

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-E-1657]

Determination of Regulatory Review Period for Purposes of Patent Extension; JUXTAPID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for JUXTAPID and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301-796-7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts

with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of the U.S. Patent and Trademark Office (USPTO) may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product JUXTAPID (lomitapide mesylate). JUXTAPID is indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia. Subsequent to this approval, the USPTO received a patent term restoration application for JUXTAPID (U.S. Patent No. 5,712,279) from Aegerion Pharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 31, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of JUXTAPID represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for JUXTAPID is 6,002 days. Of this time, 5,705 days occurred during the testing phase of the regulatory review period, while 297 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 18, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 18, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* February 29, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for Juxtapid (NDA 203-858) was submitted on February 29, 2012.

3. *The date the application was approved:* December 21, 2012. FDA has verified the applicant's claim that NDA 203-858 was approved on December 21, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 5, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 5, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA-2013-S-0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07809 Filed 4-3-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes; National Indian Health Outreach and Education II

Announcement Type: New Limited Competition.

Funding Announcement Number:
HHS-2015-IHS-NIHOE-0002.

Catalog of Federal Domestic Assistance
Number: 93.933.

Key Dates

Application Deadline Date: June 19, 2015.

Review Date: July 6–10, 2015.

Earliest Anticipated Start Date:
September 30, 2015.

Proof of Non-Profit Status Due Date:
July 3, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive applications for two limited competition cooperative agreements under the National Indian Health Outreach and Education (NIHOE) program: the Behavioral Health—Methamphetamine and Suicide Prevention Intervention (MSPI) outreach and education award and the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) outreach and education award. The Behavioral Health—MSPI outreach and education award is funded by IHS and is authorized under the Snyder Act, codified at 25 U.S.C. § 13; the Transfer Act, codified at 42 U.S.C. § 2001; the Consolidated Appropriations Act, 2014, Public Law 113–76. The HIV/AIDS outreach and education award is funded by the Office of the Secretary (OS), Department of Health and Human Services (HHS). Funding for the HIV/AIDS award will be provided by OS via an Intra-Departmental Delegation of Authority dated to IHS to permit obligation of funding appropriated by the Consolidated Appropriations Act, 2014, Public Law 113–76. Each award is funded through a separate funding stream by each respective Agency's appropriations. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports (one for each award), as indicated below. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Background

The NIHOE program carries out health program objectives in the American Indian/Alaska Native (AI/AN) community in the interest of improving Indian health care for all 566 Federally-recognized Tribes including Tribal governments operating their own health care delivery systems through Indian Self-Determination and Education Assistance Act (ISDEAA) contracts and compacts with the IHS and Tribes that

continue to receive health care directly from the IHS. This program addresses health policy and health programs issues and disseminates educational information to all AI/AN Tribes and villages. The NIHOE IIMSPI and HIV/AIDS awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as for the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and the Department of Health and Human Services (HHS) based on Tribal input through a broad based consumer network.

Purpose

The purpose of these cooperative agreements is to further IHS health program objectives in the AI/AN community with expanded outreach and education efforts for the MSPI and HIV/AIDS programs on a national scale and in the interest of improving Indian health care. This announcement includes two separate awards, each of which will be awarded as noted below. The purpose of the MSPI award is to further the goals of the national MSPI program. The MSPI is a national demonstration project aimed at addressing the dual problems of methamphetamine use and suicide in Indian Country. The MSPI supports an AI/AN community driven focus on the utilization and development of evidence-based and practice-based intervention models that promote a culturally appropriate prevention, treatment, and postvention approach to methamphetamine use and suicide. The six goals of the MSPI are to effectively prevent, reduce, or delay the use and/or spread of methamphetamine use; build on the foundation of prior methamphetamine and suicide prevention and treatment efforts in order to support the IHS, Tribes, and urban Indian health organizations in developing and implementing Tribal and/or culturally appropriate methamphetamine and suicide prevention and early intervention strategies; increasing access to methamphetamine and suicide prevention services; improving services for behavioral health issues associated with methamphetamine use and suicide prevention; promoting the development of new and promising services that are culturally and community relevant; and demonstrating efficacy and impact.

[Note: While the national MSPI program includes outreach to urban Indian organizations, outreach aimed specifically at urban Indian organizations will be addressed in a separate award announcement. However, materials developed by the grantee in the (NIHOE-II) MSPI award described in this announcement may be distributed by IHS to urban Indian organizations, at the discretion of the Agency.]

The purpose of the HIV/AIDS award is to further the goals of the national HIV/AIDS program. HIV and AIDS are a critical and growing health issue within the AI/AN population. The IHS National HIV/AIDS Program seeks to avoid complacency and to increase awareness of the impact of HIV/AIDS on AI/ANs. All activities are part of the IHS's implementation plan to meet the three goals of the President's National HIV/AIDS Strategy (NHAS) to reduce the number of people who become infected with HIV, increase access to care and optimize health outcomes for people living with HIV, and reduce HIV-related disparities. This population faces additional health disparities that contribute significantly to the risk of HIV transmission such as substance abuse and sexually transmitted infections. Amongst AI/AN people, HIV/AIDS exists in both urban and rural populations (and on or near Tribal lands); however, many of those living with HIV are not aware of their status. These statistics, risk factors, and missed opportunities for screening illuminate the need to go beyond raising awareness about HIV and begin active integration of initiatives that will help routinize HIV services. If the status quo is unchanged, prevalence will continue to increase and AI/AN communities may face an irreversible problem. Therefore, the National HIV/AIDS Program is working to change the way HIV is discussed, to change and improve the way HIV testing is integrated into health services, and to firmly establish linkages and access to care. The IHS HIV/AIDS Program is implemented and executed via an integrated and comprehensive approach through collaborations across multi-health sectors, both internal and external to the agency. It attempts to encompass all types of service delivery 'systems' including IHS/Tribal/Urban facilities. The IHS HIV/AIDS Program is committed to realizing the goals of the President's NHAS and has bridged the objectives and implementation to the IHS HIV/AIDS Strategic Plan.

Limited Competition Justification

Competition for both of the awards included in this announcement is limited to national Indian health care organizations with at least ten years of

experience providing education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between HHS and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of AI/AN communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor will they have an accurate picture of the health care needs facing AI/ANs nationwide. Organizations with less experience will lack the established relationships with Tribes and Tribal organizations throughout the country that will facilitate participation and the open and honest exchange of information between Tribes and HHS. With the limited funds available for these projects, HHS must ensure that the education and outreach efforts described in this announcement reach the widest audience possible in a timely fashion, are appropriately tailored to the needs of AI/AN communities throughout the country, and come from a source that AI/ANs recognize and trust. For these reasons, this is a limited competition announcement.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2015 is approximately \$250,000 to fund two cooperative agreements for one year; \$150,000 will be awarded for the Behavioral Health—MSPI award and \$100,000 will be awarded for the HIV/AIDS award. The amount of funding available for competing 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

Two awards will be issued under this program announcement. It is the intention of IHS and the Office of the

Secretary (OS) that one entity will receive both awards. OS and IHS will concur on the final decision as to who will receive both awards.

Project Period

The project periods for each award will be for one year and will run from September 30, 2015 with completion by September 29, 2016.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as a grant. The funding agency (IHS) is required 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 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

The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the two awards: IHS award and OS award noted below as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, developing of tools, and other products, interpreting program findings, and assisting with evaluations and overcoming any difficulties or performance issues encountered. The IHS assigned program official must approve all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to these awards and any supplemental awards prior to the presentation or dissemination of such materials to any party.

(1) Behavioral Health—MSPI Award

i. The IHS assigned program official will work in partnership with the awardee to identify and provide presentation topics on MSPI for the National Tribal Advisory Committee meetings; the Behavioral Health Work Group; webinars; and IHS Area conference calls.

ii. The IHS assigned program official will work in partnership with the awardee to identify MSPI projects in need of technical assistance.

(2) HIV/AIDS Award

IHS staff will provide support for the HIV/AIDS award as follows:

i. The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of grantee personnel, deployment of resources, release of public information materials, quality assurance, coordination of activities, training, reports, budgets, and evaluations. Collaboration includes data analysis, interpretation of findings, and reporting.

ii. The IHS assigned program official will work closely with OS and all participating IHS health services/programs, as appropriate, to coordinate award activities.

iii. The IHS assigned program official will coordinate the following for OS and the participating IHS program offices and staff:

- Discussion and release of any and all special grant conditions upon fulfillment.

- Monthly scheduled conference calls.

- Appropriate dissemination of required reports to each participating program.

iv. The IHS will, jointly with the awardee, plan and set an agenda for each of the conferences mentioned in this announcement that:

- Shares the training and/or accomplishments.

- Fosters collaboration amongst the participating program offices, agencies, and/or departments.

- Increases visibility for the partnership between the awardee and the IHS and OS.

v. IHS will provide guidance in addressing deliverables and requirements.

vi. IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned, and new findings.

vii. IHS will communicate via monthly conference calls, individual or collective site visits, and monthly meetings.

viii. IHS staff will review articles concerning the HHS, OS, and the Agency for accuracy and may, as requested by the awardee, provide relevant articles.

ix. IHS will provide technical assistance to the entity as requested.

x. IHS staff may, at the request of the entity's board, participate on study groups and may recommend topics for analysis and discussion.

B. Grantee Cooperative Agreement Award Activities

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable

lobbying restrictions provided under other law and any applicable restriction on the use of appropriated funds for lobbying activities.

The awardee is responsible for the following in addition to fulfilling all requirements noted for each award component: Behavioral Health—MSPI and HIV/AIDS.

i. To succinctly and independently address the requirements for each of the two awards listed below: Behavioral Health—MSPI and HIV/AIDS.

ii. To facilitate a forum or forums at which concerns can be heard that are representative of all Tribal governments in the area of health care policy analysis and program development for each of the two components listed above.

iii. To assure that health care outreach and education is based on Tribal input through a broad-based consumer network involving the Area Indian health boards or health board representatives from each of the 12 IHS Areas.

iv. To establish relationships with other national Indian organizations, professional groups, and Federal, State, and local entities supportive of AI/AN health programs.

v. To improve and expand access for AI/AN Tribal governments to all available programs within the HHS.

vi. To disseminate timely health care information to Tribal governments, AI/AN health boards, other national Indian organizations, professional groups, Federal, State, and local entities.

vii. To provide periodic dissemination of health care information, including publication of a newsletter four times a year that features articles on MSPI and HIV/AIDS health promotion/disease/behavioral health prevention activities and models of best or promising practices, health policy, and funding information relevant to AI/AN, etc.

The following schedule of deliverables outlines the requirements necessary to effectuate timely and effective support services to Tribal MSPI projects:

Summary of Tasks To Be Performed MSPI:

- At a minimum, the awardee shall provide Tribal MSPI program updates at the National Tribal Advisory Committee meetings and conference calls; and the Behavioral Health Work Group meetings and conference calls.

- At a minimum, the awardee shall serve as a committee member for the National Action Alliance for Suicide Prevention's American Indian/Alaska Native Task Force.

- The awardee shall participate in MSPI Area conference calls requested by the IHS assigned program official. The awardee must be included on the agenda and provide presentations on specific areas of interest identified by the Tribal MSPI programs and IHS assigned program official.

Outreach and Education

- The awardee shall provide information and education via multi-media venues, including but not limited to teleconference, webinar workshops, and/or online training modules on topics of particular importance to Tribal MSPI projects. The awardee will work with MSPI Tribal projects and the IHS assigned program official to identify topics. Topics will be discussed prior to the teleconference or webinar and will be subject to approval from the IHS assigned program official. PowerPoint slides must be submitted for approval two weeks prior to the presentation and will be made available on the IHS MSPI Web sites. Awardee's organizational Web site will link to IHS MSPI Web sites.

- The awardee shall conduct workshops and/or presentations including, but not limited to, the successes of the MSPI and promising practices and/or best practices of Tribal MSPI programs at three national conferences (venue and content of presentations to be agreed upon by the awardee and the IHS assigned program official).

- The awardee shall maintain a booth at identified meetings and conferences to provide comprehensive information on Tribal MSPI programs, curricula, findings, and strategies to local, regional, state, and Federal agencies and organizations.

- The awardee shall conduct site visits at Tribal MSPI programs, as funding is available, with two weeks advanced notification to the IHS assigned program official.

Technical Assistance

- The awardee shall review progress reports of MSPI projects identified by the program official.

- The awardee will develop and maintain orientation materials for MSPI projects including but limited to factsheets and guides.

- The awardee will provide training and technical assistance to increase AI/AN specific culture- or tradition-based interventions to be listed on the IHS Best and Promising Practice Registry.

Information Sharing

- The awardee shall develop, maintain, and disseminate

comprehensive information on Tribal MSPI programs, curricula, findings, articles, and strategies to all Tribal MSPI programs, and present the information at conference and meeting booths as described above.

- The awardee will provide postings on MSPI related information for the IHS MSPI Web site.

- The awardee will develop and/or maintain a comprehensive list of evidence-based and practice-based program development and business practice guidelines for use by Tribal MSPI programs.

- The awardee will develop and publish a semi-annual MSPI newsletter focusing on the impact and outcomes of the MSPI projects in Tribal communities to be cleared by IHS and then published on the IHS MSPI Web site.

Reporting

- The awardee shall provide semi-annual reports documenting and describing progress and accomplishment of the activities specified above, attaching any necessary documentation to adequately document accomplishments.

- The awardee shall attend bi-weekly, regularly scheduled, in-person and conference call meetings with the IHS assigned program official team to discuss the awardee's services and MSPI/related issues. The awardee must provide meeting minutes that highlight the awardee's specific involvement and participation.

- The awardee shall obtain approval from the IHS assigned program official for all PowerPoint presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to this award and any supplemental awards prior to the presentation or dissemination of such materials to any party, allowing for a reasonable amount of time for IHS review.

Deliverables

- Attendance at regularly scheduled meetings between awardee and the IHS assigned program official, evidenced by meeting minutes which highlight the awardee's specific involvement and participation.

- Participation on MSPI Area conference calls identified by the IHS assigned program official, evidenced by meeting agenda and minutes as needed.

- Report of outcomes at the following (meeting booths, workshops, site visitations and/or presentations provided):

- (a) National Tribal Advisory Committee conference calls and meetings.

(b) Behavioral Health Work Group conference calls and meetings. (PowerPoint slides in electronic form and one hard copy are to be submitted to the program official and the IHS assigned program official as required).

(c) IHS Area conference calls.

(d) IHS Area and national webinars.

(e) MSPI Project site visitations.

(f) Other AI/AN national conferences.

- Completed programmatic reviews of semi and annual progress reports of Tribal MSPI projects in order to identify projects that require technical assistance.

[Note: This review is not to replace IHS review of MSPI programs. The programmatic reviews to be conducted by grantee are secondary reviews intended solely to identify programs in need of technical assistance.]

- The awardee shall help the IHS assigned program official identify challenges faced by participating Tribal communities and assist in developing solutions.

- Copies of educational and practice-based information provided to Tribal MSPI programs (electronic form and one hard copy).

- Copies of all promotional and educational materials provided to Tribal MSPI programs and other projects (electronic form and one hard copy).

- Copies of all promotional materials provided to media and other outlets (electronic form and one hard copy).

- Copies of all articles published (electronic form and one hard copy). Submit semi-annual and annual progress reports to Division of Behavioral Health (DBH), due no later than 30 days after the reporting cycle, attaching any necessary documentation. For example: meeting minutes, correspondence with Tribal MSPI projects, samples of all written materials developed including brochures, news articles, videos, radio and television ads to adequately document accomplishments.

- The awardee will submit a deliverable schedule to the program official no later than 30 days after the start date.

HIV/AIDS

In alignment with the above program and independent from MSPI activities (both via fiscal resources and programmatic implementation), the awardee shall:

- Disseminate existing HIV/AIDS messages to AI/AN audiences in a format designed to solicit, collect, and report on community-level feedback and generate discussion regarding the disease and its prevention. This may include electronic and emerging means

of communication. At least four distinct audiences (such as women, young people, etc.) will be addressed and engaged. Preference will be given to reaching audiences with the highest HIV burden or potential increases as supported by the NHAS.

- Disseminate existing IHS HIV/AIDS program and other HIV/AIDS training materials to educators, health care providers, and other key audiences. Collect and report on relevant evaluation criteria, including impacts on underlying knowledge, attitudes, or beliefs about HIV acquisition, testing, or treatment.

- Deliver HIV/AIDS technical assistance and activity support program. Engage in documented partnerships with AI/AN communities to expand their capacity relevant to HIV/AIDS education and prevention efforts. Local activity support may include sub-awards of resources and distribution of incentives to qualified AI/AN-serving community organizations increasing HIV/AIDS education and prevention in their populations. Sub-award eligibility standards and management controls will be proposed by the awardee and will be subject to IHS approval. These activities must be conducted in accordance with Federal grant policies and procedures. Awardee will collect and maintain relevant evaluation materials and generate reports that highlight progress towards the President's NHAS goals on the community level and that collect best practices for dissemination to other communities.

- Contribute technical expertise to the IHS HIV/AIDS program and develop formal written documents responding to information requests from the public regarding HIV/AIDS initiatives.

- Develop and launch anti-stigma messaging for at least one audience, coordinated with other local activities to increase HIV screening and increase access to services, or increase positive role modeling for people living with, or at risk of, acquiring HIV/AIDS.

- Support and document issue-specific discussions with Tribal Leaders as needed to address effective prevention interventions for AI/AN populations as noted in the President's NHAS.

- Obtain approval from the IHS assigned program official of all presentations, electronic content, and other materials, including mass emails, developed by awardee pursuant to this award and any supplemental awards prior to the presentation or dissemination of such materials to any party, allowing for a reasonable amount of time for IHS review.

III. Eligibility Information

1. Eligibility

To be eligible for this "New/Competing Continuation Limited Competition Announcement", an applicant must:

Provide proof of non-profit status with the application, *e.g.*, 501(c)(3). Eligible applicants that can apply for this funding opportunity are national Indian organizations.

The national Indian organization must have the infrastructure in place to accomplish the work under the proposed program.

Eligible entities must have demonstrated expertise in the following areas:

- Representing all Tribal governments and providing a variety of services to Tribes, Area health boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in improved health outcomes for AI/ANs.

- Promotion and support of Indian education and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.

- National health policy and health programs administration.

- Have a national AI/AN constituency and clearly support critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.

- Portray evidence of their solid support of improved health care in Indian Country.

- Provide evidence of at least ten years of experience providing education and outreach on a national scale.

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 Division of Grants Management (DGM) of this decision.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

An applicant submitting any of the above additional documentation after the initial application submission due date is required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.*, FedEx tracking, postal return receipt, etc.).

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.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443-2114.

2. Content and Form Application Submission

Two complete separate signed applications are required. Both applications should address all the following components separately in each application. Each separate application 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 20 pages).
 - Background information on the organization.
 - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- Letter of Support from Organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).

- Position Descriptions 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) A-133 required 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.
- These can be found on the FAC Web site: <http://harvester.census.gov/sac/dissemin/accessoptions.html?submit=Go+To+Database>

Public Policy Requirements

All Federal-wide public policies apply to IHS grants and cooperative agreements 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 20 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 address and answer all questions listed under the narrative and place them 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 shall not be considered or scored. These narratives will assist the ORC in becoming familiar with the applicant's activities and accomplishments prior to this cooperative agreement award. If the narrative exceeds the page limit, only the first 20 pages will be reviewed. The 20-page 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.

Reminder: You are required to submit two separate complete and signed application packages. One for the Behavioral Health—MSPI cooperative agreement and one complete signed application package for the HIV/AIDS cooperative agreement. This applies to the narratives and budgets as well and all components listed below. Be sure to address each component separately in its respective application package. The page limitations below are for each narrative and budget submitted.

Part A: Program Information (8 page limitation)

Section 1: Needs

Describe how the national Indian organization has the experience to provide outreach and education efforts regarding the pertinent changes and updates in health care for each of the two components listed herein: Behavioral Health—MSPI and HIV/AIDS.

Part B: Program Planning and Evaluation (7 page limitation)

Section 1: Program Plans

Describe fully and clearly how the national Indian organization plans to address the NIHOE II MSPI and HIV/AIDS requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 566 Federally-recognized Tribes for each of the two components described herein.

Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal communities regarding both components. Identify anticipated or expected benefits for the Tribal constituency.

Part C: Program Report (5 page limitation)

Section 1: Describe Major Accomplishments Over the Last 24 Months

Identify and describe significant program achievements associated with the delivery of quality health outreach and education. Provide a comparison of the actual accomplishments to the goals established for the project period for both components, or if applicable, provide justification for the lack of progress.

Section 2: Describe Major Activities Over the Last 24 Months

Identify and summarize recent major health related outreach and education project activities of the work performed

for both components during the last project period.

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

3. *Submission Dates and Times*

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Standard Time (EST) 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. Grants.gov will notify the applicant via email if the application is rejected.

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 (Paul.Gettys@ihs.gov) at (301) 443-2114. 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 through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval must be submitted along with the hardcopy of the application that is mailed to DGM.

Paper applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EST, 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.
- Only one grant/cooperative agreement will be awarded per component.
- 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 the applicant receives a waiver to submit paper application documents, they 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 Office of Direct Service and Contracting Tribes (ODSCT) will notify the applicant that the application has been received.

- Email applications will not be accepted under this announcement.

Unique Entity Identifier (UEI) Numbering System

All IHS applicants and grantee organizations are required to obtain a UEI number and maintain an active registration in the SAM database. The UEI number is a unique 9-digit identification number provided to each entity. The UEI number is site specific; therefore, each distinct performance site may be assigned a UEI number. Obtaining a UEI number is easy, and there is no charge. To obtain a UEI

number, please contact Mr. Paul Gettys at (301) 443-2114.

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 20 page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. 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 (15 points)

(1) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (*i.e.*, Federally-funded, State-funded, etc.), and identify any memorandums of agreement with other national, Area or local Indian health board organizations. This could also include HHS' agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information to Tribes. Include information regarding technologies currently used (*i.e.*, hardware, software, services, Web sites, etc.), and identify the source(s) of technical support for those technologies (*i.e.*, in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area health boards, etc. [historical collaboration].

(2) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, and describe any memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/ANs, or any other memorandums of agreement with other Area Indian health boards, etc.

(3) Describe the population to be served by the proposed projects. Are they hard to reach? Are there barriers? Include a description of the number of Tribes who currently benefit from the technical assistance provided by the applicant.

(4) Describe the geographic location of the proposed project including any geographic barriers experienced by the recipients of the technical assistance to the health care information provided.

(5) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs. (Copies of reports will not be accepted.)

(6) Describe collaborative and supportive efforts with national, Area, and local Indian health boards.

(7) Explain the need/reason for the proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses have been assessed.

(8) Explain what measures were taken or will be taken to ensure the proposed projects will not create new gaps or weaknesses in services or infrastructure.

(9) Describe the effect of the proposed project on current programs (*i.e.*, Federally-funded, State funded, etc.) and, if applicable, on current equipment (*i.e.*, hardware, software, services, etc.). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(10) Describe how the projects relate to the purpose of the cooperative agreement by identifying how the proposed project will address national Indian health care outreach and education regarding various health data listed, *e.g.*, MSPI and HIV and AIDS, dissemination, training, and technical assistance, etc.

B. Project Objective(s), Work Plan and Approach (40 points)

(1) Identify the proposed project objective(s) for each of the two projects, as applicable, addressing the following:

- Measurable and (if applicable) quantifiable.
- Results oriented.
- Time-limited.

Example: Issue four quarterly newsletters, provide alerts and quantify number of contacts with Tribes. Goals must be clear and concise.

(2) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for the selected projects. Also address what tangible products, if any, are expected from the project, (*i.e.*, legislative analysis, policy analysis, annual conferences, mid-year conferences, summits, etc.).

(3) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a strategic plan and business plan currently in place that are being used that will include the expanded services. Include the plan(s) with the application submission.

(4) Submit a work plan in the Appendix that:

- Provides the action steps on a timeline for accomplishing each of the projects' proposed objective(s).

- Identifies who will perform the action steps.
- Identifies who will supervise the action steps taken.
- Identifies what tangible products will be produced during and at the end of the proposed project objective(s).
- Identifies who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
- Identifies any training that will take place during the proposed projects and who will be attending the training.
- Identifies evaluation activities proposed in the work plans.

(5) If consultants or contractors will be used during the proposed project, please include the following information in their scope of work (or note if consultants/contractors will not be used):

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

(6) Describe what updates will be required for the continued success of the proposed project. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

C. Program Evaluation (20 points)

Each proposed objective requires an evaluation component to assess its progress and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

(1) For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?

- At what intervals will data be collected?

- Who will collect the data and their qualifications?

- How will the data be analyzed?
- How will the results be used?

(2) For process evaluation, describe:

- How will the projects be monitored and assessed for potential problems and needed quality improvements?

- Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and what are their qualifications?

- How will ongoing monitoring be used to improve the projects?

- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.

- How will the organization document what is learned throughout the projects' grant periods?

(3) Describe any evaluation efforts planned after the grant period has ended.

(4) Describe the ultimate benefit to the AI/AN population served by the applicant organization that will be derived from these projects.

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

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the projects outlined in the work plans.

(1) Describe the organizational structure of the organization beyond health care activities, if applicable.

(2) Describe the ability of the organization to manage the proposed projects. Include information regarding similarly sized projects in scope and financial assistance, as well as other cooperative agreements/grants and projects successfully completed.

(3) Describe what equipment (*i.e.*, fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

(4) List key personnel who will work on the projects. Include title used in the work plans. In the Appendix, include position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience requirements related to the proposed project. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities. If a position is to be filled, indicate that information on the proposed position description.

(5) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary.

E. Categorical Budget and Budget Justification (10 points)

This section should provide a clear estimate of the program costs and justification for expenses for the entire cooperative agreement period for each award. The budgets and budget justifications should be consistent with the tasks identified in the work plans. Because each of the two awards included in this announcement are funded through separate funding streams, the applicant must provide a separate budget and budget narrative for each of the two components and must account for costs separately.

(1) Provide a categorical budget for each of the 12-month budget periods requested for each of the two projects.

(2) If IDC are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the Appendix. *See Section VI. Award Administration Information, 3. Indirect Costs.*

(3) Provide a narrative justification explaining why each line item is necessary or relevant to the proposed project. Include sufficient costs and other details to facilitate the determination that the cost is allowable (*i.e.*, equipment specifications, etc.).

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 by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the ODSCT 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. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.*, budget narratives, 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 for funding by the ORC, applicants must address all program requirements and provide all required documentation.

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 received a score less than the recommended funding level for approval, 60 points, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the ODSCT within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The ODSCT 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 funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2015 the approved but unfunded

application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office 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 75, Administrative Requirements.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

45 CFR part 75, subpart E. Cost Principles.

E. Audit Requirements:

- 45 CFR part 75, subpart F. Audit Requirements.

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 Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443-5204.

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 Payment Management Services, 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 DGM 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:

Mr. Chris Buchanan, Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852.
Telephone: (301) 443-1104. E-Mail: Chris.Buchanan@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to:

Mr. John Hoffman, DGM, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852.
Telephone: (301) 443-2114; or the DGM main line 301-443-5204. Fax: (301) 443-9602. E-Mail: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to:

Paul Gettys, Grant Systems Coordinator, DGM, 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: March 29, 2015.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. 2015-07780 Filed 4-3-15; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments on the National Vaccine Advisory Committee's Draft Report and Draft Recommendations for Consideration for Addressing the State of Vaccine Confidence in the United States

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, National Vaccine Program Office, Department of Health and Human Services

ACTION: Notice.

SUMMARY: The National Vaccine Advisory Committee (NVAC) was established in 1987 to comply with Title XXI of the Public Health Service Act (Pub. L. 99-660) (§ 2105) (42 U.S. Code 300aa-5 (PDF-78 KB)). Its purpose is to advise and make recommendations to the Director of the National Vaccine Program on matters related to program responsibilities. The Assistant Secretary for Health (ASH) has been designated by the Secretary of Health and Human Services (HHS) as the Director of the National Vaccine Program. The National Vaccine Program Office (NVPO) is located within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary, U.S. Department of Health and Human Services (HHS). NVPO provides leadership and fosters collaboration among the various federal agencies involved in vaccine and immunization activities. The NVPO also supports the National Vaccine Advisory Committee (NVAC). The NVAC advises and makes recommendations to the ASH in her capacity as the Director of

National Vaccine Program on matters related to vaccine program responsibilities.

Recognizing that immunizations are given across the lifespan and there are likely to be important differences in vaccine acceptance at different stages of life, in February of 2013 the National Vaccine Advisory Committee accepted an initial charge from the Assistant Secretary for Health (ASH) to report on how confidence in vaccines impacts the optimal use of recommended childhood vaccines in the United States, including reaching Healthy People 2020 immunization coverage targets. Focus of such a report may include understanding the determinants of vaccination acceptance among parents, what HHS should be doing to improve parental confidence in vaccine recommendations and how to best measure confidence in vaccine and vaccination to inform and evaluate interventions in the future.

Through a series of teleconferences, electronic communications, presentations and public discussions during the NVAC meetings, a working group identified a number of draft recommendations to further understand and address issues of vaccine confidence in the United States.

On behalf of NVAC, NVPO is soliciting public comment on the draft report and draft recommendations from a variety of stakeholders, including the general public, for consideration by the NVAC as they develop their final recommendations to the ASH. It is anticipated that the draft report and draft recommendations, as revised with consideration given to public comment and stakeholder input, will be presented to the NVAC for adoption in June 2015 at the quarterly NVAC meeting.

DATES: Comments for consideration by the NVAC should be received no later than 5:00 p.m. EDT on May 6, 2015.

ADDRESSES:

(1) The draft report and draft recommendations are available on the Web at <http://www.hhs.gov/nvpo/nvac/subgroups/nvac-vaccine-confidence-wg.html>.

(2) Electronic responses are preferred and may be addressed to: vcwg@hhs.gov.

(3) Written responses should be addressed to: National Vaccine Program Office, U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 733G, Washington, DC 20201. Attn: Vaccine Confidence Working Group.

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, Office of the Assistant Secretary for Health,