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
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November 20, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Re: Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards; CMS-4217-NC

Dear Administrator Oz:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to respond to the CMS Request for Information; Medicare Part D Reasonable and Relevant Pharmacy Contracting Standards; CMS-4217-NC. TTAG appreciates the opportunity for continued dialogue to address Medicare Part D (Part D) issues impacting Indian health care provider participation. Ensuring adequate network participation, enforcing statutory reimbursement requirements, removing unnecessary contracting barriers, and preserving operational flexibilities for Indian pharmacies are critical to the continued delivery of pharmacy services throughout Indian Country.

To address these issues, TTAG requested that CMS update, strengthen, and expand the Part D Indian Addendum so that it establishes contracting standards that recognize the unique legal status of Indian health care providers and builds upon existing statutory protections to promote accurate reimbursement, network participation, and ensure reliable access to medications for American Indian and Alaska Native (AI/AN) Medicare beneficiaries. We appreciate CMS's continued engagement with TTAG on these issues and look forward to ongoing consultation and collaboration to advance these shared goals.

Background on the Indian Part D Addendum

In 2005, CMS first promulgated a regulation requiring Part D plans to offer contracts to Indian Health Service, Tribal, and urban Indian organization (I/T/U) pharmacies.[1] CMS did so to address the fact that "I/T/U pharmacies [were] not currently well integrated in commercial pharmacy networks," and because Part D plans did "not actively solicit the inclusion of these pharmacies in their networks."[2] CMS recognized that "contracting with I/T/U pharmacies is potentially more complex than contracting with retail pharmacies given that there are several provisions in the standard contracts of

[1] 42 C.F.R. 423.120(a)(6)
[2] 70 Fed. Reg. 4193, 4253 (Jan. 28, 2005)

commercial health plans that would likely need to be modified or deleted given statutory or regulatory restrictions to which I/T/U pharmacies are subject." Because of this, CMS concluded that "standard contracting terms and conditions will not be sufficient for Part D plans to obtain the participation of I/T/U pharmacies in their networks." To address those issues and facilitate the participation of I/T/U pharmacies in Part D networks, CMS decided to require the use of a Tribal Indian Health Addendum to Medicare Part D Plan Agreement (Indian Part D Addendum) in 2005 and has continued to do so for all solicitation for applications for new cost plan sponsors.[3] This was done to address the fact that the "lack of I/T/U pharmacies in Part D plan networks would render enrollment in Part D of little use to AI/AN beneficiaries who rely primarily on I/T/U facilities for their health care."

The Part D Indian Addendum has proven to be enormously important in allowing I/T/U facilities to participate in Part D plans. It has served as the model for other needed Indian contracting addenda issued by CMS, including the Indian Addendum for Qualified Health Plans and the Indian Addendum for Medicaid Managed Care Plans as well as the new Part C Indian Addendum currently under consideration. The Part D addendum had not been updated to reflect changes in the law since it was first developed. As a result, working in collaboration with CMS, TTAG proposed updating the Indian Part D Addendum in 2023. TTAG's proposed edits sought to revise citations and references to reflect changes made after CMS developed the Indian Addendum that I/T/U providers could use when contracting with Qualified Health Plans (QHP) on the new Marketplace Exchanges. TTAG's proposed changes also sought to expand the scope of the Indian Part D Addendum to include not only Part D plans, but pharmacy benefit managers (PBMs), a managed care company, a health plan sponsor, an insurance company, a third-party payor, or any company, group, or agent that represents or is engaged by those entities.

CMS issued a revised Indian Part D Addendum in 2024, based on suggestions from TTAG. The updated Indian Part D Addendum made several significant changes to ensure continued participation of I/T/U pharmacies in Part D networks. However, CMS did not incorporate several of TTAG's recommended changes, creating the need for additional revisions. Since the 2024 update, TTAG and CMS continue to collaborate to address the remaining issues identified by TTAG. TTAG has proposed several clearer or stronger protections to create clearer operational flexibility for I/T/U pharmacies. These protections include provisions related to payment, acquisition and repackaging, alternative dispensing methods, information technology (IT) capacity limitations, US Drug Enforcement Agency (DEA) number language, and dispute resolution.

TTAG has been working through these issues with CMS Part D subject matter experts through its Part D subcommittee. TTAG has submitted a revised draft Part D Addendum to the CMS Part D team and is continuing to work through these issues. TTAG submits these recommendations in response to this RFI to provide them on the record for CMS. TTAG appreciates CMS's continued commitment to the collaborative working process to improve and modernize the Part D Indian Addendum.

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[3] *See, e.g.,* https://www.cms.gov/files/document/2027-part-d-application-final.pdf

Paying Reimbursement Rates Required by Law

TTAG remains concerned that I/T/U pharmacies continue to face significant barriers to receiving accurate reimbursement. As we have discussed, despite repeated requests from Indian health providers, Part D plans frequently resist contracting arrangements that recognize the unique legal authorities applicable to I/T/U pharmacies. During the 2024 Addendum revisions, TTAG sought to include provisions that would address payment accuracy and require Part D plans to comply with existing reimbursement payment floors required under section 206 of the Indian Health Care Improvement Act.[4] TTAG recommends revising the Part D Indian Addendum to explicitly incorporate the reimbursement requirements of Section 206 of the Indian Health Care Improvement Act and ensure that Part D plans apply payment methodologies that fully recognize the statutory protections afforded to I/T/U providers.

Section 206 provides as follows:

> (a) Right of recovery. Except as provided in subsection (f), the United States, an Indian tribe, or tribal organization shall have the right to recover from an insurance company, health maintenance organization, employee benefit plan, third-party tortfeasor, or any other responsible or liable third party (including a political subdivision or local governmental entity of a State) the reasonable charges billed by the Secretary, an Indian tribe, or tribal organization in providing health services through the Service, an Indian tribe, or tribal organization, or, if higher, the highest amount the third party would pay for care and services furnished by providers other than governmental entities, to any individual to the same extent that such individual, or any nongovernmental provider of such services, would be eligible to receive damages, reimbursement, or indemnification for such charges or expenses if-
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> (1) such services had been provided by a nongovernmental provider; and
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> (2) such individual had been required to pay such charges or expenses and did pay such charges or expenses.

This means that Part D plans must reimburse I/T/Us at either (1) the reasonable charges billed, or (2) if higher, the highest amount a Medicare Advantage plan would pay to nongovernmental providers. This statutory requirement ensures that Part D plans reimburse I/T/Us at the highest preferred provider rates they pay other providers, and it applies to I/T/Us regardless of whether they are in-network with the Part D plan. However, Part D plans routinely ignore this statutory obligation by not reimbursing I/T/U providers at preferred provider rates, and in some cases do not reimburse them at all if they are not in-network. The proposed change to the Indian Addendum would require reimbursement to I/T/U providers under Section 206 of the Indian Health Care Improvement Act.

Preventing Plans from Discounting Reimbursement Rates

TTAG's proposed changes to the Addendum would prevent plans from discounting reimbursement when I/T/Us exercise their right to acquire drugs through federal discount pharmaceutical programs. Some plans have begun asking I/T/U pharmacies to disclose how they are sourcing pharmaceutical drugs. If I/T/U pharmacies source drugs through discount programs like the Health Resources and Services

[4] 25 U.S. Code § 1621e

Administration (HRSA) 340B or the US Department of Veterans Affairs prime vendor programs, then the plans apply steep discounts to the reimbursements provided to Indian pharmacies. The plans should not be able to discount reimbursement simply because an I/T/U has exercised its right to participate in a federal discount pharmaceutical program.

In addition, Part D sponsors do not consistently recognize the operational realities of I/T/U pharmacies. I/T/U pharmacies routinely repackage pharmaceuticals into quantities appropriate for patient needs, administer medications, dispense medications through alternative delivery models, and substitute medically or chemically equivalent drugs when clinically appropriate. However, Part D plans have imposed operational restrictions, payment reductions, claw backs, or denials based on how medications are acquired, repackaged, dispensed, administered, or substituted, creating unnecessary administrative burden and barriers to timely access to medications, particularly in rural and geographically isolated Tribal communities. TTAG recommends resolving these operational access and payment policy issues by incorporating TTAG's suggested edits to the 2027 Indian Part D Addendum.

Burdensome Contracting Terms

TTAG remains concerned that certain Part D contracting requirements and sponsor-specific interpretations continue to create unnecessary barriers for I/T/U pharmacies seeking to participate in pharmacy networks. Broadly, current contracting practices do not consistently recognize the unique legal status and federal authorities of Indian health providers. Standard commercial contracting provisions are frequently applied without modification for the Indian health system, creating administrative burdens and contractual requirements that may conflict with federal law, Tribal sovereignty, and the operational structure of Tribal health programs. These requirements can delay contract execution, complicate network participation, and ultimately limit beneficiary access to pharmacy services. The Part D plans are not willing to negotiate their standard contract terms on a case-by-case basis but will follow the Indian Addendum. These issues must be addressed through changes to the Addendum.

Requirements for DEA Registration Numbers

The Part D Indian Addendum currently includes provisions requiring Tribal and Urban Indian providers to use an "IHS facility's DEA number." This has created avoidable confusion because the requirement references IHS facilities in provisions that apply to non-IHS providers. Tribal facilities obtain their own DEA numbers and do not use an IHS facility DEA number. Referencing an "IHS facility DEA number" in provisions applicable to non-IHS providers has led some Part D plans to be unwilling to contract with tribal programs that do not have an "IHS facility DEA number," which they cannot obtain. As a result, TTAG has recommended a clarifying change to the Addendum stating that Tribal and Urban programs can use their DEA number instead of the IHS's.

Dispute Resolution Parity

The current version of the Addendum provides different dispute resolution provisions for the IHS than for tribal and urban providers. This creates unequal protections across the Indian health system. Under the current version of the Addendum, the IHS and the Part

D plans must resolve any disputes in good faith, and the IHS is not required to submit to binding arbitration or comply with the Plan's standard dispute resolution provisions. While IHS facilities are afforded a clear dispute-resolution carveout, Tribal and urban Indian pharmacies remain subject to a sponsor's standard pharmacy agreement dispute process. As a result, Tribal and Urban Indian providers face barriers to entering network agreements when standard dispute-resolution provisions require waiving sovereign immunity or accepting terms inconsistent with Tribal governmental status. TTAG's edits to the Part D Addendum would provide equal dispute-resolution protections for Tribally operated and urban Indian pharmacies.

Rurality Factors and Mail Based Pharmacy Contracting

Current Part D sponsor practices do not consistently recognize the dispensing models I/T/U pharmacies use to serve rural and remote Tribal communities. TTAG's edits to the Indian Part D Addendum proposed language that would have explicitly authorized dispensing by mail, courier, clinic-based delivery, and automated dispensing systems such as Pyxis units, while ensuring reimbursement at the same rate as in-person dispensing. These proposals are still under consideration by the CMS Part D team.

Until this is resolved, I/T/U pharmacies will face ongoing uncertainty regarding whether medications distributed through alternative delivery methods will be recognized as valid dispensing events and reimbursed accordingly. This creates operational and financial risks for I/T/U providers and may limit AI/AN beneficiaries' access to prescription medications in communities where in-person pharmacy services are not readily available. TTAG recommends revising the Part D Indian Addendum to explicitly recognize these dispensing methods and ensure payment parity for medications dispensed through approved alternative delivery models.

Limited Capacity for Drug Utilization Review

Current practices of Part D sponsors also create uncertainty regarding how I/T/U pharmacies may demonstrate compliance with Part D program requirements when operating with limited IT capacity. TTAG's proposed edits to the Addendum propose that where any agreement contains a drug utilization review (DUR) or generic-equivalent substitution provision, and an I/T/U pharmacy lacks the required IT capacity to comply, the I/T/U pharmacy would be exempt from the requirement. Although alternative methods may satisfy certain drug DUR and generic-substitution requirements, Part D sponsors often apply inconsistent expectations about what constitutes an acceptable alternative. This lack of uniformity creates implementation challenges, claims-processing disputes, and additional administrative burden for I/T/U pharmacies.

Conclusion

TTAG appreciates CMS's continued engagement with Tribal leaders and Indian health providers on Medicare Part D policy and contracting issues. While the Indian Part D Addendum has played an important role in facilitating I/T/U pharmacy participation in Part D networks, persistent challenges related to reimbursement, contracting requirements, operational flexibility, and access to medications continue to limit the full effectiveness of these protections. Strengthening the Addendum and establishing

reasonable and relevant contracting standards that fully recognize the unique legal status of Indian health providers would help ensure compliance with existing federal law while reducing unnecessary barriers to network participation. These changes would promote more accurate reimbursement, improve pharmacy access in rural and underserved Tribal communities, and support the continued delivery of critical services to AI/AN Medicare beneficiaries.

We respectfully urge CMS to incorporate the recommendations outlined in this letter and continue working collaboratively with TTAG to address ongoing Part D challenges. We appreciate your consideration of these recommendations and look forward to continued consultation and partnership to improve health outcomes for AI/AN communities.

Sincerely,



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Chairman/CEO, Jamestown S'Klallam Tribe

Cc: Mark Cruz, Director, Indian Health Service, Senior Advisory to Secretary Kennedy
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