

the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 029" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/MedicalDevices>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is no longer necessary to send two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 029. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20323 Filed 8-17-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0840]

Hospira, Inc.; Withdrawal of Approval of a New Drug Application for DEXTRAN 70

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or 5% Dextrose 500 mL Glass Bottle) held by Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045. Hospira, Inc., has notified the Agency in writing that this product is no longer marketed and has requested that approval of the application be withdrawn.

DATES: Effective August 20, 2012.

FOR FURTHER INFORMATION CONTACT:

Jonathan McKnight, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION: Hospira, Inc., has requested that FDA withdraw approval of NDA 080-819, DEXTRAN 70 (6% Dextran 70 and 0.9% NaCl or 5% Dextrose 500 mL Glass Bottle) under the process in § 314.150(c)(21 CFR 314.150(c)), stating that the product is no longer marketed. By its own request, Hospira, Inc., has also waived its opportunity for a hearing provided under § 314.150(a).

Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Biologics Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 080-819, DEXTRAN 70 [6% Dextran 70 and 0.9% NaCl or 5% Dextrose 500 mL Glass Bottle], and all amendments and supplements thereto, is hereby withdrawn, effective August 20, 2012. Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 9, 2012.

Karen Midthun,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 2012-20280 Filed 8-17-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes National Indian Health Outreach and Education Program Funding Opportunity

Announcement Type: New Limited Competition.

Funding Announcement Number: HHS-2012-IHS-NIHOE-0003.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: September 10, 2012.

Review Date: September 12, 2012.

Earliest Anticipated Start Date: September 30, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the Office of Direct Service and Contracting Tribes on the National Indian Health Outreach and Education (NIHOE-III) program funding opportunity that includes outreach and education activities on the following: The Patient Protection and Affordable Care Act, Public Law 111-148 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, collectively known as the Affordable Care Act (ACA) and the Indian Health Care Improvement Act (IHCA), as amended. This national outreach and educational program is authorized under the Snyder Act, codified at 25 U.S.C. 13, and the Transfer Act, codified at 42 U.S.C. 2001(a). This program is described in the Catalog of Federal Domestic Assistance under CFDA number 93.933.

Background

The NIHOE-III programs carry 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 self-determination 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 program issues and disseminates educational information to all AI/AN Tribes and villages. These 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.

The IHS also provides health and related services through grants and contracts with urban Indian organizations to reach AI/AN residing in urban communities.

Purpose

The purpose of this IHS cooperative agreement is to encourage national Indian organizations and IHS, Tribal, and Urban (I/T/U) partners to work together to implement three distinct program activities throughout Indian Country: (1) Health Reform and How to Maximize Provisions for the IHS, Tribes, and Urban Health Clinics, (2) Medicaid Expansion for AI/ANs under the ACA, and (3) Conduct ACA/IHCIA Education and Outreach Training and Technical Assistance under the Limited Competition NIHOE Cooperative Agreement program to further health program objectives in the AI/AN community with outreach and education efforts in the interest of improving Indian health care and to ensure that all AI/AN are prepared to take advantage of the health reform opportunities, improve the quality of and access to health care services, and increase resources for AI/AN health care. The goal of this program announcement is to coordinate and conduct consumer centered outreach and education, training and technical assistance on a national scale for the 566 Federally-recognized Tribes and Tribal organizations on the changes, improvements and authorities of the ACA and IHCIA in anticipation of implementation of the health care reform date of January 1, 2014 regarding Medicaid expansion revenue opportunities and individual health insurance coverage and choices. This collaborative effort will benefit I/T/U as

well as the AI/AN communities (Tribal and urban).

II. Award Information

Type of Award

Cooperative Agreement

The IHS will accept applications for either one of the following:

- A. Two entities collaborating and applying as one entity.
- B. Two entities applying separately to accomplish appropriately divided program activities.

Estimated Funds Available

The total amount of funding identified for the current fiscal year, FY 2012, is approximately \$600,000. Individual award amounts are anticipated to be \$300,000 each if awarded to two entities applying separately; \$600,000 if awarded to two entities applying as one entity. 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

One or two awards will be issued under this program announcement.

Project Period

The project period will be for one year and will run consecutively from September 30, 2012 to September 29, 2013.

Cooperative Agreement

In the HHS, a cooperative agreement is 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

- IHS will have final approval of the selection of any consultants.
- IHS will approve the training and education curriculum content, facts, delivery mode, pre- and post-assessments, and evaluation before any materials are printed and the training is conducted.

- IHS will review and approve the final draft products before they are published and distributed.

B. Grantee Cooperative Agreement Award Activities

- Facilitate an open exchange of ideas and foster an atmosphere of open communication regarding outreach, educational training and technical assistance about these Acts.
- Provide the outreach and educational training and technical assistance about these Acts and their changes and requirements that will affect AI/AN whether doing so independently or jointly via a partnership as described previously. FY 2012 funding for ACA/IHCIA NIHOE and Implementation will focus on all national Indian organizations and I/T/U partners working together to implement three distinct program activities throughout Indian Country: (1) Health Reform and How to Maximize Provisions for the IHS, Tribes, and Urban Indian Health Clinics, (2) Medicaid Expansion for AI/ANs under the ACA, and (3) Conduct ACA/IHCIA Education and Outreach Training and Technical Assistance. The project goals are two-fold for the IHS and the selected entities:

1. Communicate IHS approved communication about the content and meaning of the ACA and the IHCIA.

2. Strengthen and unify partnerships to strategically identify and conduct activities that will be implemented throughout the I/T/U community by no later than December 31, 2013 to take full advantage of the January 1, 2014 implementation date for health care reform regarding Medicaid expansion revenue opportunities and individual health insurance coverage and choices.

III. Eligibility Information

1. Eligibility

Eligible applicants include 501(c)(3) non-profit entities who meet the following criteria.

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.

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

- Administering national health policy and health programs.

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

- Supporting improved health care in Indian Country.

- Providing education and outreach on a national scale (the applicant must provide evidence of at least ten years of experience in this area).

- Qualified national Indian organizations/entities must have experience and expertise on the variety of issues related to the provision of health care to Indian people.

- Qualified national American Indian organizations/entities must have at least two years of experience and expertise in addressing urban communities. *Note: At least one of the partnering applicant organizations must have the required time in providing health education and outreach to urban communities.

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 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. IHS will not return the application. The applicant will be notified by email or certified mail by the Division of Grants Management (DGM) of this decision.

The funding level noted includes both direct and indirect costs. Administrative costs are capped.

Proof of Non-Profit Status

A copy of the 501(c)(3) Certificate must be received with your application submission by the deadline due date of September 10, 2012.

Letters of Intent will not be required under this funding opportunity announcement.

Applicants submitting any of the above additional documentation after the initial application submission due date are 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 http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding.

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

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 not exceed ten pages).
 - Background information on the national Indian organizations.
 - 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.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF-LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required) in order to receive IDC.

- Organizational Chart (optional).
- Documentation of current 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 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 possible 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, 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

Describe how each national Indian organization has the experience to provide outreach and education efforts regarding the pertinent changes and updates in health care listed herein.

Part B: Program Planning and Evaluation (4 Page Limitation)

Section 1: Program Plans

Describe fully and clearly the direction the national Indian organization plans to address the

NIHOE III requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 566 Federally-recognized Tribes, as well as collaborative efforts regarding the urban organizations as described herein. Include proposed timelines as appropriate and applicable.

Section 2: Program Evaluation

Describe fully and clearly how the outreach and education efforts will impact changes in knowledge and awareness in Tribal and urban communities to encourage appropriate changes by increasing knowledge and awareness resulting in informed choices. Identify anticipated or expected benefits for the Tribal constituency and urban communities.

Part C: Program Report (2 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, 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 during the last project period.

B. Budget Narrative: This narrative must describe the budget requested and match the scope of work described 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 12 a.m., midnight Eastern Daylight Time (EDT) on September 10, 2012. 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 or certified mail 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 Paul Gettys, DGM (Paul.Gettys@ihs.gov) at (301)

443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If an 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 or certified mail of this decision by the Grants Management Officer of DGM. Paper applications must be received by the DGM no later than 5 p.m., EDT, on the application deadline date. Late applications will not be accepted for processing or considered for funding.

Other Important Due Dates

Proof of Non-Profit Status 501(c)(3) Certificate: Due date September 10, 2012.

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 applicant.
- 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.

Applicants that receive a waiver to submit paper application documents must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the application deadline.

Applicants that do not adhere to the timelines for Central Contractor Registry (CCR) 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 the 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 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 our standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the deadline date of September 10, 2012.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR 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 ODSCT will notify applicants 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 CCR 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, access it through <http://fedgov.dnb.com/webform>, or to expedite the process, call (866) 705-5711.

Effective October 1, 2010, all HHS recipients were asked to start reporting information on subawards, as required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act").

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.

Central Contractor Registry (CCR)

Organizations that have not registered with CCR will need to obtain a DUNS number first and then access the CCR online registration through the CCR home page at <https://www.bpn.gov/ccr/default.aspx> (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 your CCR registration will take 3-5 business days to process. Registration with the CCR is free of charge. Applicants may register online at <https://www.bpn.gov/ccrupdate/NewRegistration.aspx>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and CCR, can be found on the IHS Grants Management, Grants Policy Web site: http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_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 is limited to ten pages. 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

Criteria—Program Requirements

Project Objectives, Activities, Work Plan, Evaluation and Budget

A. Health Reform and How To Maximize Provisions for the IHS, Tribes and Urban Indian Health Clinics

(1) Identify health care economist or expert to develop models or tools that can be used by Tribes and Tribal organizations to identify revenue opportunities in the ACA and Health Insurance Exchanges.

(2) Develop a small, medium and large health care system model that Tribes and Tribal organizations can use to maximize Health Insurance Exchanges.

(3) Develop an electronic template that Tribes and Tribal organizations can use to populate data fields and generate Tribal specific analysis for informed decision making regarding health insurance coverage and choices to meet the January 1, 2014 ACA implementation date.

B. Maximize Medicaid Expansion for AI/ANs Under the ACA

(1) Identify health care economist or expert to develop models or tools that can be used by Tribes and Tribal organizations to maximize revenue opportunities in the ACA Medicaid Expansion.

2. Develop a small, medium and large health care system model that Tribes and Tribal organizations can use to maximize Medicaid Expansion opportunities.

3. Develop an electronic template that Tribes and Tribal organizations can use to populate data fields and generate Tribal specific analysis for informed decision making regarding the Medicaid Expansion revenue opportunities and health care access and coverage to meet

the January 1, 2014 ACA implementation date.

C. Conduct ACA/IHCIA Education and Outreach Training and Technical Assistance

(1) Evaluate all available ACA/IHCIA training material available for AI/AN and create additional materials as needed that are related to ACA/IHCIA.

(2) Describe how to ensure the training curriculum content addresses all new regulations implementing the ACA or IHCIA requirements.

(3) Describe the review and approval of the training course evaluation instrument.

(4) Record training sessions and describe how they will be made available to the I/T/U and AI/AN community on the Web sites of the national Indian organizations and partners.

D. Work Plan

Describe the activities or steps that will be used to achieve each of the activities proposed during the 12-month budget period.

(1) Provide a Work Plan that describes the sequence of specific activities and steps that will be used to carry out each of the three objectives.

(2) Include a detailed timeline that links activities to project objectives for the 12-month budget period.

(3) Identify challenges, both opportunities and barriers, that are likely to be encountered in designing and implementing the activities and approaches that will be used to address such challenges.

(4) Describe communication methods with partners.

E. Evaluation

(1) Provide a well-conceived logical plan for assessing the achievement of the project's process and outcome objectives and for evaluating changes in the specific problems and contributing factors.

(2) Identify performance measures by which the project will track its progress over time. A performance measure is a quantifiable indicator of progress and achievement that includes outcome, output, input, efficiency, and explanatory indicators.

F. Budget

Provide a functional categorically itemized budget and program narrative justification that supports accomplishing the program objectives, activities, and outcomes within the timeframes specified.

A. Introduction and Need for Assistance (15 Points)

1. Describe the individual entity's and/or partnering entities' (as applicable) 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.), any memorandums of agreement with other National, Area or local Indian health board organizations, HHS' agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information, information regarding technologies currently used (i.e., hardware, software, services, 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, etc.

3. Describe the population to be served by the proposed project. Include a description of the number of Tribes and Tribal members who currently benefit from the technical assistance provided by the applicant.

4. State how previous cooperative agreement funds facilitated education, training and technical assistance nationwide for AI/ANs and relate the progression of health care information delivery and development relative to the current proposed project. (Copies of reports will not be accepted.)

5. Describe collaborative and supportive efforts with national, area and local Indian health boards.

6. Describe how the project relates to the purpose of the cooperative agreement by addressing the following: Identify how the proposed project will address the changes and requirements of the Acts.

B. Project Objective(s), Work-Plan and Approach (45 Points)

1. Proposed project objectives must be:

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

2. Submit a work-plan in the appendix which includes the following information:

a. Provide the action steps on a timeline for accomplishing the proposed project objective(s).

b. Identify who will perform the action steps.

c. Identify who will supervise the action steps taken.

d. Identify what tangible products will be produced during and at the end of the proposed project objective(s).

e. Identify who will accept and/or approve work products during the duration of the proposed project and at the end of the proposed project.

f. Include any training that will take place during the proposed project and who will be attending the training.

g. Include evaluation activities planned.

3. 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):

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

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

C. Program Evaluation (15 Points)

Each proposed objective requires an evaluation component to assess its progression 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:

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

c. At what intervals will data be collected.

d. Who will collect the data and their qualifications.

e. How the data will be analyzed.

f. How the results will be used.

2. For process evaluation, describe:

- a. How the project will be monitored and assessed for potential problems and needed quality improvements.

b. Who will be responsible for monitoring and managing project improvements based on results of ongoing process improvements and their qualifications.

c. How ongoing monitoring will be used to improve the project.

d. Any products, such as manuals or policies, that might be developed and

how they might lend themselves to replication by others.

3. How the project will document what is learned throughout the project period. Describe any evaluation efforts that are planned to occur after the grant periods.

4. Describe the ultimate benefit for the AI/ANs that will be derived from this project.

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

1. Describe the organizational structure of the organization.

2. Describe the ability of the organization to manage the proposed project. 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 project.

4. List key personnel who will work on the project. Include title used in the work-plan. 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.

E. Categorical Budget and Budget Justification (10 Points)

1. Provide a categorical budget for 12-month budget period requested.

2. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

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

Appendix Items

- 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.
- 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. 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 or letter, 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 for funding by the Objective Review Committee (ORC), applicants must address all program requirements and provide all required documentation. Applicants that receive less than a minimum score will be considered to be "Disapproved" and will be informed via email or regular mail by the IHS Program Office 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 (AOR) that is identified on the face page (SF-424), of the application within 60 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 and will be mailed via postal mail or emailed to each entity that is approved for funding under this announcement. 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, and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS Program Office within 30 days of the conclusion of the ORC outlining the weaknesses and strengths of their application submitted. The IHS program office 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 2012, the approved application maybe re-considered by the awarding program office for possible funding. You 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 Office of Management and Budget (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:
 - Title 2: Grant and Agreements, Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).
 - Title 2: Grant and Agreements, 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) <http://rates.psc.gov/> and the Department of Interior (National Business Center) <http://www.aqd.nbc.gov/services/ICS.aspx>. If your organization has questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

4. Reporting Requirements

Grantees 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.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. 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 you also send a copy of your FFR (SF-425) report to your Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to your 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.

Effective October 1, 2010 IHS implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding this 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 conduct 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: http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_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: Ms. Roselyn Tso, Acting Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, Email: Roselyn.Tso@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. Andrew Diggs, Grants Management Specialist, 801 Thompson Avenue, TMP 360, Rockville, Maryland 20852, Telephone: (301) 443-5204, Fax: (301) 443-9602, Email: Andrew.Diggs@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: August 12, 2012.

Yvette Roubideaux,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS-2012-IHS-NIHOE-0001]

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

Announcement Type: Limited Competition

Catalog of Federal Domestic Assistance Number: 93.933

DATES: Key Dates:

Application Deadline Date:

September 10, 2012.

Review Date: September 12, 2012.

Earliest Anticipated Start Date:

September 30, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for the Office of Direct Service and Contracting Tribes on the National Indian Health Outreach and Education (NIHOE) I cooperative agreement. This award includes the following four components, as described in this announcement: "Line Item 128 Health Education and Outreach funds," "Health Care Policy Analysis and Review," "Budget Formulation" and "Tribal Leaders Diabetes Committee" (TLDC). This program is authorized under the Snyder Act, codified at 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance under CFDA 93.933.

Limited Competition Announcement

This is a Limited Competition announcement. The funding levels noted include both direct and indirect costs. Limited competition refers to a funding opportunity that limits the eligibility to compete to more than one entity but less than all entities.

Limited Competition Justification

Competition for the award 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 the Department of Health and Human Services (HHS) and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of American Indian/Alaska Native (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