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February 17, 2016

Ms. Betty Gould, Regulations Officer
INDIAN HEALTH SERVICE
Office of Management Services
Division of Regulatory Affairs
5600 Fishers Lane
Mailstop 09E70
Rockville, MD 20857
Submitted at <http://www.regulations.gov>

***Re: RIN 0905AC97: Comments on Proposed Rule: Catastrophic Health
Emergency Fund: Published on January 26, 2016 (81 Federal Register 4239, et seq.)***

Dear Ms. Gould:

The Suquamish Tribe appreciates the opportunity to submit these comments on the Proposed Rule governing the Catastrophic Health Emergency Fund (CHEF), RIN 0905AC97, published at 81 Federal Register 4239 (Jan. 26, 2016).

The Suquamish Tribe, of the Port Madison Reservation in Washington State, administers a Purchased/Referred Care (PRC) program under Title V of the Indian Self-Determination and Education Assistance Act. Under the Tribe's PRC program, the Tribe provides its members with health benefits cards so that they can obtain health care from various providers and specialists within the community, and the Tribe thereafter pays for the services after the members' alternate resources have been exhausted. The Tribe follows the Indian Health Service (IHS) eligibility requirements, including the payer of last resort rules, and is eligible for CHEF reimbursements for its patients with high-cost care incidents. The Tribe also has a self-funded health benefits plan for its employees, some of whom are also enrolled in the Tribe's PRC program.

The Tribe has four major concerns about this 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, exceeds the Secretary's rulemaking authority to adopt regulations governing the CHEF program. Second, the Proposed Rule, by adding tribal sources of payment to the list of alternate resources, is a major departure from longstanding IHS policy. Third, the Proposed Rule does not establish

any procedure for making a determination to award CHEF funds. Rather, the decision to award or not to award CHEF funds in a particular case is left entirely to the IHS' discretion. Finally, the Tribe is concerned that IHS developed and published this rule without first consulting with Tribes as required by Executive Order 13175 and Departmental policies, including those of the IHS. In order to be meaningful, tribal consultation must occur prior to publication in the federal register as required by the Administrative Procedure Act. We strongly believe that further action on this Proposed Rule must be suspended until the Department and the IHS have consulted with tribes and tribal organizations on this proposal.

Rulemaking Authority

The rulemaking authority for this Proposed Rule is provided to the Secretary of the Department of Health and Human Services under Section 202(d) of the Indian Health Care Improvement Act, 25 U.S.C. Section 1621a(d). Subsection 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, subsection 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 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 the 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” 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 IHCA.

Neither 25 C.F.R. Part 136 nor Section 2901 of the Patient Protection and Affordable Care Act provide the Department 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 ISDEAA. Tribal health programs may not be included in the new CHEF regulation as alternate resources to CHEF.

We are equally concerned that the preamble to the Proposed Rule would separately categorize 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 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 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. Section 136.61, either for CHEF or for the underlying Purchased/Referred Care (PRC) program (formerly Contract Health Services (CHS)). Thus, this Proposed Rule contains a major change in longstanding IHS policy. Additionally, Subsection 206(f) of the IHCA, 25 U.S.C. Section 1621e(f), precludes the IHS from billing and recovering its expenses for treatment from self-insurance plans funded by tribes 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 may 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 Patient Protection and Affordable Care Act, which sets out a statutory alternate resource rule for IHS, tribal, and urban programs.

Tribes fought hard several years ago to get the Centers for Medicare and Medicaid Services 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. This Proposed Rule now raises the same issue with respect to CHEF. Must tribes now fight this same battle with the IHS?

Finally, the Proposed Rule is unclear about whether including tribal sources of payment as alternate resources for CHEF will lead to IHS adopting the same rule for the underlying PRC program. That issue is beyond the scope of the Secretary’s rulemaking authority for CHEF, and would be highly inappropriate for the underlying PRC program.

However, the proposed CHEF regulations make the Tribe concerned about the IHS's future intentions for tribal sources of payment and PRC.

Lack of Procedure Governing the Award of CHEF Funds

Sections 202(d)(3) and (4) of the IHCA direct the 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 the 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. Section 553. Executive Order 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 this Proposed 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 programs held on October 12-13, 2010, June 1-2, 2011, and January 11-12, 2012. The Preamble also notes that 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 this Proposed Rule. The Dear Tribal Leader letter dated February 9, 2011, discusses four recommendations made by the Workgroup, none of which concern this 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;¹

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
7. Use of CHS funding for prevention services.

None of these accomplishments or recommendations can be considered consultation on this 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 this 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 the Executive Order, nor the Department's or IHS's tribal consultation policies. The Department must therefore suspend any further action on this Proposed Rule until the Department and the IHS have carried out meaningful consultation with tribes and tribal organizations as required by Executive Order 13175 and Departmental policies.

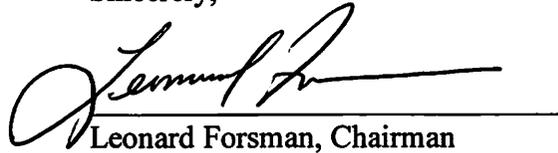
¹ Subsection 202(d)(2) of the IHCA provides that for year 2000 the threshold level is \$19,000, and for any subsequent year, not less than the threshold cost of the previous year increased by the percentage increase in the medical care expenditure category of the consumer price index for all urban consumers (United States city average) for the 12-month period ending with December of the previous year. Setting the threshold at \$19,000 for 2016 (or for whenever the regulation will become final) as proposed in Section 136.503 of the Proposed Rule is inconsistent with Section 202(d)(2).

Conclusion

For the above reasons, the Tribe requests that the word “tribal” be deleted from the definition of alternate resources in Section 136.501 and from Section 136.506, providing an alternate resource rule. Further, we ask that the Department and the IHS undertake meaningful tribal consultation—meeting the requirements of E.O. 13175 and Departmental policies—before taking any further action on this Proposed Rule.

Should you have any questions or if we can provide any additional information, please contact Leslie Wosnig via email at lwosnig@suquamish.nsn.us or by phone at 360-394-8466.

Sincerely,

A handwritten signature in black ink, appearing to read "Leonard Forsman", written over a horizontal line.

Leonard Forsman, Chairman
The Suquamish Tribe

cc: Geoff Strommer, Esq.