieves program integrity objectives through a standardized, transparent, and auditable mechanism.

The clearinghouse approach is not hypothetical. CMS has already announced its intent to test a clearinghouse-like "340B repository" model to address 340B-Medicare Part D inflation rebate duplicate discounts. HRSA should work with CMS to extend that framework rather than pursuing a parallel and far more burdensome rebate model simultaneously. The infrastructure, the legal framework, and the policy rationale are already in development. Directing resources toward a clearinghouse—rather than toward operationalizing an administrative collection that will face legal challenge and impose immediate harm on safety-net providers—is the responsible course.

PIHC further notes that the cost of clearinghouse infrastructure could be appropriately offset through participation fees assessed on manufacturers, who are the primary financial beneficiaries of duplicate discount prevention. Placing the cost of program integrity infrastructure on the safety-net providers the 340B program was designed to support—rather than on the manufacturers it was designed to counterbalance—is inconsistent with the statute's purpose and its legislative history.

IV. CONCLUSION

HRSA's ICR FRN presents PIHC with a troubling signal: that the agency intends to proceed with a rebate model despite the legal vulnerability of its prior guidance, the substantial opposition documented in the RFI record, and the availability of a better alternative. A federal court previously found that HRSA's prior rebate model guidance violated the Administrative Procedure Act by failing to adequately consider the model's impact on covered entities and by departing without reasoned explanation from the agency's longstanding policy requiring upfront 340B discounts—the same deficiencies this comment documents in detail. The burden estimate embedded in the FRN understates the true cost of compliance by a significant margin, fails to account for the financing obligations a rebate model would create, and ignores the irreversible harm to patient care that would follow from the resource diversion a rebate model requires.

PIHC respectfully requests that HRSA withdraw the proposed ICR and decline to implement a Rebate Model Pilot. In the alternative, PIHC urges HRSA to collaborate with CMS on the development of a neutral clearinghouse as the operationally sound, legally defensible, and patient-centered mechanism for addressing duplicate discount concerns. PIHC stands ready to engage constructively with HRSA and CMS in that effort.

We appreciate HRSA's consideration of these comments.

Respectfully submitted,

Larry Lehman (Apr 27, 2026 16:35:01 EDT)

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