Via electronic transmission to: http/www.regulations.gov>

November 16, 2010

Dr. Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

ATTN: CMS-6028-P

Dear Administrator Berwick:

I write on behalf of the CMS Tribal Technical Advisory Group (TTAG) which provides policy advice to the Centers for Medicare and Medicaid Services (CMS) regarding the participation of American Indians and Alaska Natives and health programs of the Indian Health Service, Indian tribes, tribal organizations and urban Indian organizations (I/T/U) in Medicare, Medicaid and CHIP programs.

Please find attached the comments of TTAG on the Proposed Rule on "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers" (CMS-6028-P).

Thank you for your consideration of these comments.

Sincerely,

Valerie Davidson, Chair

cc: Kitty Marx, Director, Tribal Affairs Group, CMS Roselyn Tso, Indian Health Service, HHS November 16, 2010

Subject: TTAG Comments on CMS-6028-P: Proposed Rule on Medicare, Medicaid,

and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria,

Payment Suspensions and Compliance Plans for Providers and Suppliers

("Proposed Rule")

These comments are filed on behalf of the CMS Tribal Technical Advisory Group ("TTAG") to the Centers for Medicare and Medicaid Services ("CMS"), Department of Health and Human Services ("HHS") in response to the request for comments on the Proposed Rule.

Imposition of Medicare, Medicaid and CHIP Provider Enrollment Fees. Under the proposed rules all "institutional providers," as defined in proposed amendments to 42 C.F.R. § 424.502, will be required under a new section 424.514 to pay a non-refundable application fee to apply to enroll as a Medicare provider. The initial fee will be \$500, and it will be adjusted annually by the percentage change in the consumer price index. The newly proposed section 455.460 permits States to require application fees that may be imposed on any provider except individual physicians and nonphysician practitioners and those institutional providers who have paid fees already to certain other entities, including for Medicare enrollment.

The only exceptions in the actual rule appears to be for those who can argue hardship, although the practical implications of trying to obtain a hardship exception is that the application will not be considered until the waiver is granted, or, if denied, until it is paid. The delay in access to Medicare reimbursement is likely to make applying for hardship waivers an illusory protection. The better course would be to process the application and require that if the application is accepted, but the hardship waiver is denied, the application fee will be deducted from future payments. This certainly creates the risk that some applications would be considered for which no application fee payment was ultimately available, but that outcome is offset by the need to avoid draconian requirements with illusory protections.

Of more immediate concern is that there appears to be no exception for governmental providers, including those that are funded by Federal agencies. To permit Medicare and Medicaid to impose enrollment fees on I/T/U providers merely transfers funds from the underfunded Indian health system to Medicare and Medicaid.

We also note that explanation for the proposed rule indicates that it will be applied only to those providers that bill "Medicare, Medicaid, or CHIP on a fee-for-service basis" 75 FR 58204, 58217. Since most I/T/U providers are reimbursed either on the encounter rates established annually by CMS and the Indian Health Service (IHS) for Indian health programs or on Federally Qualified Health Center encounter rates, if the explanation were translated into the rule as an exception to the fees, the burden of this rule on the underfunded Indian health system would be mitigated. However, so far as we can find, it is not. At the very least, it should be.

Finally, we note that the rate of increase in the fee has in many years exceeded the increases in funding for I/T/U programs, after population growth is taken into account. It is ironic that the

fees for enrollment will be better protected than the funding for actual delivery of care.

Screening Categories under Medicare and Medicaid. We are pleased to note that under section 424.518 "Indian Health Service facilities" are included in the "limited categorical risk," along with physician or nonphysician practitioners and medical groups or clinics, FQHCs, and rural health clinics, as well as others. The term "Indian Health Service facilities" is not defined, however, and it does not adequately describe the programs that should be considered limited risk. We believe that the phrase "Indian Health Service facilities" should be deleted in favor of

Health programs operated by an Indian Health Program (as that term is defined in section 4(12) of the Indian Health Care Improvement Act) or an urban Indian organization (as that term is defined in section 4(29) of the Indian Health Care Improvement Act) that receives funding from the Indian Health Service pursuant to Title V of the Indian Health Care Improvement Act.

Such language (or some simplified version of it) would encompass all I/T/U programs that are carried out pursuant to the Indian Health Care Improvement Act (IHCIA) and Indian Self-Determination and Education Assistance Act (ISDEAA) and avoid the necessity for Tribal health programs to obtain leases on tribal facilities from the IHS in order to make them "Indian Health Service facilities." As CMS recognized when the Medicaid program entered into a Memorandum of Agreement with IHS, IHS does not have any discretion with regard to entering into such leases. If the only way for a tribal health program to be considered to be in the lowest category is to have a lease, a new bureaucratic and administrative morass will open up, imposing yet more costs on the underfunded Indian health system.

The change in language also recognizes that the I/T/U enrolls in Medicare and Medicaid under many different provider types, including some that are not included in the limited category, such as community mental health centers. For the same reasons that "Indian Health Service facilities," FQHCs, and RHCs are limited risk so are all programs carried out by an I/T/U provider, regardless of the provider label. To assure that all I/T/U health programs are treated as limited risk, the exception in (b)(1) and (c)(1) should be amended, as follows:

The following prospective providers and suppliers that are not publicly-traded on the NYSE or NASDAQ or are not carried out in or through an Indian Health Service facility:

Alternatively, if the change to (a)(1)(vii) proposed earlier is accepted, the language in (b)(1) and (c)(1) should be:

The following prospective providers and suppliers that are not publicly-traded on the NYSE or NASDAQ or part of a program described in (a)(1)(vii):

The burden on I/T/U providers of meeting new screening requirements would be significant and

duplicative of screening requirements imposed already under the Indian Child Protection and Family Violence Act on many of the providers.

The Medicaid screening section 455.450 should be amended to require that Indian Health Service facilities or, even better, the Indian health programs described in our alternative language proposal above, be designated as being in the limited categorical risk.

We also recommend that section 455.452 be amended to ensure that States cannot impose screening requirements on I/T/U providers that are different than those imposed on other provider types that provide similar services. This is important because Medicaid programs typically have unique provider type, such as "Indian health clinic" or "Indian health hospital," which would be easy to isolate and focus on. While there have been vast improvements in relationships between States and Tribes, there are still too many examples of States that are either hostile to or simply ignore tribal programs.

Moratoria on Newly Enrolling Medicare and Medicaid Providers and Suppliers.

Under the proposed section 424.570, CMS may impose a moratorium on enrollment of new Medicare providers and suppliers of a particular type or the establishment of a particular type on a particular type of geographic area or nationally under various circumstances, including the fact that there may be a disproportionate number of such providers relative to the number of beneficiaries. Under the Medicaid provisions in section 455.570, States may also impose moratoria. We believe that I/T/U providers should be provided with an express exemption under both rules.

Amendments to the IHCIA expanded authority of I/T/U programs to carry out a broad range of programs, including home-and community-based services, hospice, long term care, new behavioral health programs, and many others. Since no new funding came with the new authority, these programs are not viable unless third-party revenue, and especially Medicare and Medicaid support them. It would be a great irony if those sources of funding were pulled away just as the authority was made available.

We also want to comment that the availability of other providers of the same type in a geographic area provides little protection for American Indians and Alaska Natives who need the opportunity to obtain culturally competent care that is integrated with the other health services made available to them through the I/T/U. A moratorium on enrollment impedes the expansion in I/T/U programs that is so needed.

Requirement for Consultation. Finally, we wish to express our concern about the failure of the Centers for Medicare and Medicaid Services (CMS) to seek an exchange of views, information, or advice from the Tribal Technical Advisory Group (TTAG) or to consult directly with Tribes or confer with urban Indian organizations. As our substantive comments show, these proposed regulations have the potential to have a profound impact on the operation of Indian health programs.

As a general rule, CMS has been attentive to seeking advice and consultation. It makes the absence of such communication about this rule more glaring, especially since it is evident in the

proposed rule that the drafters knew that it would affect Indian health programs. We hope it was merely an oversight and urge that better systems be put in place to ensure that all actions that have the potential to impact health programs operated by IHS, tribes, tribal organizations, and urban Indian health organizations are brought to the TTAG so that it can help key CMS staff recognize the potential impact and identify ways to mitigate it prior to proposing the rules and ensuring appropriate consultation pursuant to the Department of Health and Human Services Consultation Policy and the Presidential Executive Orders.

Unless I/T/U health programs are exempt from these rules, we believe that the effective date should be delayed, discussions with the TTAG and consultation with Tribes held, after which the Proposed Rules, with any changes that result from the advice and consultation, be published with a new comment period.