

IHS TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE

c/o Self-Governance Communication and Education

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Submitted via: www.regulations.gov

May 10, 2016

Mary Smith, Principal Deputy Director
Indian Health Service
The Reyes Building
801 Thompson Avenue, Suite 400
Rockville, MD 20852

RE: Comments on Catastrophic Health Emergency Fund Proposed Rule (RIN 0905-AC97)

Dear Principal Deputy Director Smith,

On behalf of the Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC), I am writing to comment on the Catastrophic Health Emergency Funding (CHEF) proposed rule. This proposed rule would establish definitions governing CHEF; a requirement that a Service Unit shall not qualify for reimbursement for the cost of treatment until the cost of the episode of care has reached a certain threshold; a procedure for reimbursement for certain services exceeding a threshold cost; a procedure for payment for certain cases; and, a procedure to ensure payment will not occur from CHEF if other sources of payment (Federal, State, local, or private) are available.

The TSGAC has several major concerns about the CHEF proposed rule. First, the language proposed in section 136.501 and the alternate resources provision in section 136.506, which would include Tribal sources of payment as alternate resources to CHEF, exceed the rulemaking authority of the Secretary of the Department of Health and Human Services (HHS) to adopt regulations governing the CHEF program. Second, the proposed definition of "alternative resources" includes "Tribal sources of coverage", "Tribal programs" and "Tribal self-insured plans". This marks a major departure from longstanding IHS policy, and is not acceptable. Third, the proposed definition of Purchased/Referred Care (PRC) includes the use of the word "referral" and by doing so confuses the distinction between a referral for services and an authorization for payment. It is only pursuant to an authorization for payment under which the CHEF program might provide reimbursement. And fourth, the proposed rule does not establish a procedure for making a determination to award CHEF funds. Rather, the decision to award or not award CHEF funds in a particular case remains entirely at the discretion of the IHS.

Apart from these issues, the TSGAC has concerns that the IHS developed and published the CHEF proposed rule without first consulting with Tribes as required by Executive Order (E.O.) 13175 and HHS policies, including those of the IHS. For meaningful Tribal consultation on a proposed rule, consultation must occur prior to publication in the Federal Register, as required by the Administrative Procedure Act. On April 18, 2016, TSGAC sent a letter to the IHS reiterating a verbal request made at the TSGAC quarterly meeting in late March 2016 to withdraw the proposed rule, conduct Tribal consultation, and then re-issue the rule, as the agency did not conduct adequate consultation before the release of the proposed rule. Although some portions of the proposed rule were discussed at the Purchased and Referred Care Workgroup, this cannot

substitute for Tribal consultation. We strongly believe that the IHS must suspend further action on the proposed rule until the HHS and the IHS have consulted with Tribes and Tribal organizations.

We offer additional thoughts about these issues in turn below.

Rulemaking Authority

The rulemaking authority for the proposed rule is provided to the HHS Secretary under section 202(d) of the Indian Health Care Improvement Act (IHCIA), 25 U.S.C. § 1621a(d). Section 202(d) requires the Secretary to promulgate regulations consistent with the provisions of section 202(d) to, among other things:

(5) establish a procedure that will ensure that no payment shall be made from CHEF to any provider of treatment to the extent that such provider is eligible to receive payment for the treatment from any other Federal, State, local, or private source of reimbursement for which the patient is eligible.

The proposed definition of “alternate resources” in section 136.501, and the proposed restriction on CHEF payment in Section 136.506, add the word “Tribal” to the list of alternate resources in section 202(d)(5). However, section 202(d)(5) requires the Secretary to establish a procedure to ensure that the IHS makes no CHEF payment when the patient is eligible for a “Federal, State, local, or private source” of payment—the list does not include “Tribal” sources of payment, and thus section 202(d)(5) does not give the Secretary the authority to include Tribal sources of payment in this CHEF regulation.

In a recent case in the U.S. District Court for the District of Columbia, the court struck down a regulation issued by the HHS Secretary because the regulation exceeded similarly limited secretarial rulemaking authority under a different statutory scheme. *Pharm. Research and Mfg. v. Department of Health and Human Services*, 43 F. Supp. 3d 28 (D.D.C. 2014) (finding that the Secretary’s rulemaking authority for the 340B drug discount program was restricted to three distinct matters that did not include adopting a regulation governing 340B discounts for orphan drugs, thus striking down the orphan drug regulation as exceeding the Secretary’s specific rulemaking authority). Here, the Secretary’s specific rulemaking authority to issue regulations regarding alternate resources to CHEF does not include Tribal sources of payment. There is no language in section 202(d)(5) that gives the Secretary the authority to add any other payment sources to this statutory listing of alternate sources to CHEF. As the court noted in the *Pharma* case, other general rulemaking authority cannot be relied on when the regulation concerns a specific program for which Congress provided specific authority to issue regulations. Thus, adding the word “Tribal” as well as the phrases “Tribal health care programs” and “Tribal self-insurance” to the list of alternate resources in the proposed sections 136.501, 136.506 and 136.508 exceeds the Secretary’s rulemaking authority in section 202(d)(5) of the IHCIA.

Neither 25 C.F.R. Part 136 nor section 2901 of the Patient Protection and Affordable Care Act (ACA) provide the HHS with any authority to make the CHEF program a payer of last resort to a health program operated by a Tribe or Tribal organization under the Indian Self-Determination and Education Assistance Act (ISDEAA). Tribal health programs cannot be included in the new CHEF regulation as alternate resources to CHEF.

We are equally concerned that the preamble to the CHEF proposed rule would separately categorize Tribal member plans and any Tribal self-insured plans as “private insurance,” and thereby independently render Tribal self-insured plans alternate resources as “private insurance.”

As discussed below, Congress distinguished Tribal self-insured plans from private insurance when it enacted section 206(f) of the IHCA, which bars the IHS from seeking recovery against Tribal self-insured plans. Tribal self-insured plans pay claims directly from the Tribe itself and, as a result, are not alternative or third party resources. Categorizing Tribal self-insured plans as private insurance would impermissibly shift the trust responsibility to provide CHEF services from the IHS to the Tribes themselves.

Major Change in IHS Policy

To date the IHS has never treated Tribal health plans and programs as alternate resources under 42 C.F.R. § 136.61, either for CHEF or for the underlying PRC program. Thus, the CHEF proposed rule contains a major change in longstanding IHS policy. Additionally, section 206(f) of the IHCA, 25 U.S.C. § 1621e(f), precludes the IHS from billing and recovering its expenses for treatment from self-insurance plans funded by a Tribe unless the Tribe authorizes the IHS to do so in writing. This distinguishes Tribal health plans from other third party sources of payment (Federal, State, local, and private) that the IHS can bill and collect from under Section 206. Further, the IHS is not given a special payer of last resort status vis-à-vis Tribal plans and programs in Section 2901 of the ACA, which sets out a statutory alternate resource rule for IHS, Tribal, and urban Indian programs.

Tribes fought hard several years ago to get the Centers for Medicare and Medicaid Services (CMS) to recognize Tribal health plans as payers of last resort vis-a-vis Medicare. Tribes were successful in doing that, and the IHS supported Tribal efforts. The CHEF proposed rule now raises the same issue with respect to CHEF. Must Tribes now fight this same battle with the IHS?

The CHEF proposed rule also is unclear about whether including Tribal sources of payment as alternate resources for CHEF will lead to the IHS adopting the same rule for the underlying PRC program. That issue is beyond the scope of the HHS Secretary’s rulemaking authority for CHEF and would be highly inappropriate for the underlying PRC program. However, the proposed CHEF regulations make the TSGAC concerned about the IHS’ future intentions for Tribal sources of payment and PRC.

Recent Litigation Position of the Indian Health Service

We have now learned that the Government, in court litigation, is arguing that Section 2901(b) of the ACA enacted in 2010 invalidated the IHS longstanding policy exempting Tribal self-insured health plans from the payer of last resort rule. This argument is contained in a Memorandum supporting the Government’s Motion for Summary Judgment filed on March 15, 2016 in the U.S. District Court for the District of Columbia in *Redding Rancheria v. Sylvia Burwell*, Civ. No. 14-2035 (RMC).

It has been six years since enactment of the ACA in 2010. This appears to be a new legal argument invented by IHS lawyers for litigation purposes. The IHS has not formally rescinded its longstanding policy exempting Tribal self-insured plans from the payer of last resort rule; nor has IHS invoked this new interpretation as the reason to add Tribal self-insured plans as alternate resources to CHEF in the Proposed Rule or consulted with tribes concerning this new interpretation. In fact, the Government’s Memorandum filed in the *Redding Rancheria* case argues

that this new interpretation of Section 2901(b) applies both to CHEF and to CHS/PRC programs operated by tribes under the ISDEAA.

This novel interpretation is fundamentally inconsistent with both the plain language and intent of Section 2901(b) of the ACA, 25 U.S.C. 1623(b). It does not by its terms exclude Tribal self-insured health programs from the list of programs covered. Nor was that its intent, which was instead to codify in statute longstanding IHS regulations and policies that ensured that all Tribal health programs, including self-insured plans, were covered by the payor of last resort rule. The IHS's new litigation position is completely at odds with longstanding agency practice and the intent of Tribal advocates who urged the Congress to enact Section 2901(b) of the ACA and it should be withdrawn.

Reference to “Referral” in Definition of Purchased/Referred Care

The IHS proposes to define “Purchased/Referred Care” (PRC) in § 136.501 in part to mean “any health service that is—(1) Delivered based on a referral by, or at the expense of, an Indian health program.” It appears that the proposed regulation is attempting to recognize that a PRC “referral” does not equate to an “authorization” for services, but it ultimately seems to conflate the two terms. We believe the inclusion of the term “referral” in the definition of PRC for purposes of this CHEF regulation confuses the distinction between a referral for services and an authorization for payment.

In addition, it appears that the inclusion of the term referral is unnecessary for purposes of defining the PRC program in this CHEF regulation as the reference to the PRC program is solely for the purpose of identifying the expenditures for which CHEF program funding might be used. It is only under an authorization for payment, not a referral for services, that a PRC program incurs an obligation for payment and makes an expenditure. As such, it is only pursuant to an authorization for payment, and a subsequent payment for services, from a PRC program that the CHEF program might provide reimbursement to the PRC program.

Finally, exercising caution in the definition of “referral” under the PRC program is particularly important given the use of the term “referral” under section 1402(d)(2) of the ACA pertaining to qualifications for cost-sharing protections. To facilitate the effective implementation of the ACA’s cost-sharing protections, it is important that a clear distinction be made between a referral for services and an authorization for payment. Again, the definition of PRC, as proposed in this regulation, could confuse these distinctions and inhibit implementation of the comprehensive cost-sharing protections under section 1402(d)(2).

For these reasons, and for purposes of the operation of the CHEF program, we recommend that the definition of PRC in this proposed rule be modified as follows:

“6. Purchased/Referred Care (PRC)— any health service that is— (a) delivered based on an authorization for payment of an Indian health care program ~~delivered based on a referral by, or at the expense of, an Indian health program~~; and (b) provided by a public or private medical provider or hospital which is not a provider or hospital of the IHS health program.”

Lack of Procedure Governing the Award of CHEF Funds

Sections 202(d)(3) and (4) of the IHCA direct the HHS Secretary to develop regulations that establish a procedure for the reimbursement of costs that exceed the statutory threshold amount

and a procedure for the payment of CHEF in cases where the exigencies of the medical circumstances warrant treatment prior to the authorization of CHEF. But the proposed reimbursement procedure at 136.504 only sets out how to submit a claim and the content that must be provided in a claim. The regulations identify the Area PRC programs as the entities that will review each claim and provide that IHS headquarters will determine whether an alternate resource exists.

The proposed regulations do not, however, provide any criteria or procedures governing how the Area PRC directors are to review CHEF claims or how the IHS headquarters will determine whether an alternate resource exists. Proposed section 136.504(a) provides that Area PRC programs will review claims for “patient eligibility, medical necessity, notification requirements for emergent and non-emergent care, medical priorities, allowable expenditures, and eligibility for alternate resources.” But the regulations provide no procedure for how the Area PRC programs will review such claims and decide which claims to award and which to deny or how to address limitations on the availability of CHEF funds. Rather, such determinations are left entirely to the discretion of the Area PRC programs. Similarly, the determination as to whether an alternate resource exists is left entirely to the discretion of the IHS headquarters. We believe that procedures governing the reimbursement of CHEF funds should include procedures guiding the award making process as well as the submission process.

Tribal Consultation

The preamble to CHEF proposed rule states: “This proposed rule serves as Tribal consultation with affected Tribes by giving interested Tribes the opportunity to comment on the regulation before it is finalized.” Issuing a proposed rule is not Tribal consultation. Tribal consultation requires more than just the notice and comment procedures that the Administrative Procedure Act provides for the general public in 5 U.S.C. § 553. E.O. 13175 requires Federal agencies to consult with Tribal officials in the development of “Federal policies that have Tribal implications.” The term “policies that have Tribal implications” includes regulations that have substantial direct effect on one or more Indian Tribes.

The preamble acknowledges that E.O. 13175 applies to the CHEF propose rule and notes that E.O. 13175 was complied with by consultation at meetings of the IHS Director’s Workgroup on Improving the Contract Health Services (CHS) program held on October 12-13, 2010, June 1-2, 2011, and January 11-12, 2012. The preamble also notes that the IHS issued two “Dear Tribal Leader” letters on February 9, 2011, and May 6, 2013, “related to the development of these regulations.”

However, if one looks closely at these Dear Tribal Leader letters and how they describe the recommendations of the Workgroup, it is clear that neither the Workgroup nor the Dear Tribal Leader letters afforded Tribal consultation on the CHEF proposed rule. The Dear Tribal Leader letter dated February 9, 2011, discusses four recommendations made by the Workgroup, none of which concern the proposed rule. They are:

1. Creating a technical subcommittee charged with calculating total current CHS need and estimates of future CHS need;
2. Improve and promote current CHS business practices;
3. Evaluate parity of Current CHS formula; and
4. Making the IHS Budget Formulation Workgroup apply the true medical inflation index to distribution of future CHS appropriation increases.

The Dear Tribal Leader Letter dated May 6, 2013, was another update regarding accomplishments and recommendations of the Workgroup for Improving the CHS program. The letter noted the following accomplishments:

1. Implementation of an optional 2% of new CHS funds for prevention services;
2. Improved methodology for estimating data on CHS deferrals and denials;
3. Use of the Federal Disparity Index methodology to estimate unmet CHS need;
4. Development of a standard CHS curriculum to orient Federal and Tribal staff;
5. Establishment of a CHS Listserve to serve as a forum to network with Federal/Tribal CHS experts;
6. Designation of a CHS standing agenda item for National and Area Budget Formulation sessions;
7. Revision of the CHS Chapter of the Indian Health Manual; and
8. Partnering with IHS nursing to implement CHS Case Management guidelines.

The letter noted the following additional recommendations of the Workgroup to improve the CHS program:

1. Using the current CHS distribution formula only to distribute new CHS funding and not to redistribute base CHS funding;
2. Expansion of Medicare-Like Rates for non-Hospital services;
3. Creation of a new CHS Delivery Area for North Dakota, South Dakota, and Arizona;
4. Convening a Subcommittee of the Workgroup as soon-as-possible for a meeting in June 2013 to address short and long term improvements for the CHEF program including, (1) a definitive listing of CHEF covered services, (2) options for CHS programs to be reimbursed at 100 percent once a case is completed or receives 50 percent advance payment, (3) determine if CHEF should provide a higher percentage in advance, (4) identify approaches to better distinguish catastrophic case currently not submitted for reimbursement due to depletion of CHEF funds, (5) identify ways that the IHS can assist smaller clinics and CHS programs to increase access to CHEF, and (6) provide estimates for lowering the CHEF threshold to \$19,000;
5. Continue to include CHS as a standing agenda item for annual Area and National Budget Formulation sessions;
6. Establish consistent training on CHEF guidelines during the annual National IHS Director's Tribal Consultation Session and make this training accessible via the IHS training portal; and Use of CHS funding for prevention services.

None of these accomplishments or recommendations can be considered consultation on the CHEF proposed rule. The Workgroup recommendations specific to CHEF listed in the May 6, 2013, Dear Tribal Leader letter say nothing about development of regulations for CHEF; and there is no mention of changing IHS policy to make Tribal health plans or programs alternate resources to CHEF.


E.O. 13175 requires a Federal agency, prior to the formal promulgation of a regulation that has Tribal implications, to consult with Tribal officials "early in the process of developing the proposed regulation." The above examination of the Workgroup recommendations and the Dear Tribal Leader letters indicate that the Workgroup was not formed or intended as a mechanism for Tribal consultation on the CHEF proposed rule. The preamble notes that "IHS intends to consult as fully as possible with Tribes prior to publication of a final rule." This does not meet the requirements of E.O. 13175 or the HHS or IHS Tribal consultation policies.

Therefore, HHS must therefore suspend any further action on the proposed rule until it and the IHS have carried out meaningful consultation with Tribes and Tribal organizations as required by E.O. 13175 and departmental policies.

Conclusion

Thank you for the opportunity to provide these comments on the CHEF proposed rule. We appreciate the continuing efforts of IHS to meet the extraordinary medical costs associated with the treatment of victims of disasters or catastrophic illnesses who qualify to receive service at agency facilities. TSGAC remains willing to assist IHS in this endeavor in any way possible. If you have any questions or wish to discuss these comments further, please contact me at (860) 862-6192 or via email at lmalerba@moheganmail.com.

Sincerely,



Chief Lynn Malerba, Mohegan Tribe of Connecticut
Chairwoman, IHS TSGAC

cc: P. Benjamin Smith, Director, Office of Tribal Self-Governance
TSGAC Members and Technical Workgroup