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August 12, 2016

Submitted via: <http://www.regulations.gov>

Dr. Audrey Clarke
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: RIN 0991-AC06: USET SPF Comments on Proposed Rule; Health and Human Services Grant Regulation: Published on July 13, 2016 (81 Federal Register 45270, et seq.)

Dear Dr. Clarke,

The United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) is pleased to provide the Department of Health and Human Services (HHS) with the following comments in response to the Notice of Proposed Rulemaking, RIN 0991-AC06, published at 81 Federal Register 45270 (July 13, 2016). As USET SPF notes below, Tribal Nations and organizations around the country will be substantially affected by this Proposed Rulemaking because it is contrary to the Indian Self-Determination and Education Assistance Act (ISDEAA). We are disappointed with the lack of meaningful Tribal consultation on the Proposed Rule, especially with the clear impact the rule would have on Tribal Nations. USET SPF requests that HHS suspend rulemaking until meaningful Tribal consultation has occurred.

USET SPF is a non-profit, intertribal organization representing 26 federally recognized Tribal Nations from Texas across to Florida and up to Maine¹. Both individually, as well as collectively through USET SPF, our member Tribal Nations work to improve health care services for American Indians. Our member Tribal Nations operate in the Nashville Area of the Indian Health Service (IHS), which contains 36 IHS and Tribal health care facilities. Our citizens receive health care services both directly at IHS facilities, as well as in Tribally-operated facilities operated under contracts with IHS pursuant to the ISDEAA, P.L. 93-638.

Need for Tribal Consultation

In addition to the legal ramifications outlined below, publishing this notice of Proposed Rulemaking, which will have a direct impact on Tribal Nations and organizations, without adequate consultation violates the President's Executive Order 13175 and HHS' own Tribal consultation policy. The Executive Order requires agencies to consult with Tribal officials in the development of federal

¹ USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

policies that have Tribal implications, including proposed regulations. Consultation must occur prior to publishing a Proposed Rule. In this case, HHS wrongly equates Tribal consultation with the opportunity to comment afforded to the general public by the Administrative Procedure Act at 5 U.S.C. § 553.

The Proposed Rulemaking

This Proposed Rulemaking would amend the HHS grant regulation at 45 C.F.R. Part 75 to make Subparts E and F governing audits and cost principles applicable to ISDEAA contracts, compacts, and funding agreements, including § 75.505 sanctions enforceable through remedies in § 75.371. The Proposed Rulemaking would also amend 45 C.F.R. Part 75 to regulate what cost disallowances are subject to the one year restriction on remedies in § 450j-1(f) of the ISDEAA.

The preamble to the Proposed Rulemaking notes that the Office of Management and Budget (OMB) adopted Uniform Administrative Requirements, Cost Principles, and Audit Requirements to supersede and streamline the OMB Circulars. These OMB Uniform Requirements were published as “final guidance” to federal agencies on December 26, 2013 (78 Federal Register 78590). The OMB “final guidance or Super Circular” is not a regulation, but rather guidance to federal agencies that supersedes OMB Circulars. The HHS Secretary adopted the OMB Uniform Requirements, with specific HHS modifications, as a regulation governing HHS grants and cooperative agreements codified at 45 C.F.R. Part 75.

HHS has made no attempt to engage with the OMB to understand how the Super Circular was developed. In the course of OMB’s preparation of the Super Circular, OMB engaged with Tribal Nations and organizations to determine how to prioritize their final guidance with existing federal Indian law, most notably the ISDEAA. Through that process, OMB developed language in 2 CFR § 200.101(b)(3) to make clear that other than the Single Audit Act, where a provision in the Super Circular conflicts with the ISDEAA, that the ISDEAA provision shall prevail and govern. Instead of applying this clear, over-arching principle to the Proposed Rule, HHS does the opposite and creates a new regulatory framework that, in part, conflicts with the ISDEAA.

The purpose and organization of Part 75 is described in 45 C.F.R. § 75.100. Subparts B through D set forth the Uniform Administrative Requirements for grant and cooperative agreement awards, including the requirements for HHS awarding agency management of federal grant programs before the federal award has been made, and the requirements HHS awarding agencies may impose on non-federal entities in the federal award. Subpart E establishes principles for determining the allowable costs incurred by non-federal entities under federal grant and cooperative agreement awards. Subpart F sets forth standards for single agency audits of non-federal entities expending federal awards under federal grant and cooperative agreement awards.

The Proposed Rulemaking would make Subparts E and F (including enforcement of remedies) applicable to ISDEAA contracts, compacts, and funding agreements, and would also regulate implementation of § 450j-1(f) of the ISDEAA.

The ISDEAA Precludes Application of Grant and Cooperative Agreement Rules to ISDEAA Contracts, Compacts, and Funding Agreements

Section 450e-1 of the ISDEAA provides that the requirements of the Federal Grant and Cooperative Agreement Act (FGCA), 31 U.S.C. § 6301, et seq. shall not apply to self-determination contracts, compacts and funding agreements. The purpose of the FGCA, described in § 6301, is to prescribe criteria for federal agencies to use in selecting the appropriate legal instrument (procurement contracts, grants, or cooperative

agreements) in making federal awards; and also to promote competition in making awards through these legal instruments.

Self-determination contracts and compacts are not procurement contracts.² Nor are they grants and cooperative agreements.³ Rather, § 450(l) of the ISDEAA contains a required model self-determination contract that must be used by the Secretary and Tribal Nations and organizations. Entering into a self-determination contract/compact is mandatory under § 450f(a) of the ISDEAA, unless the Secretary declines under specific declination criteria. Section 450j(a) of the ISDEAA precludes application of contracting, grant, or cooperative agreement laws and regulations to self-determination contracts, notwithstanding any other provision of law.

The ISDEAA Restricts the Secretary's Rulemaking Authority to Regulate ISDEAA Contracts, Compacts, and Funding Agreements

Section 450k(a)(1) of the ISDEAA restricts the Secretary's rulemaking authority to regulate self-determination contracts/compacts by providing that the Secretary may not promulgate any regulation relating to self-determination contracts/compacts, or the approval, award, or declination of such, except as authorized in § 450k(a) or other provision of the ISDEAA. Further, § 450k(a)(2) requires that regulations governing self-determination contracts/compacts must be promulgated in conformance with negotiated rulemaking procedures and as a single set of regulations codified in Title 25 of the Code of Federal Regulations.

The Secretaries of HHS and the Department of the Interior adopted joint regulations governing self-determination contracts/compacts that are codified at 25 C.F.R. Part 900. Further, section 450k(c) of the ISDEAA authorizes the Secretaries of HHS and Interior, with the participation of Tribal Nations and organizations, to revise or amend these joint regulations, provided that prior to issuance, the Secretaries: (1) present the proposed revisions to certain congressional committees; (2) consult with national and regional Indian organizations; and (3) publish the proposed revisions in the Federal Register 60 days prior to their effective date.

Section 458aaa-16 of the ISDEAA governs the rulemaking authority of the HHS Secretary to regulate self-governance compacts and funding agreements entered into pursuant to Title V of the ISDEAA. Section 458aaa-16 sets strict timelines for promulgation of regulations and requires that the Secretary utilize negotiated rulemaking procedures. The Secretary promulgated regulations codified 42 C.F.R. Part 137. The Secretary's authority to further regulate Title V compacts and funding agreements has expired.

While the joint regulations adopted by the Secretaries of HHS and Interior at 25 C.F.R. Part 900 may be revised in accordance with § 450k(c), this Proposed Rulemaking does not meet the requirements of that section. The restrictions in the ISDEAA on the Secretary's rulemaking authority preclude the use of the HHS grant rules to regulate ISDEAA contracts, compacts, and funding agreements.

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 restricted Secretarial rulemaking

² See, definition in § 450b(j) of the ISDEAA.

³ Under § 450e-1 a grant agreement or cooperative agreement may be utilized in lieu of a self-determination contract when mutually agreed to by the Secretary and the tribe or tribal organization involved. However, that option is rarely if ever utilized.

authority under a different statutory scheme. *Pharm. Research v. Department of Health and Human Services*, 43 F. Supp. 3d 38 (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). As the court noted, other general rulemaking authority cannot be relied on when the regulation concerns a specific program for which Congress provided specific authority to issue regulations.

OMB Issuance of New Uniform Guidance Superseding the OMB Circulars Does Not Authorize the Secretary to Regulate ISDEAA Contracts, Compacts, and Funding Agreements by Amending the HHS Grant Rules

The preamble to the Proposed Rulemaking asserts that this proposed amendment to the grant rules is required by the ISDEAA and HHS is implementing regulations because the ISDEAA itself specifies that ISDEAA contracts and compacts are subject to the Single Audit Act and OMB Circulars. USET SPF disagrees with the HHS interpretation of ISDEAA in regards to this issue. We agree that section 450c(f) of the ISDEAA does make the single agency audit reports required by the Single Audit Amendments of 1996, 31 U.S.C. § 7501, et seq., applicable to self-determination contracts. Additionally, the joint regulation at § 900.40(b) provides for evaluation of Tribal management systems by an independent auditor through the single agency audit report that is required by § 450c(f) of the ISDEAA and OMB Circular A-128. However, this **does not** require amendment of the grant rules to make subsequent OMB guidance applicable to ISDEAA agreements.

With respect to cost principles, § 900.45(e) of the joint regulation provides that the Tribal financial system shall be sufficient to determine the reasonableness, allowability, and allocability of self-determination contract costs based upon the terms of the self-determination contract and applicable OMB Circulars as amended by the ISDEAA and these regulations. The applicable OMB Circulars may be Circular A-87 cost principles for State, Local, or Tribal Governments, A-122 cost principles for Non-Profit Organizations, or A-21 cost principles for Educational Institutions, as agreed to by the Secretary and the Tribal Nation(s) or Tribal organizations. However, as with audits, this does not require amendment of the HHS grant rules to make subsequent OMB guidance applicable to ISDEAA agreements.

Rather, § 900.37 provides that: "The only provisions of the OMB Circulars and the only provisions of the "common rule" that apply to self-determination contracts are: (1) the provisions adopted in these regulations, (2) those expressly required or codified in the Act, and (3) those negotiated and agreed to in a self-determination contract." The new OMB guidance is not adopted in the joint regulation; nor is the new OMB guidance expressly required or codified in the ISDEAA. Section 900.37 does leave the door open for Tribal Nations and Tribal organizations and the Secretary to negotiate and agree to substitute the new OMB guidance for the Circulars adopted in the joint regulation. However, imposing the new OMB guidance by making the grant rules apply to ISDEAA contracts and funding agreements violates § 900.37.

Under 25 CFR § 1000.395, the ISDEAA regulations make clear that OMB circulars do not apply where there are exceptions for Tribal Nations and Tribal organizations (such as 2 C.F.R. § 200.101(b)(3) excepting Tribal Nations from the Super Circular if the ISDEAA is in conflict), as well as the exceptions included in 25 U.S.C. § 450j-1k, which include a long list of allowable expenditures that Tribal Nations and Tribal organizations can make without any additional Secretary approval. Insofar as the Proposed Rule creates new requirements, including but not limited to procurement restrictions, oversight and/or monitoring that HHS would seek to impose in the areas listed in 25 U.S.C. § 450j-1k, the Proposed Rule is invalid.

The same is true for Title V of the ISDEAA, which contains its own provision governing audits and cost principles in § 458aaa-5(c). That section does require single agency audit reports pursuant to 31 U.S.C. § 7501, et seq. Section 458aaa-5(c) also requires a Tribal Nation to apply cost principles under the applicable OMB circular, except as modified by § 450j-1 of the ISDEAA, other provisions of law, or by any exemptions granted by OMB. However, § 458aaa-5(c) provides that: “No other audit or accounting standards shall be required by the Secretary.” The Title V regulations at §§ 137.165 – 173 provide for single agency audit reports and application of OMB Circulars consistent with § 458aaa-5(c). Section 137.168, however, also provides that: “No other audit or accounting standards shall be required by the Secretary.”

Therefore, USET SPF believes that HHS is incorrectly interpreting the ISDEAA and its implementing regulations by asserting they require this Proposed Rulemaking.

We also take this opportunity to point out that the Proposed Rulemaking would allow the Secretary to apply the remedies for non-compliance in § 75.371 to ISDEAA contracts, compacts, and funding agreements. A close look at these remedies illustrates that they are inconsistent with ISDEAA contracting. Section 75.371 provides:

If a non-federal entity fails to comply with federal statutes, regulations, or the terms and conditions of a federal award, the HHS awarding agency or pass-through entity may impose additional conditions, as described in § 75.207. If the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:

- (a) Temporarily withhold cash payments pending correction of the deficiency by the non-federal entity or more severe enforcement action by the HHS awarding agency or pass-through entity.
- (b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action of compliance.
- (c) Wholly or partly suspend (suspension of award activities) or terminate the federal award.
- (d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376.
- (e) Withhold further federal awards for the project or program.
- (f) Take other remedies that may be legally available.

Imposing these remedies and sanctions on Tribal Nations and organizations carrying out ISDEAA agreements would clearly violate the ISDEAA. For example, § 450j-1(l) of the ISDEAA precludes these types of remedies. The Secretary may only suspend, withhold, or delay payment of funds for a period of 30 days beginning on the date the Secretary makes a determination that a Tribal Nation or organization failed to substantially carry out a self-determination contract without cause. The Secretary must provide the Tribal Nation or organization with reasonable advance notice, technical assistance, and a hearing on the record not later than 10 days after the date of such a determination. Section 1(e)(2) of the model contract and § 450m-1(b) of the ISDEAA preclude unilateral modifications of self-determination contracts to impose new conditions and under § 450m, self-determination contracts may only be rescinded and the contracted programs reassumed, based upon (1) the violation of the rights or endangerment of the health, safety, or welfare of any persons, or (2) gross negligence or mismanagement of contract funds.

Conclusion and Recommendation

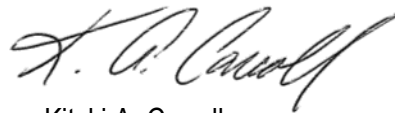
USET SPF believes that the Proposed Rulemaking violates the ISDEAA and its implementing regulations, and we question the rulemaking authority of the Secretary to adopt the Proposed Rule. Tribal Nations and organizations must be consulted regarding this regulatory initiative prior to it being made a Final Rule. And for the reasons outlined above, the notice of Proposed Rulemaking, to the extent that it proposes to amend the HHS grant rules to impose requirements on ISDEAA contracts, compacts, and funding agreements, must be withdrawn.

USET SPF looks forward to the opportunity for meaningful Tribal consultation on this critical policy matter. Should you have any questions or require additional information, please do not hesitate to contact Ms. Liz Malerba, USET SPF Director of Policy and Legislative Affairs, at (202) 624-3550 or by e-mail at lmalerba@usetinc.org.

Sincerely,



Brian Patterson
President



Kitcki A. Carroll
Executive Director

CC: USET Executive Officers Committee
Wanda James, USET Deputy Director
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Hilary Andrews, USET Health Policy Analyst

“Because there is strength in Unity”