Tribal Technical Advisory Group
to the Centers for Medicare and Medicaid Services
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February 11, 2005

Dr. Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
Room 314 G, Hubert H. Humphrey Bldg.
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: Medicare Part D Implementation in Indian Country -- Payment Rate Issue

Dear Dr. McClellan:

I write at the instruction of the Tribal Technical Advisory Group to seek your assistance with a significant policy issue regarding implementation of the Medicare permanent prescription drug benefit (Part D) at pharmacies operated by the Indian Health Service, tribes/tribal organizations, and urban Indian organizations (I/T/U pharmacies).

First, let me report that the workgroup comprised by the TTAG to address Part D implementation issues has found the CMS program staff assigned to these issues to be cooperative and responsive to the challenges of making Part D work in Indian Country. They have reviewed our proposals and conducted a number of conference calls with us to work toward resolution of a variety of issues. We greatly appreciate the time and quality attention they have given to this work. We were not able to reach accord with the CMS program staff on the critical issue of the reimbursement rate for Indian programs, however, so we address that issue to you here.

Reimbursement Rate Issue. The issue about which I write concerns the reimbursement rate for drugs dispensed by I/T/U pharmacies to American Indian/Alaska Native (AI/AN) dual eligibles who must enroll in a Medicare Part D Plan effective January 1, 2006. The TTAG is very concerned that the required transfer of these beneficiaries from Medicaid to Medicare could result in reimbursement rates lower than our pharmacies currently receive from Medicaid. Clearly, reduction in revenue to Indian health programs was not Congress's objective in enacting Part D. We hope you will assist us in assuring this does not occur.

What Tribes seek. The TTAG workgroup (as well as over 50 tribes/tribal organizations who submitted comments on the Part D proposed regulations) seek a regulatory "hold harmless" mechanism to assure that the reimbursements I/T/U pharmacies would have received from Medicaid for dual eligibles will be maintained under Part D. In a conference call set up to discuss Indian Country implementation issues, your Special Assistant, Tim Trysla, suggested that a CMS requirement that I/T/U pharmacies be reimbursed at the applicable State Medicaid rate (AWP-x% + dispensing fee) would be the simplest and most efficient way to achieve the "hold harmless" objective. We concurred and fully support his suggestion. In fact, this is the mechanism CMS approved for use by the two Prescription Drug Discount card sponsors endorsed by CMS to operate the Transitional Assistance program for low-income Indian beneficiaries at I/T/U pharmacies.

CMS Program response. In subsequent conferences, however, CMS program staff reported that their legal advisors rejected the suggested Medicaid payment rate requirement for Part D, citing the "noninterference" provision in Sec. 1860D-11(i) of the MMA, which states:

"(i) NONINTERFERENCE. In order to promote competition under this part and in carrying out this part, the Secretary --

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered drugs."

TTAG response. We are mindful of this provision's limitations on Secretarial action, but do not believe it is the only applicable legal standard that must be taken into consideration. In Sec. 1860D-4(b)(1)(C)(iv), Congress gave the Secretary the authority to issue standards with respect to network pharmacy access for I/T/U pharmacies. Through this provision, Congress recognized that without help from the Secretary, the unique nature of I/T/U pharmacies could limit their ability to fully participate in Part D Plan networks, and as a result, AI/ANs enrolled in Part D Plans would be denied full access to Part D Plan benefits.

Critical to this discussion is a recognition that the United States has a trust responsibility to provide health care to AI/AN under federal laws and treaties with Indian tribes. This responsibility is carried out by the Secretary of Health & Human Services. The authority granted to the Secretary by Sec. 1860D-4 is the MMA mechanism Congress provided to assure that the United States' trust responsibility for Indian health care is carried out in Part D implementation.

It is also important to recognize that by its own terms, the objective of Sec. 1860D-11's "noninterference" limitation is "to promote competition". We do not believe that the requirement we seek will have any adverse impact on competition. As you know, I/T/U pharmacies have authority to access drugs from the Federal Supply Schedule and the 340B drug-pricing program; thus, they (and the Medicare patients they serve) will not be part of the "market" for which Part D Plan Sponsors will negotiate discounts/rebates from drug manufacturers. Negotiating such discounts is, of course, a key feature of the Part D program. Since the I/T/U pharmacies (and their patient base) will not be a factor in the rebate negotiations, there is no adverse impact on competition by treating these pharmacies differently in Part D implementation.

It is likely that without Secretarial assistance, I/T/U pharmacies will have problems gaining access to Part D Plan pharmacy networks; thus, Congress, in Sec. 1860D-4, gave the Secretary authority establish standards to assure such access. There is little incentive for Sponsors to seek out I/T/U pharmacies to join their networks, especially since Sponsors will have to devote additional administrative time and effort to negotiating Indian-specific addenda with these entities, most of which have a very small Medicare patient base. CMS will require Plans to *offer* contracts to I/T/U pharmacies, but if mutually acceptable terms (such as an appropriate reimbursement rate) are not achieved, contracts will not be *executed* and the pharmacy will not be part of that Plan's network.

In negotiating reimbursement rates, the large companies that will be operating Part D Plans will have far greater negotiating strength than small tribal pharmacies.[1] While sympathetic to this plight, CMS program people responded that small retail pharmacies may find themselves in a similar position vis-à-vis large Plans, but since they do not get special attention in Part D, small Indian pharmacies should not expect special attention either. But the two types of pharmacies are very different. Retail pharmacies go into business voluntarily to engage in a commercial enterprise with a profit-making expectation. I/T/U pharmacies, however, exist to *carry out the United States' trust responsibility to Indians; they are not commercial, for-profit entities.* This distinction is critical and merits recognition from CMS as a matter of policy.

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[1] We raised with CMS the idea of multiple tribes pursuing group negotiations with a Plan Sponsor. CMS was favorable to this idea and included it as a potential strategy in the guidance materials it provides to entities that want to apply to be designated as a Part D Plan Sponsor.

It is important to recognize that through the 100% FMAP, the Federal government has full economic responsibility for drugs I/T/U pharmacies dispense to AI/ANs enrolled in Medicaid. The Federal government will retain that full economic responsibility when the AI/AN dual eligibles move to Medicare Part D, as CMS will pay their premiums. In many reservation areas, the I/T/U pharmacies are the only locations where these AI/AN dual eligibles can utilize their Part D benefits. Thus, there are at least three reasons why CMS should take steps to assure I/T/U pharmacies can contract with Plans and receive reasonable reimbursement rates: (1) fulfill the United States' trust responsibility to Indians; (2) assure that Indian dual eligibles have an accessible pharmacy at which to use their Part D benefits; and (3) prevent a windfall to Part D Plan Sponsors who collect premium payments from CMS but pay no claims for an Indian beneficiary who has no accessible network pharmacy at which to utilize his/her Part D benefit.

Action we seek from you as CMS Administrator. We ask you to exercise the Secretary's authority in Sec. 1860D-4 and to establish *as a matter of policy* that Part D Plan Sponsors be required to contract with I/T/U pharmacies and be required to reimburse those pharmacies at least at the State Medicaid reimbursement rates (AWP-x% + dispensing fee). The following objectives would be achieved by such a policy:

- Assure I/T/U pharmacies have reasonable access to pharmacy network status (MMA Sec. 1860D-4(b)(1)(C)(iv))
- Assure that AI/AN Medicare beneficiaries have convenient access to a pharmacy where they can fully utilize their Part D benefits (MMA Sec. 1860D-4(b)(1)(C)(ii))
- Hold I/T/U pharmacies harmless from loss of revenue for AI/AN dual eligibles who must move from Medicaid to Medicare in 2006
- Carry out in a meaningful way the United States' trust responsibility for AI/AN health care.

On behalf of the entire TTAG, I express our sincere appreciation for the high level of support you have provided to the TTAG and to the challenging issues we all face in assuring that Indian and Alaska Native people and the health programs that serve them have full access to all CMS programs.

Sincerely yours,

Valerie Davidson,
Chair, CMS Tribal Technical Advisory Group
Executive Vice President, Yukon-Kuskokwim Health Corporation (AK)

cc: Dorothy Dupree