Tribal Technical Advisory Group
To the Centers for Medicare & Medicaid Services
c/o National Indian Health Board 910 Pennsylvania Avenue, SE Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

Transmitted via e-mail: Kitty.marx@cms.hhs.gov

April 21, 2016

Andrew Slavitt, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Mail Stop S2-26-12
Baltimore, MD 21244-1850

Re: Medicaid Covered Outpatient Drugs Final Rule: Request for Further Guidance to State Health Officers and State Medicaid Directors Regarding Application to I/T/U Pharmacies

Dear Administrator Slavitt:

On behalf of the Tribal Technical Advisory Group (TTAG),[1] I respectfully ask that the Centers for Medicare and Medicaid Services (CMS) prepare a supplemental State Health Officials Letter (SHO), or other sub-regulatory guidance for State Medicaid Agencies, to further address and clarify how States may reimburse IHS, Tribal, and Urban Indian Programs (I/T/Us) for covered outpatient drugs under the final Covered Outpatient Drug rule published February 1, 2016.[2]

Reimbursement for I/T/U pharmacies was briefly addressed in SHO #16-001[3], but we are concerned that some statements in that SHO, and some provisions of the final rule, could be misinterpreted by States as a constraint on their rate-setting flexibility under the rule, to the detriment of affected I/T/Us. Specifically, we ask that CMS provide additional guidance clarifying that:

- *Any* State may elect to reimburse I/T/U pharmacies through the OMB encounter rate, not only those States that are currently using that methodology;

- Because "Actual Acquisition Cost" (AAC) is an aggregate payment limit and the final rule does not mandate any specific reimbursement methodology, States have the same flexibility to establish AAC for I/T/Us as for other pharmacies. They may base AAC on various benchmarks and surveys, but are not compelled to adopt published Federal Supply Schedule (FSS) prices for I/T/U pharmacies that procure some covered drugs through FSS; and

[1] The TTAG advises the Centers for Medicare and Medicaid Services (CMS) on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care programs funded in whole or part by CMS. In particular, the TTAG focuses on providing policy advice designed to improve the availability of health care services to American Indians and Alaska Natives under these federal health care programs, including through providers operating under the health programs of the Indian Health Service, Indian Tribes, Tribal organizations, and urban Indian organizations.
[2] 81 Fed. Reg. 5170 (February 1, 2016); CMS-2345-FL).
[3] February 11, 2016.

- The final rule's requirement that States establish "professional" dispensing fees does not preclude appropriate dispensing fees for prescriptions dispensed by qualified Community Health Aides or other qualified paraprofessionals in compliance with applicable State and federal laws.

We briefly address each topic below.

1. The Encounter Rate Option.

SHO# 16-001 instructs:

> *States that pay IHS and Tribal providers through encounter rates can continue to pay that rate*, since this will satisfy the requirements in §447.518(a)(2), which specify that the state's methodology for these entities must be in accordance with the definition of AAC in §447.502.

(SHO# 16-001, p. 3, emphasis added.) Without further guidance from CMS, we are concerned that some States may focus on the first clause of this statement, and mistakenly conclude that *only* States *already* paying through an encounter rate may choose that methodology under the final rule.

As you know, an encounter rate methodology is in fact available for *all* States, and SHO# 16-001 was not announcing a grandfather policy. CMS explained in the final rule's preamble:

> [I]f a state pays I/T/Us at the encounter rate, it will satisfy the requirements in §447.518(a)(2) … that the state's payment must be in accordance with the definition of AAC. *We have determined that the encounter rate is one model that states may use to reimburse I/T/U pharmacies, given that the rates are designed to address provider costs.*…[N]othing in this final rule prevents states from using the encounter rate as a model to reimburse I/T/U pharmacies.

(81 Fed. Reg. at 5316, emphasis added.) Further, it is clear CMS expected that some States not now reimbursing through the encounter rate might choose to do so under the new rule: it noted that the "current CMS SPA review and approval process" would ensure that "states establishing such pharmacy rates" would first obtain tribal input and advice. (81 Fed. Reg. at 5316.)

To prevent any possible misunderstanding, we respectfully ask that CMS issue additional guidance to States clarifying that reimbursement at the encounter rate is an available option for *all* States.

2. AAC for Pharmacies Purchasing Drugs Purchased Through FSS.

SHO# 16-001 states at p. 3: "For drugs purchased through the Federal Supply Schedule (FSS), reimbursement should not exceed the FSS price." The statement is part of a broader discussion of the many data sources States may draw on to establish rates that will satisfy the definition of AAC,

and we do not believe CMS intended to instruct States that they must cap payment for FSS drugs -- or to I/T/U pharmacies that purchase them -- at published FSS prices, nor that States must adopt separate payment rates for such drugs or pharmacies.

Throughout the final rule's preamble, CMS emphasized that the rule was "not designed to mandate state payment rates" or to require States to "use a specific formula or methodology to establish their AAC reimbursement."[4] It repeatedly declared that States enjoy "the flexibility to establish an AAC reimbursement based on several different pricing benchmarks" -- including national or state price surveys, AMP data, WAC, or other sources -- so long as the State can provide data to support the reimbursement model it selects.[5] It made clear that AAC is an "aggregate" rate that may be established "using aggregate data,"[6] and that States are not required to implement AAC "at the individual claim level,[7]" determine "the actual price of each drug at the time it was purchased,"[8] or "determine AAC for every drug dispensed by every pharmacy in their state."[9]

Although the final rule requires that States specify their reimbursement methodology for I/T/U pharmacies[10] – a requirement we applaud -- it does not require States to adopt different reimbursement rules for such pharmacies or to set different rates for drugs purchased through the FSS. Indeed, except to state that they are excluded from Average Manufacturer Price (AMP), *the final rule makes no reference to FSS drugs at all*. The preamble mentions them only once with reference to AAC, in the context of a larger discussion of the States' rate-setting discretion, merely noting that tribal entities "may be able to purchase CODs under the FSS" and that, in such cases, States "can access FSS pricing via the Department of Veteran's Affairs Web site." [11]" Nothing in the rule or its preamble suggests that States enjoy any less flexibility regarding drugs purchased through FSS than for other drugs, requires that FSS drugs have a separate reimbursement rate, or establishes FSS prices as a payment cap for FSS drugs or I/T/U pharmacies. To the contrary, we believe the final rule and preamble make clear that States enjoy exactly the same flexibility to set reimbursement for FSS drugs and I/T/U pharmacies as they do for all other drugs and pharmacy providers, provided that *aggregate* reimbursement complies with the AAC requirement.

The issue is important to I/T/Us, because for many drugs their actual acquisition cost may significantly exceed current published FSS prices. This is so for several reasons. First, few if any I/T/U pharmacies purchase all their covered drugs through FSS: some drugs simply aren't available through FSS and must be acquired by I/T/Us from wholesalers or manufacturers, often at premium prices and without the benefit of the discounts available to large-volume purchasers. Second, FSS drug availability varies, and a drug with a published FSS price this month might not have been

---

[4] E.g., 81 Fed. Reg. 5175, 5176, 5312, 5314, 5338.
[5] E.g., 81 Fed. Reg. 5319, 5175, 5176, 5338.
[6] E.g., Fed. Reg. 5293, 5319; 42 C.F.R. § 447.12(b)("The agency payments … must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of …() AAC plus a professional dispensing fee established by the agency; or (2) Providers' usual and customary charges to the general public.")
[7] 81 Fed. Reg. 5293.
[8] 81 Fed. Reg. 5175.
[9] 81 Fed. Reg. 5319.
[10] 42 C.F.R. § 447.518(a)(iii).
[11] 81 Fed. Reg. 5319.

available through FSS when an I/T/U pharmacy purchased it last month. Third, FSS drug prices fluctuate frequently, sometimes dramatically, so that a drug's published FSS price might be quite different on the date it was purchased by an I/T/U pharmacy than on the date it was dispensed and the still later dates it was billed to and paid by Medicaid. Especially in combination, these facts mean an I/T/U pharmacy's actual cost of acquiring covered outpatient drugs may be substantially higher than posted FSS prices.

For all these reasons, it is essential that State Medicaid agencies be permitted to establish reimbursement rates, for I/T/U providers as for others, that satisfy AAC requirements *in the aggregate*, and that reflect the complex and changing mix of drug suppliers and prices. We believe the final rule confers that flexibility, and that it imposes no special payment cap for FSS drugs or I/T/U pharmacies that can access FSS.[12] We ask CMS to clarify that State flexibility extends to reimbursement rates for I/T/U pharmacies and FSS drugs, and that States remain free, consistent with AAC, to establish rates that are based on a variety of data sources, which may include FSS prices, national and State price surveys, AMP data, and other price benchmarks.

3. "Professional" Dispensing Fees.

Finally, we ask CMS to clarify that the requirement for adequate "*professional* dispensing fees[13]" does not preclude States from establishing fees for the dispensing-related services of qualified I/T/U paraprofessionals, such as Community Health Aides and Practitioners (CHA/Ps) in Alaska, if appropriate under other applicable State and federal laws.[14]

We think it is clear that the addition of the word "professional" to "dispensing fee" in the final rule was not intended to restrict who may be paid such fees, but to give due recognition to the professional nature of the complex and vital work pharmacists perform, and to ensure that States set dispensing fees adequate to compensate for that work. In some parts of Alaska, working in concert with Tribal Pharmacies, CHA/Ps perform several activities that, according to the rule, comprise a "professional" dispensing service, including "beneficiary counseling" and "providing the completed prescription to the Medicaid beneficiary." [15] The preamble also clarifies that States retain "the flexibility to … adjust the professional dispensing fee for practitioner type or services rendered."[16] As we read the rule, States may properly set a "professional dispensing fee" for the qualified services of CHA/Ps and other paraprofessionals that reflects the limited services they provide and their practitioner type. We ask that CMS confirm States have that discretion.

---

[12] For example, we believe the final rule should be read to allow the approach the State of Alaska adopted in 2014, after the proposed rule was published and in anticipation of the new AAC requirement. In light of the facts discussed above, and in consultation with Alaska tribal health providers, in lieu of separate reimbursement for FSS-acquired drugs, the State ultimately adopted a benchmark-based rate for I/T/Us (WAC-15%) that was significantly lower than that for other pharmacies (WAC+1%) and that reflects actual, aggregate acquisition costs for both pharmacy types.

[13] 42 C.F.R. § 447.512; 42. C.F.R. § 447.502 definition of "professional dispensing fee."

[14] We understand the State of Alaska is evaluating the possibility of establishing such fees, given the important role CHA/Ps play in delivering covered outpatient drugs to American Indian and Alaska Native recipients in Alaska's small and remote communities.

[15] 42 C.F.R. 447.502, "professional dispensing fee" definition; see also 81 Fed. Reg. 5291.

[16] 81 Fed. Reg. 5310, 5311.

Thank you for considering these requests, and for your continued efforts to consider the needs and circumstances of I/T/U programs when establishing and amending Medicaid rules. Please contact Devin Delrow, NIHB Federal Relations Director at ddelrow@nihb.org if you have any comments or questions about the issues addressed in this letter.

Sincerely,

W. Ron Allen,
Tribal Chairman and CEO, Jamestown S'Klallam Tribe
Chairman, Tribal Technical Advisory Group

cc: Vikki Wachino, Deputy Administrator and Director for Medicaid & CHIP Services

Kitty Marx, Director, CMS Division of Tribal Affairs

John Coster, Director, CMS Division of Pharmacy, Disabled and Elderly Health Programs Group