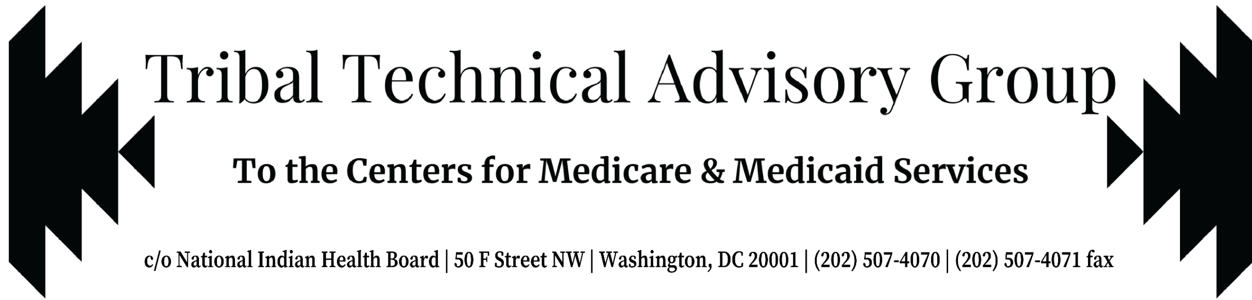


April 20, 2026

Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane,
Rockville, MD 20857

**Re: Request for Information: 340B Rebate Model Pilot Program (91 FR 7287)**

Mr. Engels,

On behalf of the CMS Tribal Technical Advisory Group (TTAG), I write to respond to the Health Resources and Services Administration (HRSA) Request for Information (RFI) for the 340B Rebate Model Pilot Program (91 FR 7287). TTAG recognizes that this request follows prior stakeholder concerns regarding implementation of a 340B rebate-based structure, proposed to strengthen oversight and address duplicative discounts. In this context, TTAG supports efforts to strengthen program integrity and financial accountability. However, HRSA should endeavor to achieve its intended goals while preserving the 340B program's core discount structure.

The TTAG is very concerned that many tribal healthcare programs do not have funds available to pay for drugs up front and then obtain a rebate, and as a result, will be shut out of the 340B program if it moves to a rebate model. TTAG writes to reiterate that the program trajectory of a rebate-based model presents unresolved financial, operational, and administrative risks that require a full evaluation through formal Tribal Consultation and Urban Confer before further advancement, given its anticipated impact on participating Tribal health facilities.

**Impacts on the Indian Health System Necessitate Tribal Consultation and Urban Confer**

Foremost, the proposed rebate model has clear implications for Tribes and UIOs that warrant formal engagement through Tribal consultation, pursuant to Executive Order 13175 and the Department of Health and Human Services' Tribal consultation policy, and Urban Confer. This shift from an upfront discount structure to a retrospective rebate model represents a fundamental change to how the 340B program operates and directly affects the financing and delivery of services within Tribally operated and UIO facilities. TTAG is not aware of any formal engagement on the 340B restructuring and respectfully requests that HRSA initiate Tribal consultation and Urban Confer before advancing any rebate-based framework.

The scale and structure of the 340B program underscore the significance of any policy change affecting it. In 2024 alone, covered entities purchased approximately $81.4 billion in outpatient drugs through the 340B program, reflecting its central role in

sustaining safety-net care delivery nationwide. HRSA explicitly recognizes that the program enables covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Within this framework, Tribal, IHS-operated entities, and UIOs are recognized participants, with Tribal contract and compact facilities accounting for approximately $87.0 million in 340B purchases in 2024. Although smaller in aggregate volume, this participation reflects the program's inclusion of federally funded Tribal health systems and UIOs as beneficiaries of the national safety-net infrastructure.

Ensuring financial accountability within a system of this scale is essential. However, integrity mechanisms cannot come at the cost of the program's ability to function as a reliable financing tool for safety-net providers or the government's trust responsibility to Tribal Nations.

**Rebate Models are Incompatible with the Indian Health System**

TTAG remains concerned that the proposed rebate model is financially incompatible with the Indian health system. Indian Health Service (IHS), Tribal, and UIO (I/T/U) facilities operate within a chronically underfunded system that relies heavily on third-party revenue. Many Tribal facilities and UIOs rely on the immediacy of 340B savings to support pharmacy operations, maintain cash flow stability, and sustain access to essential and high-cost medications for patients. The programmatic shift to post-purchase reimbursement, in which providers must cover full acquisition costs upfront with no guarantee of timely or complete rebate recovery, introduces significant financial strain and risk for Tribal and UIO facilities due to the timing gap between acquisition and repayment.

The absence of standardized and enforceable manufacturer rebate processes compounds these concerns. In the absence of enforceable standards governing manufacturer reimbursement timelines, compliance, or a clear appeals process for denied claims, this structure introduces significant revenue uncertainty that disproportionately impacts resource-constrained Tribal and UIO facilities. If rebates are delayed, denied, or inconsistently processed, providers must absorb those costs, resulting in direct impacts on facility revenue and financial stability. From a program integrity perspective, this structure increases complexity, creates additional junctures of failure, and shifts financial risk onto providers least able to absorb it.

TTAG is also concerned about the administrative feasibility of a rebate model for Tribal facilities and UIOs. The rebate pilot would require additional claims data submission, transaction tracking, and reconciliation across multiple manufacturers and systems. Many Tribal pharmacies, health systems, and UIOs often operate with limited staffing and infrastructure capacity, and these additional requirements would divert resources away from patient care and essential clinical operations. Overextending

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[1] Health Resources & Services Administration. (2025, December). 2024 340B Covered Entity Purchases. 340B Drug Pricing Program. https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases

already limited staff can impact program data accuracy and compliance and threaten overall program participation.

TTAG supports efforts to strengthen program integrity and accountability through mechanisms that preserve point-of-sale discounting while minimizing the burden on participating entities. Approaches like standardized claim validation or centralized verification processes may offer more effective paths forward if designed to operate in real-time, ensure consistency across manufacturers, and avoid shifting financial and administrative responsibility onto providers or patients. Any oversight-focused changes should maintain the core 340B structure, ensuring that discounts are available at the point of purchase and that clear, uniform rules and mechanisms for appeals are in place without disrupting service delivery.

## Conclusion

For these reasons, the TTAG strongly urges HRSA to exempt Indian Health Service, Tribal, and UIO providers from any rebate-based 340B pilot model. TTAG emphasizes that any disruption to the 340B program has direct implications for American Indian and Alaska Native patient access in areas that are already largely unserved. 340B savings support access to essential and high-cost medications in Tribal and Urban Indian communities. Therefore, we urge HRSA to conduct formal engagement with Tribes and UIOs through Tribal Consultation and Urban Confer before further consideration or implementation of a rebate model in place of the existing 340B discounts.

Sincerely,

W. Ron Allen, TTAG Chair
Chairman, Jamestown S'Klallam Tribe

Cc: Mark Cruz, Senior Advisor to the Secretary
Rachel Ryan Pedersen, Acting Director, CMS, DTA