Tribal Technical Advisory Group
to the Centers for Medicare and Medicaid Services
National Indian Health Board 101 Constitution Ave NW, #8B02 Washington, DC 20001 (202) 742-4262 (202) 742-4285 fax www.nihb.org

June 28, 2004

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Humphrey Building
Washington, DC 20201

Re: Indian Principles for Medicare Part D

Dear Dr. McClellan,

In anticipation of the implementation of the permanent prescription drug benefit in 2006 pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the CMS Tribal Technical Advisory Group (TTAG) offers the following recommendations for CMS to consider when drafting the regulations governing this benefit for American Indians and Alaskan Natives (AI/AN) served by the IHS, Indian tribes, tribal organizations, and urban Indian organizations (I/T/Us). Our recommendations address the issue of central concern to the TTAG - -*Access* to Part D benefits for AI/AN Medicare beneficiaries.

Section 1860D-4(b)(1)(C)(iv) of the Social Security Act as amended by Section 101 of the MMA gives the Secretary the authority to include standards to ensure access for I/T/U pharmacies. Therefore, the TTAG requests that CMS include provisions in the Part D regulations that recognize the following principles:

1) Expenditures by I/T/Us on AI/AN beneficiaries (who do not meet the low income requirements) on drugs should count toward the deductible and Catastrophic Coverage level of $5,100 total ($3,600 out of pocket).
2) Tribes should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.
3) I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B(b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.
4) IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.
5) Apply to Part D, current CMS policies regarding AI/AN income and assets that are not to be taken into account for determination of eligibility for Medicaid.
6) Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health

programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.

7) Any I/T/U pharmacy that participates in a PDP network should be allowed to continue to access drugs from the FSS or 340b programs and should not be required to purchase drugs from the PDP.
8) Tribes should be exempt from formulary requirements and therefore may utilize permissible substitutes. The reason for this exemption is to accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries as well as limitations on the availability of drugs through FSS or 340b.
9) An alternative regulation could require PDP to reimburse all I/T/U pharmacies for services as if they were a contracted network provider.
10) In order for a network to be adequate under network adequacy standards, it should offer specific contracts with terms outlined in principle #11 (see below) to *all* I/T/U pharmacies in the network. This requirement would apply to each PDP serving an area that includes one or more I/T/U pharmacies.
11) Any I/T/U pharmacy that wants to participate as a Part D provider should be allowed to do so and PDPs should be required to include the following elements in their agreements with I/T/U pharmacies:
    a) Acknowledge the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
    b) State that the terms of the contract may not change, reduce, expand, or alter the eligibility requirements for services at the I/T/U as determined by the MMA; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to Provider by the IHS for operation of a health program, including one or more pharmacies or dispensaries.
    c) Reference federal law and federal regulations applicable to tribes and tribal organization, for example, the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq.* and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
    d) Recognize that I/T/Us are non-taxable entities.
    e) Clarify that tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
    f) Confirm that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
    g) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
    h) Recognize that an I/T/U formulary cannot be restricted to that of the PDP.
    i) Declare that the Agreement may not restrict access the I/T/U otherwise has to Federal Supply Schedule or 340b drugs.
    j) State that the I/T/U should not be required to impose co-payments or deductibles on its Indian beneficiaries.
    k) Authorize I/T/U pharmacies to establish their own hours of service.

We appreciate the great amount of work it will require to draft implementing regulations for Part D, therefore, we will continue to work on AI/AN specific issues and provide our input to CMS in our advisory capacity.

Sincerely,

Valerie Davidson
Chair, CMS TTAG
Executive Vice-President,
Yukon-Kuskokwim Health Corporation

cc: Dorothy Dupree
TTAG Members