Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

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Submitted at http://www.regulations.gov

April 2, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2345-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-2345-P: Comments on Medicaid Program; Outpatient Drugs

Dear Administrator,

Please find attached comments prepared by the Tribal Technical Advisory Group (TTAG) to the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services in response to the proposed rule issued by the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) titled "Medicaid Program; Outpatient Drugs" and assigned reference number CMS-2345-P (proposed rule).

TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children's Health Insurance Program, and any other health care program funded (in whole or in part) by the Centers for Medicare and Medicaid Services ("CMS").[1]

Tribal Consultation

We appreciates the opportunity to comment on the Proposed Rule in response to the notice of proposed rulemaking and that CMS has announced in the Proposed Rule that it will engage in consultation with Tribes pursuant to E.O. 13175 and the HHS Tribal Consultation Policy (December 2010) prior to the formal promulgation of this regulation.[2] The consultation policy carried out in conjunction with formal notices of proposed rulemaking and final promulgation is new enough that we

[1] http://www.cmsttag.org/docs/ttag_charter_final.pdf, January 11, 2012.

[2] 77 Fed. Reg. 5350. We are puzzled that there is no reference to the CMS Tribal Consultation Policy adopted on November 17, 2011, but trust that the consultation will satisfy the provisions of both the HHS Policy and the CMS Policy. The CMS Tribal Consultation Policy, which specifically provides that CMS will have "[c]onsulted with Tribal officials throughout all stages of the process of developing the proposed regulation; [m]ade available to the Administrator any written communications submitted to CMS by Tribal officials; and [p]rovided a Tribal summary impact statement in a separately identified portion of the preamble to the regulation as it is to be issued in the *Federal Register* (FR), which consists of a description of the extent of CMS's prior consultation with Indian Tribes, a summary of the nature of their concerns and CMS's position supporting the need to issue the regulation, and statement of the extent to which the concerns of Tribal officials have been met." Pg. 3-4.

admit to some uncertainty about how the comments received during Tribal consultation will be addressed in the rulemaking.

In light of the commitment to engage in consultation we assume, we hope correctly, that CMS will consider fully all comments received in consultation in its decisions with regard to the final rule, even though those comments will have been received after the April 2, 2012, deadline for receipt of comments. If not, the consultation will be of limited utility, and the reference to it in the Proposed Rule may have actually misled some Tribes into believing that they could, perhaps even should, wait to submit comments until they could do so during the consultation process. The Tribal consultation process is an infinitely more flexible way to assure that the full effects of a proposed rule are well understood and addressed in a way that is most supportive of the Indian health programs consistent with;

- the government to government relationship between Indian Tribes and the United States,[3]
- "the Federal Government's historical and unique legal relationship with, and resulting responsibility to, the American Indian people,"[4]
- the special trust responsibilities and legal obligations of the United States to Indians;[5] including the obligation "to ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy[.]"[6]

Provisions of the Rule of Particular Concern

Much of the Proposed Rule addresses matters that are frankly outside our knowledge base. Thus, with some trepidation that we may be missing the most important parts, we focus on those provisions that appear to us to have the greatest potential impact on the Indian Health Service (IHS), tribal and urban Indian organization (I/T/U) pharmacies. We hope that to the extent the provisions on which we have not commented, which may have an impact that is recognized by CMS, CMS will share more information during the consultation process so that further comments can be provided during the formal Tribal consultation process.

As the Proposed Rule notes, I/T/U pharmacies may purchase drugs through the Federal Supply Source (FSS) or the 340B programs.[7] The Proposed Rule also notes that these I/T/U pharmacies are then reimbursed under Medicaid State Plans. In the Proposed Rule, CMS indicates that it considered alternative methodologies, but chose instead to propose no specific methodologies for the I/T/U programs and instead "to invite public comment on Medicaid payment levels for these facilities."[8] The Proposed Rule goes on to say, however that CMS is proposing "that States that do not have specific methodologies develop such methodologies for these providers consistent with [CMS's] proposed shift from [estimated acquisition cost (EAC)] to [actual acquisition cost (AAC)]."[9]

In addition, the Proposed Rule requires that States must submit a State Plan Amendment through the formal review process (including all consultation requirements), when submitting plans to change how

[3] CMS Tribal Consultation Policy, Section 2, pg. 1.
[4] 25 U.S.C. § 1601(1).
[5] 25 U.S.C. § 1602.
[6] 25 U.S.C. § 1602(1).
[7] Access to FSS drugs by urban Indian programs was not made available until the amendments to the Indian Health Care Improvement Act (IHCIA) became effective on March 23, 2010. 25 U.S.C. § 1660g.
[8] 77 Fed. Reg. 5350.
[9] *Id*.

dispensing is reimbursed. The Proposed Rule notes that States must still substantiate "how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries." Most importantly, from our perspective with regard to dispensing fees, the Proposed Rule requires that "[w]here the professional dispensing fee might differ because of unique circumstances for 340B covered entities or IHS and tribal pharmacies, the State should look at these circumstances to determine if a different professional dispensing fee is warranted for these entities."[10]

Finally, the Proposed Rule says that States should not revise one component of the reimbursement formula without appropriately evaluating the other part.

Comments on Proposed Rule

As noted in the Proposed Rule, I/T/U pharmacies are reimbursed by State Medicaid programs under a variety of methods. We are not familiar with them all, but certainly in some cases States have obtained approval under State Plan Amendments to reimburse I/T/U pharmacies for all prescriptions dispensed on a single day to a single patient using the cost based encounter rate, while other States reimburse the I/T/U pharmacies as they would any other pharmacy.[11] Each model has its strengths. Neither creates any meaningful risk in our view of over-recovery, nor unfortunately of beginning to fully provide the resources needed to achieve the policies objectives adopted by Congress in the IHCIA.

Pharmacy services are part of the core services provided by IHS and tribal health programs.[12] Access to pharmaceuticals is critically important for American Indian and Alaska Native (AI/AN) patients of these programs, who in many cases would be unable to afford, or in many cases, even have access to, pharmaceuticals, except through the Indian health program pharmacies, which are often the only pharmacies in vast rural and remote areas.

Resources for the hospital and clinic (H&C) component of the IHS budget through which pharmacy is funded have not begun to keep up with the increase in take-home drug costs.[13] In the period from FY 2002 through FY 2010 drug costs have increased by 76 percent, which the H&C budget increased by only 52 percent. The shortfall is consuming other health services. And, even more worrisome, drug shortages are resulting in astonishing variations in drug costs from one order to the next, even from FSS supplies.

Moreover, whatever the level of reimbursement, it does not appear likely to lead to over-recovery. An IHS study of fiscal year 2003 reimbursement that compared IHS actual costs to Medicaid reimbursement based on average wholesale price (AWP), the highest benchmark ever relied upon for reimbursement, less a discount, plus a dispensing fee, demonstrated that the average Medicaid reimbursement per prescription was nearly 27 percent lower than the average actual costs.[14]

We do not object to the actual proposed language 42 C.F.R. § 447.518 that requires the State plan to describe the agency's payment methodology for prescription drugs, including those dispensed by an I/T/U pharmacy. So long as the allowable methodologies include reimbursement on the same basis as

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[10] *Id*.

[11] Given the significantly poorer health status of AI/ANs and rates of diabetes and other chronic diseases, the incidence of multiple prescriptions on a single day is almost certainly high.

[12] We are less familiar with the urban Indian health programs so do not comment as specifically regarding them.

[13] And, of course, the H&C funds also have to support a huge range of other program increases from addressing patients with more complex needs to changing standards of care.

[14] This Study was provided to CMS in February 2004.

retail pharmacies and the OMB encounter rate already approved by CMS in a number of State plans. I/T/U pharmacies lack the infrastructure to track true actual cost per drug dispensed, and, in fact, it does not appear that true actual cost is anticipated as the basis for reimbursement for any pharmacy. Instead, a new estimate of actual cost will be used by States. Even though the data used for the new estimates may not include certain sources available to I/T/U pharmacies (such as FSS), the I/T/U pharmacies rarely rely on a single source so there is certainly an overlap in the data. Moreover, as noted above, the reimbursement from Medicaid, even when based on a much higher metric, that is now proposed, did not result in over-recovery.

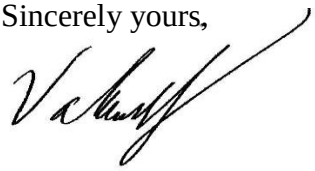
We do appreciate the requirement that dispensing fee calculations take into account special circumstances of I/T/U pharmacies. There are certainly differences. Virtually all I/T/U pharmacies engage in a higher level of clinical pharmacy counseling when drugs are dispensed than is usually available. In addition, the operational costs of I/T/U pharmacies are understandably higher than many (maybe most) retail pharmacies given their relatively small volume and the locations in which they operate.

We applaud the restraint shown by CMS with regard to setting forth specific I/T/U methodologies. However, we believe that CMS may need to provide more guidance to States regarding allowable methodologies, as we discussed above, to ensure that they do not mistakenly believe that current models based on how reimbursement is made to other pharmacies or the encounter rates may not be allowable.

Conclusion

We hope these comments are helpful in CMS's preparation for a meaningful and substantive consultation with Tribes regarding these proposed rules. Negative changes in Medicaid pharmacy reimbursement for I/T/U programs truly jeopardize one of the critical components of these programs and, thus, the well-being of Indian people. Thank you in advance for consideration of these recommendations and please let us know if there is any other information CMS TTAG can provide to assist your analysis of this matter.

Sincerely yours,



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