

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2013-N-0001]
Joint Meeting of the Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee; Notice of Joint Meeting
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communication Advisory Committee and Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

DATES: *Date and Time:* The meeting will be held on August 15, 2013 from 9 a.m. to 5 p.m.

ADDRESSES: Food and Drug Administration, White Oak Campus.

Location: FDA White Oak Conference Center, Bldg. 31, Rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Luis G. Bravo, Designated Federal Official, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, Silver Spring, MD 20993, 1-877-287-1373 (choose option 5), email: RCAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and

scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Federal Food, Drug & Cosmetic Act (the FD&C Act) requires tobacco product manufacturers and importers to report quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products or tobacco smoke by brand and subbrand. The FD&C Act also requires the Agency to publish a list of HPHCs by brand and by quantity in each brand and subbrand by April of 2013, in a format that is understandable and not misleading to the layperson.

On August 15, 2013, the Committees will meet in joint session to discuss the results of the FDA consumer research "Experimental Study on the Public Display of Lists of Harmful and Potential Harmful Tobacco Constituents" [OMB Control No. 0910-0736] to assess the impact of HPHC information on consumer perceptions and comprehension, and how to effectively communicate information about the HPHCs of tobacco products to the general public.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 1, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 25, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably

accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 26, 2013. Interested persons can also log on to <https://collaboration.fda.gov/rcac/> to hear and see the proceedings.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Luis G. Bravo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 18, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-14947 Filed 6-21-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Indian Health Service
Tribal Self-Governance Program, Negotiation Cooperative Agreement, Announcement Type: New—Limited Competition

Funding Announcement Number: HHS-2013-IHS-TSGN-0001.

Catalog of Federal Domestic Assistance Number: 93.444.

Key Dates

Application Deadline Date: July 31, 2013.

Review Date: August 12, 2013.

Earliest Anticipated Start Date: August 30, 2013.

Signed Tribal Resolutions Due Date: July 31, 2013.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition Negotiation Cooperative Agreement applications 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. 458aaa–2(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA), available at <https://www.cfda.gov/>, 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 and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume IHS Programs, Services, Functions and Activities (PSFAs), or portions thereof, which enables Tribes to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual PSFAs the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), or (3) compact with the IHS to assume control over health care PSFAs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive; Tribes may choose to combine them based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs to the needs of their communities.

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 Tribal Self-Governance authorities within the IHS. The OTSG: (1) Serves as the primary liaison and advocate for Tribes participating in the TSGP, (2) develops, directs, and implements Tribal Self-Governance policies and procedures, (3) provides information and technical assistance to Self-Governance Tribes, and (4) advises the IHS Director on IHS compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN) that negotiates Self-Governance

instruments (Compacts and Funding Agreements) on behalf of the IHS Director. A Tribe should contact the respective ALN to begin the Self-Governance negotiations process and discuss methods to expand current PSFAs. The ALN shall provide an overview of the TSGP and provide technical assistance as the Tribe explores the option of participating in or expanding current PSFAs within the TSGP.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray costs related to preparing for and conducting TSGP negotiations. TSGP negotiations are a dynamic, evolving, and Tribally-driven process that requires careful planning and preparation by both Tribal and Federal parties, including the sharing of precise, up-to-date information. The design of the negotiations process: (1) Enables a Tribe to set its own priorities when assuming responsibility for IHS PSFAs, (2) observes the government-to-government relationship between the United States and each Tribe, and (3) involves the active participation of both Tribal and IHS representatives, including the OTSG. 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.

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 organization preparation relating to the administration of health care programs. During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. A draft Compact, Funding Agreement, and funding table are developed, typically by the Tribe, and distributed to both the Tribal and Federal negotiation teams. These draft documents are used as the basis for pre- and final negotiations. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, Funding Agreement, and Tribal shares. At final negotiations, Tribal and Federal negotiation teams

come together to determine and agree upon the terms and provisions of the Tribes Compact and Funding Agreement.

The Tribal negotiation team must include a Tribal leader from the governing body. This representative may be a Tribal leader or a designee, like the Tribal Health Director. The Tribal negotiation team may also include technical and program staff, legal counsel, and other consultants. The Federal negotiation team is led by the ALN and generally includes an OTSG Program Analyst and a member of the Office of the General Counsel. It may also include other IHS staff and subject matter experts as needed. The ALN is the only member of the Federal negotiation team with delegated authority to negotiate on behalf of the IHS Director.

Negotiations provide an opportunity for the Tribal and Federal negotiation teams to work together in good faith to enhance each Self-Governance agreement. Negotiations are not an allocation process; the negotiation teams to mutually review and discuss budget and program issues. As issues arise, both negotiation teams work through the issues to reach agreement on the final documents. After the negotiations are complete, the Compact and Funding Agreement are signed by the authorizing Tribal official and submitted to the ALN who then reviews the final package to ensure each document accurately reflects what was agreed to during negotiations. Once the ALN completes this review, the final package is submitted to the OTSG to be prepared for the IHS Director's signature. After the Compact and Funding Agreement have been signed by both parties, they become legally binding and enforceable agreements.

The receipt of a Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use its own resources to develop and negotiate its Compact and Funding Agreement. 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.

Limited Competition Justification

There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria (refer to Section III.1. Eligibility of this announcement). See 25 U.S.C. 458aaa–2(e); 42 CFR 137.24–26; see also 42 CFR 137.10. Tribes eligible to compete for the Negotiation Cooperative Agreements include: any Indian Tribe

that has not previously received a Negotiation Cooperative Agreement; any Indian Tribe that has previously received a Negotiation Cooperative Agreement but chose not to enter the TSGP; and those Indian Tribes that received a Negotiation Cooperative Agreement, entered the TSGP, and would like to plan for the assumption of new or expanded PSFAs.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current Fiscal Year (FY) 2013 is approximately \$240,000. Individual award amounts are anticipated to be \$48,000.

Competing awards issued under this announcement are subject to the availability of funds. In the absence of funding, 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.

Project Period

The project period is for 12 months and runs from August 30, 2013 to August 29, 2014.

Cooperative Agreement

In the HHS, a cooperative agreement is administered under the same policies as a grant. The funding agency (IHS) has substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated.

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) 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.

(2) Meet with Negotiation Cooperative Agreement recipient to provide program information and discuss methods currently used to manage and deliver health care.

(3) Identify and provide statutes, regulations, and policies that provide

authority for administering IHS programs.

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

B. Grantee Cooperative Agreement Award Activities

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement and prepare to discuss each PSFA in comparison to the current 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 Funding Agreement.

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

III. Eligibility Information

1. Eligibility

To be eligible for this Limited Competition Negotiation Cooperative Agreement under this announcement, an applicant must:

A. Be an "Indian Tribe" as defined in 25 U.S.C. 450b(e); a "Tribal Organization" as defined in 25 U.S.C. 450b(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 already participating in the Alaska Tribal Health Compact of 1998. See Consolidated Appropriations Act, 2012, Public Law 112-74. 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. Those Alaska Tribes not represented by a Self-Governance Tribal consortium Funding Agreement within their area may still be considered to participate in the TSGP.

B. Submit a Tribal resolution from the appropriate governing body of each Indian Tribe to be served by the ISDEAA Compact authorizing the submission of the 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. Draft resolutions can be submitted with the application in lieu of an official signed resolution; however an official signed Tribal resolution must be received by

the Division of Grants Management (DGM) prior to the Objective Review. If the DGM does not receive an official signed resolution by the Review Date listed under the Key Dates section on page one of this announcement, then the application shall be considered incomplete and ineligible for review or further consideration.

Official signed resolutions can be mailed to the DGM, Attn: Mr. John Hoffman, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852. Applicants submitting Tribal resolutions after or aside from the online electronic application submission must ensure that the information is received by the IHS, DGM. It is highly recommended that the documentation be sent by a delivery method that includes delivery confirmation and tracking. Please contact Mr. John Hoffman by telephone at (301) 443-5204 prior to the Review Date regarding submission questions.

C. Demonstrate, for three fiscal years, financial stability and financial management capability. The Indian Tribe must provide evidence that, for the three years prior to participation in Self-Governance, the Indian Tribe has had no significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance Funding Agreements with any Federal agency. See 25 U.S.C. 458aaa-2; 42 CFR 137.15-23.

For Tribes or Tribal organizations that expended \$300,000 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 database.

For Tribes or Tribal organizations that expended less than \$300,000 (\$500,000 for Fiscal Years ending after December 31, 2003) in Federal awards, the Tribe or Tribal Organization must provide evidence of the program review correspondence from IHS or Bureau of Indian Affairs officials. See 42 CFR 137.21-23.

Please note that meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a Tribe or Tribal organization is eligible for participation in the IHS TSGP under Title V of the ISDEAA, 25 U.S.C. 458aaa-2; 42 CFR 137.15-23.

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

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the DGM of this decision.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at <http://www.Grants.gov> or https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_funding

Additional information regarding the TSGP may also be found on the OTSG Web site at: <http://www.ihs.gov/selfgovernance>.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys, Grants Systems Coordinator, at (301) 443-2114 or by email at Paul.Gettys@ihs.gov.

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:

- Table of contents.
- 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.
 - Budget Justification and Narrative (must be single spaced and not exceed five pages).
 - Project Narrative (must be single spaced and not exceed ten pages).
 - Background information on the Tribe or Tribal organization.
 - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
 - Tribal Resolution(s).
 - 501(c)(3) Certificate (if applicable).
 - 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).

Public Policy Requirements

All Federal-wide public policies apply to IHS grants with exception of the Discrimination policy.

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate Word document that is no longer than ten pages and must: be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½" x 11" paper.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming more familiar with the grantee's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first ten pages will be reviewed. The 10-page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

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

Part A: Program Information (4-Page Limitation)

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 knowledge and expertise to assume or expand 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 B: Program Planning and Evaluation (4-Page Limitation)

Section 1: Program Plans

Project Objective(s), Work Plan and Approach

State in measurable terms the objectives and appropriate activities to achieve the following Cooperative Agreement Recipient Award Activities:

(a) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement and prepare to discuss each PSFA 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 Funding Agreement.

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

Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded, including how the Tribe plans to demonstrate improved health services to the community. Include 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

Define the criteria to be used to evaluate planning activities. Describe fully and clearly the methodology that will be used to determine if the needs identified are being met and if the outcomes are being achieved.

Describe fully and clearly 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.

Part C: Program Report (2-Page Limitation)

Section 1: Describe major accomplishments over the last 24 months. Please identify and describe significant health related 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 including those related to the accomplishments listed in the previous section.

B. *Budget Narrative*: This narrative must describe the budget requested and match the scope of work described in the project narrative. The page limitation should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12:00 a.m., midnight Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. The applicant will be notified by the DGM via email of this decision.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys, DGM Grants Systems Coordinator, by telephone at (301) 443-2114 or via email at Paul.Gettys@ihs.gov. 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.

If the applicant needs to submit a paper application instead of submitting electronically via Grants.gov, prior approval must be requested and obtained (see Section IV.6 below for additional information). The waiver must be documented in writing (emails are acceptable), *before* submitting a paper application. A copy of the written approval must be submitted along with

the hardcopy that is mailed to the DGM. Once the waiver request has been approved, the applicant will receive a confirmation of approval and the mailing address to submit the application. Paper applications that are submitted without a waiver from the Acting Director of DGM will not be reviewed or considered further for funding. The applicant will be notified via email of this decision by the Grants Management Officer of DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

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.
- Although IHS shall only award one Negotiation Cooperative Agreement per applicant per grant cycle, a Tribe may also apply for a Planning Cooperative Agreement within the same grant cycle. Both applications shall be reviewed separately for merit by the ORC based on the evaluation criteria.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the <http://www.Grants.gov> Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the <http://www.Grants.gov> Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If an applicant receives a waiver to submit paper application documents, the applicant must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or <http://www.Grants.gov> registration or that fail to request timely assistance with

technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in <http://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 electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- 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.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- 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 fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the OTSG will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

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

All IHS 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 it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward 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 were not registered with Central Contractor Registration (CCR) and have 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). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3-5 business days to process. Registration with the SAM is free of charge. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The narrative section 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 points. A minimum score of 60 points is required for funding. 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 knowledge and expertise to assume or expand 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 (30 points)

State in measurable terms the objectives and appropriate activities to achieve the following Cooperative Agreement Recipient Award Activities:

(1) Determine the PSFAs that will be negotiated into the Tribe's Compact and Funding Agreement and prepare to discuss each PSFA in comparison to the current 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 Funding Agreement.

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

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

C. Program Evaluation (10 points)

Define the criteria to be used to evaluate objectives associated with the project. Describe fully and clearly: (1) the methodology that will be used to determine if the needs identified are being met and if the outcomes identified are being achieved, and (2) 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.

D. Organizational Capabilities, Key Personnel and Qualifications (20 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 (15 points)

Submit a line-item budget with a narrative justification for 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(s) highlighting proposed project staff and their supervisors as well as other key contacts within the organization and key community contacts.
- 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 by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the minimum criteria shall be reviewed for merit by the ORC based on evaluation criteria. The ORC is composed of both Tribal and Federal reviewers appointed by the OTSG to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. Applicants will be notified by DGM, via email, to outline minor missing components (i.e., signature on the SF-424, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the

due date listed in the email of notification of missing documents required.

To obtain a minimum score the applicant must address all program requirements and provide all required documentation. If an applicant receives less than the minimum score, it will be considered to be "Disapproved" and will be informed via email by the OTSG of their application's deficiencies. A summary statement outlining the strengths and weaknesses of the application will be provided to each disapproved applicant. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF-424), of the application within 30 days of the completion of the Objective Review.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (<https://www.grantsolutions.gov>). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The 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.

Disapproved Applicants

Applicants who: (1) received a score less than the recommended funding level for approval, 60 points; and (2) were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from OTSG outlining the weaknesses and strengths of the application within 30 days of the conclusion of the ORC. The OTSG will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved" but were not funded due to lack of funds, will have their applications held by DGM for a period of one year after the official conclusion of the Objective Review. If additional funding becomes available during the

course of FY 2013, the approved application may be re-considered by the OTSG for possible funding. The applicant will also receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed 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 IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

- A. The criteria as outlined in this Program Announcement.
- B. Administrative Regulations for Grants:
 - 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments.
 - 45 CFR Part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and other Non-profit Organizations.
- C. Grants Policy:
 - HHS Grants Policy Statement, Revised 01/07.
- D. Cost Principles:
 - 2 CFR Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).
 - 2 CFR Part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).
- E. Audit Requirements:
 - OMB Circular A-133, Audits of States, Local Governments, and Non-profit Organizations.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. 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 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) http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm. For questions regarding the indirect cost policy, please call the DGM staff at (301) 443-5204 to request assistance.

4. 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. Reports must be submitted electronically via 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, 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 budget/project period.

B. Financial Reports

Federal Financial Report FFR (SF-425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Division of Payment Management, HHS at: <http://www.dpm.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

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

C. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward 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 subawards and executive compensation under Federal assistance awards.

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 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and 2) the primary awardee will have a \$25,000 subaward 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 Grants Management Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

Telecommunication for the hearing impaired is available at: TTY (301) 443-6394.

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Anna Johnson, Program Official, Office of Tribal Self-Governance, 801 Thompson Avenue, Suite 240, Rockville, MD 20852, Phone: (301) 443-7821, Fax: (301) 443-4666, Email: Anna.Johnson2@ihs.gov, Web site: www.ihs.gov/selfgovernance.
2. Questions on grants management and fiscal matters may be directed to: John Hoffman, Grants Management Specialist, Division of Grants Management, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852,

Phone: (301) 443-5204, Fax: (301) 443-9602, Email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: 301-443-2114; or the DGM main line 301-443-5204, Fax: 301-443-9602, E-Mail: Paul.Gettys@ihs.gov.

VIII. Other Information

The Public Health Service strongly encourages all 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.

Dated: June 13, 2013.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2013-14932 Filed 6-21-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Program Planning Cooperative Agreement

Announcement Type: New—Limited Competition.

Funding Announcement Number: HHS-2013-IHS-TSGP-0001.

Catalog of Federal Domestic Assistance Number: 93.444.

Key Dates

Application Deadline Date: July 31, 2013.

Review Date: August 12, 2013.

Earliest Anticipated Start Date: August 30, 2013.

Signed Tribal Resolutions Due Date: July 31, 2013.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting limited competition Planning Cooperative Agreement applications 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. § 458aaa-2(e). This program is described in the Catalog of Federal Domestic Assistance (CFDA), available at <https://www.cfda.gov/>, 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 and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume IHS Programs, Services, Functions and Activities (PSFAs), or portions thereof, which enables Tribes to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP is one of three ways that Tribes can choose to obtain health care from the Federal Government for their members. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS, (2) contract with the IHS to administer individual PSFAs the IHS would otherwise provide (referred to as Title I Self-Determination Contracting), or (3) compact with the IHS to assume control over health care PSFAs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive; Tribes may choose to combine them based on their individual needs and circumstances. Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs to the needs of their communities.

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 Tribal Self-Governance authorities within the IHS. The OTSG: (1) Serves as the primary liaison and advocate for Tribes participating in the TSGP, (2) develops, directs, and implements Tribal Self-Governance policies and procedures, (3) provides information and technical assistance to Self-Governance Tribes, and (4) advises the IHS Director on IHS compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN) that negotiates Self-Governance instruments (Compacts and Funding Agreements) on behalf of the IHS Director. A Tribe should contact the respective ALN to begin the Self-Governance planning process or discuss methods to expand current PSFAs. The ALN shall provide an overview of the TSGP and provide technical assistance as the Tribe explores the option of