Tribal Technical Advisory Group

To the Centers for Medicare & Medicaid Services

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

November 15, 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-2325-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 in Medicare, Medicaid and CHIP programs.

Please find attached the comments of TTAG on the Proposed Rule on the Review and Approval Process for Section 1115 Demonstrations (CMS-2325-P).

Thank you for your consideration of these comments.

Sincerely,

Valerie Davidson, Chair

cc: Kitty Marx, Director, Tribal Affairs Group, CMS
Serena Chu, Program Analyst, U.S. Dept. of Veterans Affairs

November [10], 2010

Subject: TTAG Comments on CMS-2325-P: Proposed Rule on Review and Approval Process for Section 1115 Demonstrations ("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 implementing provisions of section 10201(i) of the Patient Protection and Affordable Care Act of 2010 ("ACA") pertaining to experimental, pilot, and demonstration projects approved under section 1115 of the Social Security Act relating to Medicaid and the Children's Health Insurance Program ("CHIP"). In addition, and specific to American Indians and Alaska Natives ("AI/AN"), under Section 5006 of the American Recovery and Reinvestment Act ("ARRA") Congress required States to create a process to seek advice on a regular, ongoing basis from designees of Indian health programs on *all* changes to the Medicaid and CHIP programs that are "likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations."[1] This Proposed Rule would codify the requirements of Section 5006 of the ARRA regarding consultation with designees of Indian health programs but only as they pertain to section 1115 demonstrations.

The TTAG comments and recommendations on the Proposed Rule are summarized as follows:

- TTAG supports the Proposed Rule.
- TTAG recommends that the Proposed Rule be amended to define the phrase "likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations."
- TTAG recommends that CMS define "Indian Health Program" in the Proposed Rule using the definition for Indian Health Program found in section 4, paragraph 12 of the Indian Health Care Improvement Act ("IHCIA"), as amended.
- TTAG recommends that CMS clarify in the Proposed Rule that the administrative record that will be maintained by CMS pursuant to § 431.416(f) will be publicly accessible, including access to the documents through the CMS Web site.
- TTAG concurs with the inclusion, and stresses the importance of the requirement under the proposed § 431.408(b)(4), whereby States are to document their consultation activities with tribes and "must include issues raised and the potential resolution for such issues."
- TTAG strongly supports the CMS proposal under § 431.416 to publish all comments electronically.
- TTAG and CMS both recognize that this Proposed Rule does not fully codify the requirements in section 5006(e) of the ARRA (which calls for a State to seek advice from Indian health programs and urban Indian organizations concerning Medicaid and CHIP policies before submitting a Medicaid or CHIP State plan amendment, demonstration request or application that would directly affect Indian health programs

[1] This requirement includes the review of proposed Medicaid section 1115 demonstration projects.

and Indian beneficiaries) and that additional regulatory action will be needed to fully codify this provision of the ARRA.

Background

"Section 1115 demonstration projects" are authorized under section 1115 of the Social Security Act.[2] These demonstration projects may result in the "waiving" of various program requirements under Medicaid and the Children's Health Insurance Program (CHIP). Congress and HHS recognize that there is a need to increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects are publicly available and to promote greater transparency in the review and approval of demonstrations.

The ACA (enacted in March, 2010) and the ARRA (enacted in February, 2009) each contain provisions requiring adequate opportunities for interested parties to provide meaningful input into the development of section 1115 demonstration projects by States.

- The provision in the ACA under section 10201(i) was not limited to Tribal governments and organizations but was limited in scope to only applying to State and Federal actions involving section 1115 demonstration projects.

- In contrast, the ARRA section 5006(e) provision establishes a requirement on HHS only as it pertains to American Indians and Alaska Natives but is broader in scope to encompass all Medicaid and CHIP policies and not just section 1115 demonstration projects.[i] In particular, section 5006(e)(2) of the ARRA calls for consultation by States with "designees of such Indian Health Programs and Urban Indian Organizations" prior to submission of any changes in the Medicaid and CHIP programs, including proposed section 1115 demonstration projects, that are likely to have a direct effect on Indians, Indian health programs, or urban Indian organizations.

CMS has already begun to take administrative action on the provision in the ARRA. The provision under the ARRA on consultation with Indian organizations (and now, in part, being codified through this Proposed Rule under 42 CFR part 431) was made effective July 1, 2009 by CMS and was summarized in a letter to State Medicaid directors dated January 22, 2010 (SMDL #10-001). In addition, CMS reported rejecting one State's Medicaid section 1115 demonstration application since this provision was made effective because of the State's failure to comply with the provision. CMS is also in the process of issuing a State Plan Amendment "preprint" whereby States will more readily identify the consultation process to be employed with Indian organizations to satisfy this provision of law.

[2] Section 10201(i) of the ACA amended section 1115 of the Social Security Act. Medicaid section 1115 demonstration projects permit a State to implement policies that may otherwise not be permitted under Medicaid in order to expand access to health services, achieve program savings, or accomplish other agreed upon goals with HHS. States are typically expected to be able to demonstrate the benefits of the approach being sought within a 5-year period of the demonstration.

Indian-Specific Provisions in Proposed Rule

The Proposed Rule at § 431.408 includes a discussion on satisfying the requirements under the ARRA to seek advice from Indian health organizations and urban Indian organizations regarding section 1115 demonstrations. As mentioned above, a broader statutory requirement to engage in consultations with Indian tribes on Medicaid and CHIP was established in section 5006(e) of the ARRA, but this Proposed Rule solely pertains to section 1115 demonstrations.[3]

Federal Review Process

Under the Proposed Rule (§431.416), language is included identifying the steps to be taken by CMS itself with regard to the review process for section 1115 demonstration projects. CMS is proposing the following timeframes and action steps that CMS will follow with regard to the section 1115 demonstration project review process.

- Within 15 days of receipt of a complete application from a State, CMS will notify the State of the start of a 30-day review period.
- CMS will publish notice of the 30-day review period.
- CMS will not render a decision on the demonstration application until at least 45 days after notice of receipt of a complete application from the State.
- CMS will maintain an administrative record that may include, but is not limited to, the demonstration application, public comments sent to CMS, the final special terms and conditions, and the State acceptance letter.

CMS proposes to publish electronically all comments received on section 1115 demonstrations. The agency is also proposing to post a listing of the issues raised through the public notice process. CMS is not proposing to provide written response to public comments. CMS will also maintain an "administrative record" on section 1115 demonstrations, but the Proposed Rule is not clear in indicating that the "administrative record" will be made public and will be accessible via the CMS Web site.

Although the *Federal* review process outlined above for section 1115 demonstration applications provides an opportunity to Tribal governments and Tribal organizations for review and input, no provision is included in the Federal public notice and approval process that is specific to Tribal governments and organizations.[4]

CMS proposes to solicit contact information for an electronic mailing list for the distribution of information to individuals and organizations interested in Medicaid demonstration projects.

Analysis of Proposed Rule

Through recently-enacted laws, Congress required States and the Federal government to establish a more open process for the review and input on Medicaid section 1115 demonstration projects. In addition, and specific to American Indians and Alaska Natives, Congress required States to create a process to seek advice on a regular, ongoing basis from designees of Indian health programs on *all* policy changes to the Medicaid and CHIP programs that are "likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations."[5] The opportunity to offer advice is to be made available by the State prior to submission of any

[3] This section of the ARRA also established in Federal law the CMS Tribal Technical Advisory Group.
[4] Tribes and tribal organizations are not specifically referenced in the CMS Proposed Rule under the Federal review process. There is a general provision allowing for review and comment.
[5] This includes the review of proposed Medicaid section 1115 demonstration projects.

proposed changes involving Medicaid or CHIP to the Federal government. [6,7] This Proposed Rule is limited in scope to changes involving Medicaid/CHIP section 1115 demonstration projects.

CMS has already begun to enforce the Indian-specific solicitation of advice requirements established under the ARRA. This Proposed Rule would codify those ARRA-related requirements pertaining to section 1115 demonstrations as well as codify the section 1115 demonstration-related requirements placed on States and the Federal government in the ACA.

The Proposed Rule calls for Tribal input to be sought prior to State governments or the Federal government instituting policies that impact American Indians and Alaska Natives. In addition, the Proposed Rule recognizes the need to consult with tribes directly and not solely the operators of Indian health programs. The Proposed Rule (at § 431.408(b)) clarifies the statutory language in this regard as it requires "a process to consult with the *Indian tribes*, Indian Health Programs, and Urban Indian Organizations in the State." (emphasis added)[8] The addition of the term "Indian tribes" helps facilitate the government-to-government relationship between tribes and the Federal government.

Section 5006(e) of the ARRA is applicable when the change to the Medicaid or CHIP program is "likely to have a *direct effect* on Indians, Indian Health Programs, or Urban Indian Organizations" (emphasis added). The term "direct effect" is not defined in the Proposed Rule. As discussed below, a uniform definition of the term will facilitate an appropriate and consistent application of the provision by States.

Given that this Proposed Rules applies only to actions on section 1115 demonstration projects, additional regulatory action will be needed to fully codify section 5006(e) of the ARRA which calls for a State to seek input from designees of Indian health programs for all Medicaid and CHIP policy changes. In addition, there is a need to ensure the HHS Tribal consultation policies apply to all programs and agencies within HHS, not just Medicaid and CHIP.

<u>TTAG Comments on Proposed Rule</u>

TTAG supports the Proposed Rule. TTAG recommends, though, that CMS clarify in the Proposed Rule that the administrative record that will be maintained by CMS pursuant to § 431.416(f) will be publicly accessible, including access to the documents through the CMS Web site.

We commend CMS for already taking administrative action on the ARRA section 5006(e) provision regarding consultation with Indian organizations (which is now being codified through this Proposed Rule under 42 CFR part 431). The policy was made effective by CMS July 1, 2009 and was summarized in a letter to State Medicaid directors dated January 22, 2010 (SMDL #10-001). In addition, TTAG would like to acknowledge the process CMS undertook to seek input on issuing a State Plan Amendment "preprint" whereby States will more readily

[6] Indian health programs include those operated by the Indian Health Service, tribes or tribal organizations under the Indian Self-Determination and Education Assistance Act (ISDEAA), or Urban Indian Organizations under the Indian Health Care Improvement Act (IHCIA).
[7] Section 2107(e)(I) of the Social Security Act was also amended to apply these requirements to the Children's Health Insurance Program (CHIP).
[8] In contrast, section 5006(e) of the ARRA was less explicit in that the statutory language requires States to seek advice "from designees of such Indian Health Programs and Urban Indian Organizations."

establish the consultation process to be employed with Indian organizations to satisfy this provision of law.

TTAG concurs with the inclusion, and stresses the importance of the requirement under the proposed § 431.408(b)(4), whereby States are to document their consultation activities with tribes and "must include issues raised and the potential resolution for such issues." In addition, TTAG strongly supports the CMS proposal under § 431.416 to publish all comments electronically.

As indicated below, TTAG recommends that the Proposed Rule be clarified and amended to define the phrase "likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations."

Section 5006(e) is applicable when the change to the Medicaid program is "likely to have a *direct effect* on Indians, Indian Health Programs, or Urban Indian Organizations" (emphasis added). A variant of this phrase ("direct impact") is found in the Proposed Rule. We have two recommendations with regard to the use of this phrase in the Proposed Rule. First, to be consistent with the statute, we recommend that Section 431.408, as proposed, be amended by striking "direct impact" and replacing it with "direct effect".

Secondly, we believe that the phrase "direct effect" (or "direct impact" if the suggestion above is not accepted) be defined. We believe that any Medicaid or CHIP program change that will have an effect on who is eligible for a service, who the provider of such services may be, the conditions applicable to such service, the geographic area in which services may be available, or the reimbursement for services has a "direct effect" on current or potential recipients, including Indians. In fact, due to often poorer-than-average health status among AI/AN populations and higher concentrations of poverty than the general populations, AI/AN may have a greater-than-average representation in a State's Medicaid and CHIP programs than in the State's general population. We recommend that Section 431.408(b)(1) of the Proposed Rule be amended by adding to the end of the paragraph a definition of "direct effect" as follows:

> For purposes of this subsection, "direct effect" means any change that will affect who may be eligible for services, the geographic area in which services under the demonstration will be available, the services that may be provided, who the provider of the services may be, the reimbursement available to providers for services under the demonstration, or any other change than affects access, delivery, or quality of services.

The term "Indian Health Program" is contained in section 5006(e) of the ARRA and is used in this Proposed Rule. The term, though, is not defined in the Proposed Rule nor do we believe it is defined anywhere except in the Indian Health Care Improvement Act, as amended. To the extent a definition is not provided elsewhere, TTAG recommends that CMS define "Indian Health Program" in the Proposed Rule using the definition for Indian Health Program found in section 4, paragraph 12 of the IHCIA, as amended. [9] TTAG recommends that CMS add to Section 431.404, as proposed, a definition of the phrase "Indian Health Program" as follows:

[9] Section 4 (12) of the IHCIA, as amended, reads: "The term 'Indian health program' means (A) any health program administered directly by the [Indian Health] Service; (B) any tribal health program; and (C) any Indian tribe or tribal organization to which the Secretary provides funding pursuant to section 23 of the Act of June 25, 1910 (25 U.S.C. 47) (commonly known as the 'Buy Indian Act')."

> "Indian Health Program" has the meaning given that phrase in Section 4(12) of the Indian Health Care Improvement Act, Public Law 94-437, as amended, (25 U.S.C. 1603(12))

In addition, TTAG recommends that the term "program" be substituted for the term "provider" in §431.408(b)(1) of the Proposed Rule to be consistent with the statutory language and other portions of the Proposed Rule.

TTAG and CMS concur in that, given this Proposed Rules only applies to actions on section 1115 demonstration projects, additional regulatory action will be needed to fully codify section 5006(e) of the ARRA which calls for a State to seek input from designees of Indian health programs for all Medicaid and CHIP policy changes.

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[i] Section 5006 of ARRA. PROTECTIONS FOR INDIANS UNDER MEDICAID AND CHIP.
(e) CONSULTATION ON MEDICAID, CHIP, AND OTHER HEALTH CARE PROGRAMS FUNDED UNDER THE SOCIAL SECURITY ACT INVOLVING INDIAN HEALTH PROGRAMS AND URBAN INDIAN ORGANIZATIONS.—
(1) CONSULTATION WITH TRIBAL TECHNICAL ADVISORY GROUP (TTAG).—The Secretary of Health and Human Services shall maintain within the Centers for Medicaid & Medicare Services (CMS) a Tribal Technical Advisory Group (TTAG), which was first established in accordance with requirements of the charter dated September 30, 2003, and the Secretary of Health and Human Services shall include in such Group a representative of a national urban Indian health organization and a representative of the Indian Health Service. The inclusion of a representative of a national urban Indian health organization in such Group shall not affect the non-application of the Federal Advisory Committee Act (5 U.S.C. App.) to such Group.
(2) SOLICITATION OF ADVICE UNDER MEDICAID AND CHIP.—
(A) MEDICAID STATE PLAN AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 501(d)(1) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public
Law 111–3), (42 U.S.C. 1396a(a)) is amended— (i) in paragraph (71), by striking ''and'' at the end; (ii) in paragraph (72), by striking the period at the end and inserting ''; and''; and (iii) by inserting after paragraph (72), the following new paragraph: ''(73) in the case of any State in which 1 or more Indian Health Programs or Urban Indian Organizations furnishes health care services, provide for a process under which the State seeks advice on a regular, ongoing basis from designees of such Indian Health Programs and Urban Indian Organizations on matters relating to the application of this title that are likely to have a direct effect on such Indian Health Programs and Urban Indian Organizations and that— ''(A) shall include solicitation of advice prior to submission of any plan amendments, waiver requests, and proposals for demonstration projects likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations; and ''(B) may include appointment of an advisory committee and of a designee of such Indian Health Programs and Urban Indian Organizations to the medical care advisory committee advising the State on its State plan under this title.''.