

the shortest time intervals, including transit time to a slaughter facility, between administration of the last dose of the drug and slaughter or collection of milk for human consumption, respectively.

Since the 1980s, the Agency has assumed that poultry spent at least 6 hours in transit to a slaughter facility, cattle and pigs spent at least 12 hours in transit to a slaughter facility, and dairy cows were milked at 12-hour intervals. These assumptions led the Agency to define practical zero withdrawal as 6 hours for poultry and 12 hours for cattle and pigs and practical zero-milk discard time as 12 hours for lactating dairy cows. Accordingly, we currently assign a zero-day withdrawal period or zero-day milk discard time to new animal drugs if data from scientific studies or other available information confirm that residue concentrations in edible tissues or milk from treated animals are safe for human consumption after 6 hours withdrawn from drug for poultry or after 12 hours withdrawn from drug for cattle, pigs, sheep, goats, and lactating dairy animals (*i.e.*, practical zero withdrawal and practical zero-milk discard time). A zero-day withdrawal period or zero-day milk discard time is often communicated to the end user by a labeling statement (*e.g.*, “zero-day withdrawal period,” “zero-day milk discard time,” or “no withdrawal period or milk discard time is required”).

The concept of practical zero withdrawal does not apply to drugs administered to laying hens (eggs only), food-producing aquatic animals, or honey bees. In these situations, we apply an “absolute zero withdrawal approach,” meaning that collection time or transit time is not considered and drug residues in eggs from treated hens, edible tissues from treated food-producing aquatic animals, and honey from treated honey bees must be below the assigned tolerance at all times during and after administration of a drug that has been assigned a zero-day withdrawal. Samples intended to support a zero-day withdrawal in these species are collected while animals are on the drug or immediately following the final drug administration.

II. Issues for Consideration

We recognize that the animal agriculture industry has undergone significant changes since the 1980s, when the current assumptions about transit time to slaughter and milking frequency were formulated. An accurate understanding of current industry practices and the end user’s interpretation of labeling statements is

necessary to approve labeling that ensures the safe and effective use of new animal drugs, which is central to our mission to protect and promote public health. Therefore, we are requesting comments on current industry practices regarding transit times to slaughter for food-producing animals, milking frequency, and how end users interpret a zero-day withdrawal period or zero-day milk discard time. We welcome comments on these topics for all food-producing animals except laying hens, honey bees, and food-producing aquatic animals because, as noted earlier, the concept of practical zero withdrawal does not apply to these classes of food-producing animals.

We invite comments on any or all the questions from individuals with direct knowledge of current industry practices. Please include the sector within the industry from where this information is derived (*e.g.*, a veterinarian, cooperative, individual producer, hauler, trade organization, packers and processors, etc.), as well as the source of the information (*e.g.*, survey, farm practices, published information, etc.) We specifically request comment on the following:

1. What is the minimum amount of time that food-producing animals spend in transit to a slaughter facility in the United States (*i.e.*, minimum transit time)? Please include the animal species and animal class(es) for each time provided.

2. What is the minimum amount of time that food-producing animals spend at slaughter facilities in the United States prior to being slaughtered for human consumption (*i.e.*, minimum holding time)? Please include the animal species and animal class(es) for each time provided.

3. What milking frequencies do United States commercial dairy operations commonly use (*e.g.*, two times per day, three times per day, greater than three times per day)? To what extent is each milking frequency used nationally, regionally, or within a particular sector (*e.g.*, 25 percent of dairies nationally, 30 percent of dairies in the Midwest, 50 percent of dairies serviced by a veterinary practice, etc.)?

4. How do end users of new animal drugs interpret labeling that has a “zero-day withdrawal period” or “zero-day milk discard time,” or that states “no withdrawal period or milk discard time is required”?

We will consider the submitted comments to evaluate if our current approach to assigning zero-day withdrawal periods and zero-day milk discard times to new animal drugs is appropriate.

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New.

Funding Announcement Number:
HHS–2019–IHS–TSGN–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:
93.444.

Key Dates

Application Deadline Date: October 23, 2019.

Earliest Anticipated Start Date:
November 22, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-

Determination Contracting; and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally-driven initiative and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the OTSG to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) Serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements (FA). Prospective Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning process. Also, Tribes currently participating in the TSGP, who are interested in expanding existing or adding new PSFAs, should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP negotiations are a dynamic, evolving, and tribally-driven process that requires careful planning, preparation and sharing of precise, up-to-date information by both Tribal and Federal parties. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) Enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs; (2) observe and respect the Government-to-Government relationship between the U.S. and each Tribe; and (3) involve the active

participation of both Tribal and IHS representatives, including the OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and FA, the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the Government-to-Government relationship between the Tribe and the Secretary of the U.S. Department of Health and Human Services (HHS). The FA: (1) Describes the length of the agreement (whether it will be annual or multi-year); (2) identifies the PSFAs, or portions thereof, the Tribe will assume; (3) specifies the amount of funding associated with the Tribal assumption; and (4) includes terms required by Federal statute and other terms agreed to by the parties. Both documents are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and mutually enforceable after both parties sign the documents. Either document can be renegotiated at the request of the Tribe.

The negotiations process has four major stages, including: (1) Planning; (2) pre-negotiations; (3) negotiations; and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal organization complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal Government planning and organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d). The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, FA and Tribal shares. They may take the form of a formal meeting or a series of informal meetings or conference calls.

In advance of final negotiations, the Tribe should work with the IHS to secure the following: (1) Program titles and descriptions; (2) financial tables and information; (3) information related

to the identification and justification of residuals; and (4) the basis for determining Tribal shares (distribution formula). The Tribe may also wish to discuss financial materials that show estimated funding for next year, and the increases or decreases in funding it may receive in the current year, as well as the basis for those changes.

Having reviewed the draft documents and funding tables, at final negotiations both negotiation teams work together in good faith to determine and agree upon the terms and provisions of the Tribe's Compact and FA. Negotiations are not an allocation process; they provide an opportunity to mutually review and discuss budget and program issues. As issues arise, both negotiations teams work through the issues to reach agreement on the final documents.

There are various entities involved throughout the negotiations process. For example, a Tribal government selects its representative(s) for negotiations and the Tribal negotiations team, which may include a Tribal leader from the governing body, a Tribal health director, technical and program staff, legal counsel, and other consultants. Regardless of the composition of the Tribal team, Tribal representatives must have decision making authority from the Tribal governing body to successfully negotiate and agree to the provisions within the agreements. The Federal negotiations team is led by the ALN and may include area and headquarters staff, including staff from the OTSG, the Office of Finance and Accounting, and the Office of the General Counsel. The ALN is the only member of the Federal negotiations team with delegated authority to negotiate on behalf of the IHS Director. The ALN is the designated official that provides Tribes with Self-Governance information, assists Tribes in planning, organizes meetings between the Tribe and the IHS, and coordinates the Agency's response to Tribal questions during the negotiations process. The ALN role requires detailed knowledge of the IHS, awareness of current policy and practice, and understanding of the rights and authorities available to a Tribe under Title V of the ISDEAA.

In post-negotiations, after the Compact, FA and all negotiations are complete, the documents are signed by the authorizing Tribal official and submitted to the ALN who reviews the final package to ensure each document accurately reflects what was negotiated. Once the ALN completes this review, then the final package is submitted to the OTSG to be prepared for the IHS Director's signature, provided that no outstanding issues delay or prevent

signature. After the Compact and FA have been signed by both parties, they become legally binding and enforceable agreements. A signed Compact and FA are necessary for the payment process to begin. The negotiating Tribe then becomes a “Self-Governance Tribe” and a participant in the TSGP.

Acquiring a Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use other resources to develop and negotiate its Compact and FA. *See* 42 CFR 137.26. Tribes that receive a Negotiation Cooperative Agreement are not obligated to participate in Title V and may choose to delay or decline participation or expansion in the TSGP.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total funding identified for fiscal year (FY) 2019 is approximately \$240,000. Individual award amounts are anticipated to be \$48,000. The funding available for competing and subsequent continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately five awards will be issued under this program announcement.

Period of Performance

The period of performance is for one year.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. However, the funding agency (IHS) is anticipated to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for IHS.

Substantial IHS Involvement

Description for Cooperative Agreement

A. Provide descriptions of PSFAs and associated funding at all organizational levels (Service Unit, Area, and Headquarters), including funding formulas and methodologies related to determining Tribal shares.

B. Meet with Negotiation Cooperative Agreement recipients to provide program information and discuss

methods currently used to manage and deliver health care.

C. Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

D. Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

III. Eligibility Information

1. Eligibility

To be eligible for the New Negotiation Cooperative Agreement under this announcement, an applicant must:

(A) Be an “Indian Tribe” as defined in 25 U.S.C. 5304(e); a “Tribal Organization” as defined in 25 U.S.C. 5304(l); or an “Inter-Tribal Consortium: as defined at 42 CFR 137.10. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity. *See* Consolidated Appropriations Act, 2014, Public Law 113–76 and Consolidated Appropriations Act, 2018, Public Law 115–141. By statute, the Native Village of Eyak, Eastern Aleutian Tribes, and the Council for Athabaskan Tribal Governments have also been deemed Alaska Native regional health entities and therefore are eligible to apply. Those Alaska Tribes not represented by a Self-Governance Tribal consortium FA within their area may still be considered to participate in the TSGP.

(B) Applicant must request participation in self-governance by resolution or other official action by the governing body of each Indian tribe to be served. Please see IV. Application and Submission Information, 2. Content and Form Application Submission, Additional Required Documentation, Tribal Resolution(s) for details.

(C) Demonstrate for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe’s Self-Determination Contracts or Self-Governance FAs with any Federal Agency. *See* 25 U.S.C. 5383; 42 CFR 137.15–23.

For Tribes or Tribal organizations (T/TO) that expended \$750,000 or more (\$500,000 for fiscal years ending after December 31, 2003) in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse.

For T/TO that expended less than \$750,000 (\$500,000 for fiscal years

ending after December 31, 2003) in Federal awards, the T/TO must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. *See* 42 CFR 137.21–23

Meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a T/TO is eligible for participation in the IHS TSGP under Title V of the ISDEAA. *See* 25 U.S.C. 5383; 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the “Eligibility and Funding” page on the OTSG website located at: <http://www.ihs.gov/SelfGovernance>.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under the Award Information, Estimated Funds Available section, or exceed the Period of Performance outlined under the Award Information, Period of Performance section will be considered not responsive and will not be reviewed. The Division of Grants Management (DGM) will notify the applicant.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement is hosted on <https://www.Grants.gov>.

Please direct questions regarding the application process to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Abstract (one page) summarizing the project.
- Application forms:
 - SF–424, Application for Federal Assistance.
 - SF–424A, Budget Information—Non-Construction Programs.
 - SF–424B, Assurances—Non-Construction Programs.

- Project Narrative (not to exceed 10 pages). See IV.2.A Project Narrative for instructions.

- Background information on the organization.

- Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Justification and Narrative (not to exceed 5 pages). See IV.2.B Budget Narrative for instructions.

- One-page Timeframe Chart.
- Tribal Resolution(s) (please see additional information below).

- Letters of Support from organization's Board of Directors.

- Biographical sketches for all Key Personnel.

- Contractor/Consultant resumes or qualifications and scope of work.

- Disclosure of Lobbying Activities (SF-LLL).

- Certification Regarding Lobbying (GG-Lobbying Form).

- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).

- Organizational Chart (optional).

- Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

- Face sheets from audit reports.

Applicants can find these on the FAC website: <https://harvester.census.gov/facdissem/Main.aspx>.

Additional Required Documentation Tribal Resolution(s)

Submit Tribal resolution(s) from the appropriate governing body of the Indian Tribe to be served by the ISDEAA Compact authorizing the submission of a Negotiation Cooperative Agreement application. Tribal consortia applying for a TSGP Negotiation Cooperative Agreement shall submit Tribal Council resolutions from each Tribe in the consortium. Tribal resolutions can be attached to the electronic online application.

The DGM must receive an official, signed Tribal resolution prior to issuing a Notice of Award (NoA) to any applicant selected for funding. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official, signed Tribal resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal resolution

must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal resolution is not in lieu of the required signed resolution, but is acceptable until a signed resolution is received. If an official signed Tribal resolution is not received by DGM when funding decisions are made, then a NoA will not be issued to that applicant and it will not receive IHS funds until it has submitted a signed resolution to the Grants Management Specialist listed in this Funding Announcement.

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements with the exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate document that is no more than 10 pages and must: (1) Have consecutively numbered pages; (2) use black font 12 points or larger; (3) be single-spaced; (4) and be formatted to fit standard letter paper (8-1/2 x 11 inches).

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria) and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the page limit, the application will be considered not responsive and not be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—4 Pages)

Section 1: Needs

Introduction and Need for Assistance

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs; and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the

need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

Part 2: Program Planning and Evaluation (Limit—4 Pages)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measurable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(A) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function, and Activity in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(B) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(C) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations.

(D) Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health services to the community and incorporate the proposed timelines for negotiations.

Organizational Capabilities, Key Personnel, and Qualifications

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

Section 2: Program Evaluation

Describe fully and clearly how the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

Part 3: Program Report (Limit—2 Pages)

Section 1: Describe major accomplishments over the last 24 months associated with the goals of this announcement. Please identify and describe significant health related program accomplishments associated with the delivery of quality health

services. This section should highlight major program achievements over the last 24 months.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities associated with the delivery of quality health services over the last 24 months. This section should address significant program activities and include those related to the accomplishments listed in the previous section.

B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line of the budget. The budget narrative should specifically describe how each item will support the achievement of proposed objectives. Be very careful about showing how each item in the “other” category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>). If problems persist, contact Mr. Paul Gettys (Paul.Gettys@ihs.gov), DGM Grant Systems Coordinator, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Tribes can apply for a Planning Cooperative Agreement and a Negotiation Cooperative Agreement in the same cycle, so long as the project

proposals are different for each application. Tribes cannot apply for both the Planning Cooperative Agreement and the Negotiation Cooperative Agreement within the same grant cycle with the same proposed project.

- Only one Negotiation grant/cooperative agreement will be awarded per applicant per grant cycle under this announcement.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the <https://www.Grants.gov> website to submit an application. Find the application by selecting the “Search Grants” link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If the applicant cannot submit an application through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. The waiver must: (1) Be documented in writing (emails are acceptable), before submitting an application by some other method; and (2) include clear justification for the need to deviate from the required application submission process.

Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions. A copy of the written approval must be included with the application that is submitted to DGM. Applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in <https://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.

- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at <https://www.grants.gov>).

- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.

- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to twenty working days.

- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by the NOFO.

- Applicants must comply with any page limits described in this funding announcement.

- After submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify the applicant that the application has been received.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B, which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access the request service through <https://fedgov.dnb.com/webform>, or call (866) 705-5711.

The Federal Funding Accountability and Transparency Act of 2006, as amended (“Transparency Act”), requires all HHS recipients to report information on sub-awards.

Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that are not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM

home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge, but can take several weeks to process. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, are available on the IHS Grants Management, Policy Topics web page: <https://www.ihs.gov/dgm/policytopics/>.

V. Application Review Information

Weights assigned to each section are noted in parentheses. The 10-page narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (25 Points)

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the: (1) Knowledge and expertise to assume or expand PSFAs; and (2) the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

B. Project Objective(s), Work Plan and Approach (25 Points)

State in measurable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each Program, Service, Function and Activity in comparison to the level of services provided so that an informed decision can be made on new or expanded program assumption.

(2) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(3) Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations. Clearly describe how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health care services to the community and incorporate the proposed timelines for negotiations.

C. Program Evaluation (25 Points)

Describe fully the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project.

D. Organizational Capabilities, Key Personnel and Qualifications (15 Points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 Points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.*, data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility

criteria shall be reviewed for merit by the Objective Review Committee (ORC) based on evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds will not be referred to the ORC and will not be funded. The applicant will be notified of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the IHS OTSG within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF-424) of the application.

A. Award Notices for Funded Applications

The Notice of Award (NoA) is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be held for one year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

- Uniform Administrative Requirements for HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, “Cost Principles,” located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, “Audit Requirements,” located at 45 CFR part 75, subpart F.

2. Indirect Costs

This section applies to all recipients that request reimbursement of indirect costs (IDC) in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award’s budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) <https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes>. For questions regarding the indirect cost policy, please call the Grants Management Specialist listed under “Agency Contacts” or the main DGM office at (301) 443–5204.

3. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a

“Grant Note” in GrantSolutions.

Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the period of performance.

B. Financial Reports

Federal Financial Report (FFR or SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at <https://pms.psc.gov>. The applicant is also requested to upload a copy of the FFR (SF–425) report into our grants management system, GrantSolutions. Failure to submit timely reports may result in adverse award actions blocking access to funds.

Grantees are responsible and accountable for accurate information being reported on all required reports: the Progress Reports and Federal Financial Report.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 sub-award obligation dollar threshold met for any specific reporting period.

Additionally, all new (discretionary) IHS awards (where the period of performance is made up of more than one budget period) and where: (1) The period of performance start date was October 1, 2010 or after, and (2) the primary awardee will have a \$25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy website at <https://www.ihs.gov/dgm/policytopics/>.

D. Compliance With Executive Order 13166 Implementation of Services

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person’s race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. The HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/>.

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>; and <https://www.hhs.gov/civil-rights/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <https://www.hhs.gov/civil-rights/for-individuals/disability/index.html>. Please contact the HHS OCR for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> or call (800) 368–1019 or TDD (800) 537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically

appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the IHS.

Recipients will be required to sign the HHS-690 Assurance of Compliance form which can be obtained from the following website: <https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf>, and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW, Washington, DC 20201.

E. Federal Awardee Performance and Integrity Information System (FAPIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIS), at <http://www.fapis.gov>, before making any award in excess of the simplified acquisition threshold (currently \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than \$10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an

applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113.

Disclosures must be sent in writing to: U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include "Mandatory Grant Disclosures" in subject line), Office: (301) 443-5204, Fax: (301) 594-0899, Email: Robert.Tarwater@ihs.gov.

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: <https://oig.hhs.gov/fraud/report-fraud/>, (Include "Mandatory Grant Disclosures" in subject line), Fax: (202) 205-0604 (Include "Mandatory Grant Disclosures" in subject line) or Email: MandatoryGranteeDisclosures@oig.hhs.gov.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 & 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. *Questions on the programmatic issues may be directed to:* Roxanne Houston, Program Officer, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E05, Rockville, MD 20857, Phone: (301) 443-7821, Email: Roxanne.Houston@ihs.gov, Website: <http://www.ihs.gov/self-governance>.

2. *Questions on grants management and fiscal matters may be directed to:* Vanietta Armstrong, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: (301) 443-4792, Fax: (301) 594-0899, Email: Vanietta.Armstrong@ihs.gov.

3. *Questions on systems matters may be directed to:* Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD

20857, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 594-0899, E-Mail: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Chris B. Buchanan,

Assistant Surgeon General, RADM, U.S. Public Health Service Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance Planning Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS-2019-IHS-TSGP-0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: October 23, 2019.

Earliest Anticipated Start Date: November 22, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Planning Cooperative Agreements for Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at <https://beta.sam.gov> (formerly known as Catalog of Federal Domestic Assistance) under 93.444.