



Tribal Technical Advisory Group



To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board | 660 N. Capitol Street NW, Suite 750 | Washington, DC 20001
(202) 507-4070 | (202) 507-4071 fax

October 1, 2026

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

Re: HRSA Tribal Consultation on the 340B Rebate Model Pilot Program

Administrator Engels,

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to submit Tribal consultation comments regarding the Health Resources and Services Administration's (HRSA) 340B Drug Rebate Model Pilot Program. While TTAG serves as an advisory body to CMS on policy issues related to the Social Security Act, the 340B Model Pilot Program issue is perhaps one of the most significant policy issues affecting Indian health programs at this moment in time. It will have an extreme financial impact Tribal health programs and will result in adverse impacts on the patients we serve. Because of this, TTAG is compelled to provide our consultation comments to HRSA on this issue.

Throughout the rulemaking process, this consultation, and the recent US Department of Health and Human Services (HHS) Secretary's Tribal Advisory Committee (STAC), Tribal leaders repeatedly identified the financial strains and administrative burdens the pilot program would impose on Indian Health Care Providers (IHCPs). For IHCPs, 340B savings are a critical mechanism for stretching limited healthcare resources and supporting patient care. These savings have allowed providers to maintain critical services and, where resources permit, reinvest 340B savings into our health systems to expand needed services for American Indian and Alaska Native (AI/AN) patients. HRSA must implement the 340B Rebate Model in a manner that preserves IHCP's ability to use 340B savings to stretch limited healthcare resources. TTAG again requests that HRSA fully consider these comments and exempt all IHCPs from the pilot model. During the recent STAC meeting, you and Secretary Kennedy both recognized that Indian 340B providers are not "large hospital systems and extensive networks of affiliated hospital outpatient sites" that are creating the issues you are trying to address in the pilot program. Indeed, our health systems are exactly the types of providers the

CMS TTAG Letter to Administrator Engels
HRSA Tribal Consultation on the 340B Rebate Model Pilot Program
October 1, 2026
Page 2 of 4

340B program was designed to assist. A recent analysis shows that Tribal 340B providers purchased \$115 million worth of 340B Drugs in 2025. This is just 00.12% of the \$100 billion in total 340B purchases. When Congress created the 340B Program, it considered requiring safety-net providers to receive a discount after dispensing drugs to patients, as HRSA now proposes. However, Congress removed this requirement from the 340B Program authorizing legislation, realizing that "a rebate program would pose significant challenges that the clinics would be unable to meet given their overall lack of administrative resources and federally appropriated budgets." Those risks are very real, as you heard again during the STAC meeting.

TTAG is disappointed to hear that your Office of General Counsel is raising concerns that creating an exemption for Tribal 340B providers could be seen as arbitrary and capricious and lead to legal challenges. While your General Counsel may understandably raise similar concerns for other providers participating in the 340B program, Indian 340B providers are uniquely situated. It is important to recognize that unlike other 340B providers, Tribal 340B providers are legally constrained in how they can use the savings generated by the 340B program. Tribal 340B providers must use their funds to carry out their obligations under their agreements with the Indian Health Service, which are subject to single agency audit requirements. In this way they are distinct from any other 340B provider.

Further, sovereign nations, not interest groups, operate these programs, and HRSA has ample legal authority to address them distinctly. The United States has a unique legal and political relationship with Tribal Nations, grounded in the Constitution, federal law, case law, and executive orders. Born out of this relationship are the federal government's trust and treaty responsibilities to protect Tribal interests, including the provision of quality healthcare AI/AN people. The federal government's trust and treaty responsibilities extend across all HHS operating divisions, including HRSA and the 340B program. Federal statutes, regulations, and programs routinely provide distinct treatment for Tribal Nations, Tribal organizations, and urban Indian organizations because of the unique political status and the federal government's trust and treaty responsibilities. An exemption for IHCPs would be consistent with this longstanding legal and political relationship and should not be viewed through the same lens as classifications that do not arise from the government-to-government relationship.

HRSA has long recognized the unique legal status of Indian health care programs and has exercised its administrative authority to account for the federal trust responsibility when implementing federal health programs. For example, in recognition of the trust responsibility and the importance of IHS programs in meeting the health needs of AI/AN people, Congress explicitly deemed Tribal and urban Indian programs to be treated as

CMS TTAG Letter to Administrator Engels
HRSA Tribal Consultation on the 340B Rebate Model Pilot Program
October 1, 2026
Page 3 of 4

community health centers in the FQHC definition. Section 1905(l)(2)(A)(iv) of the Social Security Act states:

“(iv) was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990; and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services.”

Additionally, HRSA designates all IHS and Tribal facilities as automatic Health Professional Shortage Areas (HPSAs). Whether implementing authorities expressly established by Congress, such as the inclusion of Tribal and urban Indian programs in the FQHC definition, or exercising administrative discretion, such as the automatic designation of IHS and Tribal facilities as HPSAs, HRSA has consistently recognized the unique status of Indian health care programs in carrying out federal law.

Other HHS operating divisions similarly recognize the unique legal and political status of IHCPs and implement program-specific policies, exemptions, and authorities that account for that status across federal health programs. HHS, for example, recently approved two Section 1115 demonstration applications for traditional health care practices services in the Medicaid program that are limited to Indian health care providers. Other examples include:

- The American Recovery and Reinvestment Act (ARRA) of 2009, Section 5006, provides five protections for Indians and Indian health programs, including cost-sharing exemptions, resource exclusions, exemptions from Medicaid estate recovery, managed care protections and tribal consultation requirements, including the codification of the CMS TTAG.
- The Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 requires states to accept Tribal documents as first-tier documents to verify citizenship and identity.
- CMS exempts AI/AN Medicaid beneficiaries from work requirements under HR 1.
- The payment methodology for Medicaid and Medicare services provided by IHCPs is a unique reimbursement methodology established jointly by CMS and IHS.

These examples demonstrate that tailoring program requirements and exemptions for Indian health care providers is a well-established practice across HHS.

CMS TTAG Letter to Administrator Engels
HRSA Tribal Consultation on the 340B Rebate Model Pilot Program
October 1, 2026
Page 4 of 4

If any questions remain about the legal basis for an exemption or potential litigation risk, TTAG encourages HRSA to ensure its analysis is informed by counsel with substantial expertise in federal Indian law, Tribal sovereignty, and the federal trust responsibility. Any assessment of litigation risk should account for the unique legal and political relationship between Tribal Nations and the federal government as well as the federal government's distinct obligation to AI/AN people.

Conclusion

TTAG requests that HRSA exempt IHCPs from the pilot and any potential permanent implementation of a rebate model. An exemption would recognize the unique status of IHCPs, protect scarce resources dedicated to patient care, and allow HRSA to implement the 340B program in a manner consistent with the federal trust responsibility and the government-to-government relationship. TTAG appreciates HRSA's consideration of these comments and the opportunity to comment.

Sincerely,

A handwritten signature in black ink that reads "W. Ron Allen". The signature is fluid and cursive, with the first name "W." and last name "Allen" clearly legible.

W. Ron Allen
Chairman/CEO, Jamestown S'Klallam Tribe

Cc: Mark Cruz, Director, Indian Health Service, Senior Advisor to Secretary Kennedy
Rachel Ryan Pedersen, Acting Director, Division of Tribal Affairs, CMS
Commander Sharyl Trail, PsyD, Director, Office of Tribal Affairs, HRSA