August 12, 2016

Via Electronic submission to www.regulations.gov

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

I. Introduction.

The Department of Health and Human Services (“HHS”) recently proposed regulations that would extend the audit requirements and cost principles currently applicable to HHS grants to self-determination contracts and self-governance compacts entered into by Tribes and tribal organizations under the Indian Self-Determination and Education Assistance Act (“ISDEAA”). See Notice of Proposed Rulemaking, RIN 0991-AC06, published at 81 Federal Register 45270 (July 13, 2016). Our firm specializes in representing Indian Tribes and we submit these comments on behalf of several Tribes and tribal organizations that administer federal programs under the authority of the ISDEAA. As explained further below, the proposed regulations are contrary to the letter and spirit of the ISDEAA, are onerous to apply, and have been issued contrary to the Department’s tribal consultation policy. Accordingly, we request HHS withdraw these regulations in their entirety. Instead, and after consulting with Tribes, HHS should exempt tribal health programs from all provisions of the 45 C.F.R. Part 75 regulations.
II. ISDEAA Agreements are Unique Government-to-Government Agreements which are Not Governed by Rules Applicable to Grants and Cooperative Agreements.

The Part 75 provisions are not suited to ISDEAA self-determination contracts and self-governance compacts. Part 75 is intended to address routine grants, cooperative agreements and procurement contracts, not unique intergovernmental agreements executed under the ISDEAA. ISDEAA contracts are an expression of the government-to-government relationship that exists between the United States and Indian Tribes and they are also inextricably tied to the government’s trust responsibility—key principles which distinguish such agreements from HHS grants and awards. See e.g., 42 C.F.R. §137.30 (“A self-governance compact is a legally binding and mutually enforceable written agreement that affirms the government-to-government relationship between a Self-Governance Tribe and the United States.”).

Self-determination contracts are not procurement contracts, 25 U.S.C. § 450b(j), nor are they grants and cooperative agreements.1 Instead, self-determination contracts have unique terms and conditions mandated by the ISDEAA. For instance, 25 U.S.C. § 450f(l) of the ISDEAA contains a required model self-determination contract that must be used by the Secretary and Tribes and tribal organizations. Additionally, entering into a self-determination contract is mandatory under § 450f(a) of the ISDEAA, unless the Secretary declines the contract proposal under specific declination criteria set forth in the statute. And, when interpreting the ISDEAA, the Department must do so “liberally in favor of the Indians, with ambiguous provisions interpreted to their benefit.” Montana v. Blackfeet Tribe, 471 U.S. 759, 766 (1985); see also County of Oneida v. Oneida Indian Nation, 470 U.S. 226, 247 (1985) (canon of construction “rooted in the unique trust relationship between the United States and the Indians”).

By contrast, the Part 75 regulation defines the terms “cooperative agreement” and “grant agreement” as being “consistent with [the Federal Grant and Cooperative Agreement Act (FGCA),]” 31 U.S.C. §§ 6302-6305.” 45 C.F.R. § 75.2 (definitions). The purpose of the FGCA is to prescribe criteria federal agencies are to use in selecting the appropriate legal instrument in making federal awards; and also to promote competition in making awards. Part 75 incorporates the FGCA definitions, but notes that “Different definitions may be found in Federal statutes or regulations that apply more specifically to particular programs or activities.” 45 C.F.R. § 75.2 (emphasis added). Section 450e-1 of the ISDEAA provides that the requirements of the FGCA

1 See 25 U.S.C. §§ 450b(j) and 450j(a)(1) (defining “self-determination contract” and “contracts and cooperative agreements” entered into under section 450e of title 25 as non-procurement contracts and agreements); see also 42 C.F.R. § 137.10 (definition of “compact”). Under 25 U.S.C. § 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. That option is never utilized. More importantly, that provision clearly sets out that a self-determination contract is something distinct from a grant or cooperative agreement covered under Part 75.
shall not apply to self-determination contracts. And, § 450j(a) of the ISDEAA expressly precludes application of federal contracting, grant, or cooperative agreement laws and regulations to self-determination contracts, notwithstanding any other provision of law. Thus, the ISDEAA clearly uses different definitions for “contract” and “compact” than those set forth in Part 75, which apply “more specifically” to the programs and activities Indian Tribes carry out under the ISDEAA.

A. The Proposed Rule Violates the ISDEAA and the ISDEAA Regulations

The proposed rule violates the ISDEAA because it would allow the Secretary to apply the remedies for non-compliance in § 75.371 to ISDEAA contracts, compacts, and funding agreements. 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.

(Emphasis added.)

These § 75.371 sanctions clearly contradict the ISDEAA. For instance, 25 U.S.C. § 450j-1(f) bars any action related to disallowance of costs made over one year after the Secretary receives the Tribe’s audit. And, § 450j-1(l) precludes these types of remedies, and provides 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 Tribe or tribal organization failed to substantially carry out a self-determination contract without cause. The Secretary must also provide the Tribe or tribal 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. § 450j-1(l). Further, 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. Thus, the remedies for non-compliance in the HHS grant rules cannot be harmonized with the ISDEAA.

The proposed rule also exceeds the Secretary’s rulemaking authority delegated in the ISDEAA. Section 450k(c) of the ISDEAA authorizes the Secretary, with the participation of Indian Tribes and tribal organizations, to revise or amend ISDEAA Title I regulations (controlling self-determination contracts), provided that prior to issuance, the Secretary: (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. The Department’s proposed rulemaking does not meet these statutory requirements.

Section 458aaa-16 of the ISDEAA governs the Secretary’s rulemaking authority under Title V (governing self-governance compacts), and that section sets strict timelines for promulgation of regulations while also mandating that the Secretary utilize negotiated rulemaking procedures. Further, the Secretary promulgated regulations codified at 42 C.F.R. Part 137—regulations which state that the Secretary may not impose any other audit or accounting standards than that specified in 42 C.F.R. § 137.167. See 42 C.F.R. § 137.168. The Department’s proposed rulemaking violates these provisions of Title V and its implementing regulations.

The courts have recognized that the Secretary’s authority to promulgate regulations is not boundless. See, e.g., 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 in that case, the Secretary’s general rulemaking authority does not supplant regulations concerning a specific program for which Congress provided specific authority to issue regulations. Such is the case here.
B. The Proposed Rulemaking is Not Required by the ISDEAA

The given justification for HHS’s action is inconsistent with the ISDEAA. The preamble to the proposed rule asserts that it is required by the ISDEAA and its implementing regulations because the ISDEAA itself specifies that ISDEAA contracts and compacts are subject to the Single Audit Act and OMB Circulars. This is incorrect. Section 450c(f) of the ISDEAA only requires ISDEAA contractors to submit a single agency audit report each year, consistent with the Single Audit Amendments of 1996, 31 U.S.C. § 7501, et seq. The regulation at 25 C.F.R. § 900.40(b) explains that this audit report is used to evaluate tribal management systems. However, these audit provisions do not require amendment of the HHS grant rules to make subsequent OMB guidance applicable to ISDEAA agreements, and the cost principles applicable to ISDEAA agreements do not require such a change either. For instance, 25 C.F.R. § 900.45(e) provides that each tribal financial system must 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 the ISDEAA regulations. These provisions say nothing about amendment of the HHS grant rules.

To the contrary, the ISDEAA and its implementing regulations already specify the rules that apply to self-determination contracts, including such rules as use of funds for matching or cost participation requirements, allowable uses of funds without approval of the Secretary, suspension, withholding, or delay in payment of funds, use of program income earned, use of savings, rebudgeting and financial management, property management and procurement processes. See, e.g. 25 U.S.C. §§450j-1(j) through (o); and 25 C.F.R. §§ 900.42-900.60. And, 25 U.S.C. § 450j-1(k) includes a long list of allowable expenditures that Tribes and tribal organizations can make without any additional Secretary approval.

The ISDEAA regulations expressly limit the applicable OMB Circulars. 25 C.F.R. § 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 ISDEAA and its regulations include a number of exceptions from the OMB circulars. See e.g., 25 U.S.C. §450j-1(k). For instance, 42 C.F.R. § 137.167(c) makes clear that OMB circulars do not apply where there are exceptions for Tribes and tribal organizations (such as 2 C.F.R. § 200.101(b)(3) excepting Tribes from the Super Circular if the ISDEAA is in conflict).

The new OMB Super Circular is not adopted in the joint regulation, nor is the new OMB guidance expressly required or codified in the ISDEAA. Section 900.37 does allow Tribes and tribal organizations and the Secretary to negotiate and agree to substitute the new OMB guidance for the Circulars adopted in the ISDEAA regulations, but it by no means allows the Secretary to
unilaterally impose the new OMB guidance by making HHS grant rules apply to ISDEAA agreements. And, insofar as the proposed rule creates new requirements, oversight or monitoring in any of the areas listed in § 450j-1(k), including but not limited to procurement restrictions, the proposed rule is invalid because it violates subsection (k)’s prohibitions.

Title V of the ISDEAA contains its own provision governing audits and cost principles. See 25 U.S.C. § 458aaa-5(c). That section also requires single agency audit reports, and requires an Indian Tribe 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 are consistent with this statutory provision.

C. The Super Circular Already Explains How it Applies to ISDEAA Contracts

The OMB Super Circular was drafted to expressly accommodate these ISDEAA provisions. The Super Circular was developed to provide “final guidance” to federal agencies on general grant and contract requirements, but significantly, the Super Circular does:

not broaden the scope of applicability from existing government-wide requirements, affecting Federal awards to non-Federal entities including state and local governments [and] Indian tribes.

78 Fed. Reg. 78590. Instead, it expressly states that:

[S]ince nothing in this guidance can supersede the requirements of Federal statute, flexibilities such as those enshrined in the Indian Self-Determination and Education Assistance Act (ISDEAA) would not be contravened by this policy.


3 In fact, procurement, grant and cooperative agreement regulations of broad applicability were exactly the type of administrative requirements that Tribes were to be relieved of under the ISDEAA. See 25 U.S.C. § 450k(a)(1) (restricting the Secretary’s rulemaking authority by providing that the Secretary may not promulgate any regulation relating to self-determination contracts, or the approval, award, or declination of such contracts, except as authorized in the ISDEAA); § 450k(a)(2) (requiring regulations governing self-determination contracts to be promulgated in conformance with negotiated rulemaking procedures and the regulations codified in Title 25 of the CFR); S. REP. 103-374 at 2-3 (1994) (the 1994 ISDEAA amendments were intended to remove administrative barriers, ensure any regulations applicable to ISDEAA contracts were “relatively simple, straightforward, and free of unnecessary requirements or procedures,” and remove the authority of the Secretary to promulgate regulations under the Act).
HHS's proposed rulemaking disregards these express instructions. Although HHS asserts that it must adopt this rule change to “clarify how the Uniform Administrative Requirements interact with the prior-enacted [ISDEAA],” 81 Fed. Reg. 45271, this assertion is wrong. OMB already engaged with Tribes and tribal organizations in developing the Super Circular. As a result, OMB developed language in 2 CFR § 200.101(b)(3) making clear that, other than the Single Audit Act, whenever a provision in the Super Circular conflicts with the ISDEAA, the ISDEAA shall prevail and govern. This principle could not be clearer, and any additional clarification in the Part 75 regulation concerning how the Super Circular and ISDEAA are to be read together is unnecessary. At root, the proposed new regulation creates an entirely new regulatory framework that conflicts with the ISDEAA and with the Super Circular’s accommodation of the ISDEAA.

III. Application of the Part 75 Provisions to Tribes Contracting or Compacting under the ISDEAA is Impractical.

Tribal health programs should be exempt from the Part 75 provisions in their entirety, since the ISDEAA and its implementing regulations occupy the field with detailed requirements designed specifically for the unique government-to-government agreement such contracts and compacts embody. For the several reasons stated earlier, ISDEAA contracts are not subject to the Part 75 provisions as a matter of law. However, currently portions of tribal health programs are subject to these provisions because in addition to ISDEAA funds, Tribes also administer HHS grant funds. This means that even if a tribal health program receives over 90% of its funding from its ISDEAA contract, but (as is typical) administers less than 5% (or 1%) of its health program in the form of HHS grants (usually a diabetes grant), the Tribe must administer two separate sets of policies and procedures. This is not practical.

Given the impracticability of maintaining two separate systems, tribal health providers may de facto be forced to comply with the more onerous and ill-fitting regulatory regime. This accomplishes through the back door what HHS is forbidden to do through the front door. For this reason, we encourage HHS to exempt all tribal health programs from Part 75, and instead acknowledge that tribal programs are only subject to the requirements set forth in the ISDEAA and its implementing regulations for all HHS funds they receive, whether through an ISDEAA contract, grant, cooperative agreement, or other funding mechanism. Streamlining and simplifying federal regulatory requirements will permit Indian Tribes carrying out ISDEAA contracts and compacts to focus their attention on service delivery to improve the health status of their tribal citizens and other beneficiaries.
IV. Tribal Consultation Must Occur Before the Secretary Issues a Notice of Proposed Rulemaking Impacting Tribes.

The notice of proposed rulemaking has a direct impact on Tribes and tribal organizations. As such, the President’s Executive Order 13175 and HHS tribal consultation policies require tribal consultation. Specifically, the Executive Order requires agencies to consult with tribal officials in the development of federal policies that have tribal implications, including proposed regulations. Consultation must occur prior to publishing a proposed rule. Although HHS may equate tribal consultation with the opportunity to comment afforded to the general public by the Administrative Procedure Act, 5 U.S.C. § 553, they are not one and the same.

HHS’s tribal consultation policy goes further. It requires the Department and its divisions to consult with Tribes before any action is taken that will “significantly affect Indian tribes,” have “tribal implications” or have “substantial direct effects” on one or more Indian Tribes. The Department recognizes in its policy that: “An integral element of this government-to-government relationship is that consultation occurs with Indian Tribes.” U.S. Department of Health and Human Services, Tribal Consultation Policy, § 2. Each Department Operating and Staff Division must have an accountable process to “ensure meaningful and timely input by Indian Tribes in the development of policies that have Tribal implications.” Tribal Consultation Policy, § 4.A. With respect to issues relating to tribal self-governance and tribal self-determination, each agency Division “shall make all practicable attempts where appropriate to use consensual mechanisms for developing regulations, including negotiated rulemaking.” Tribal Consultation Policy, § 4.D.

The Department’s proposed rule stands in violation of Executive Order 13175 and the HHS Tribal Consultation Policy. No timely and meaningful government-to-government consultation occurred with Indian Tribes concerning “these important regulatory changes” (81 Fed. Reg. 45270).

V. Conclusion.

In summary, the proposed rulemaking violates the ISDEAA, its implementing regulations and the Department’s tribal consultation policy. The proposed rule should be withdrawn. In its place, the Secretary should issue an exemption from these grant rules for Tribes and tribal organizations, after providing meaningful consultation with Indian Tribes and tribal organizations consistent with the Department’s tribal consultation policy and Executive Order 13175.
If you have any questions about the information discussed above, please contact me at lloyd@sonosky.net.

Sincerely,

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