

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

Guidance for industry on formal meetings between FDA and biosimilar biological product sponsors or applicants	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
CBER .....	1	2	2	15	30
Total .....					480
Information Packages:					
CDER .....	15	2	30	30	900
CBER .....	1	2	2	30	60
Total .....					960
Total .....					1,440

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**C. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>. (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. See <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf>.

Dated: May 29, 2015.

**Leslie Kux,**

Associate Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Dental Preventive and Clinical Support Centers Program; Office of Clinical and Preventive Services, Division of Oral Health**

*Announcement Type:* New and Competing Continuation.

*Funding Announcement Number:* HHS-2015-IHS-TDCP-0001.

*Catalog of Federal Domestic Assistance Numbers:* 93.933.

*Key Dates:*

Application Deadline Date: August 3, 2015.

Anticipated Review Dates: August 6-7, 2015.

Earliest Anticipated Start Date:

September 30, 2015.

Signed Tribal Resolutions Due Date:

August 3, 2015.

Proof of Non-Profit Status Due Date:

August 3, 2015.

**I. Funding Opportunity Description**

*Statutory Authority*

The Indian Health Service (IHS) is accepting competitive grant applications for the Dental Preventive and Clinical Support Centers Program. This program is authorized under the authority of 25 U.S.C. 13, Snyder Act; 42 U.S.C. 2001, Transfer Act; Indian Health Care Improvement Act (IHCA), amended 2010. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

*Background*

The primary customers of a support center are IHS, Tribal, and urban dental programs and personnel throughout an IHS area or broad geographic region. The primary customers are not dental patients or Tribes. The primary function of a support center is not the direct provision of clinical care. Well-designed support centers will impact upon patients' oral health, and document positive oral health outcomes for patients, primarily by providing guidance to field programs and addressing the assessed and perceived needs of dental personnel and IHS/ Tribal/urban (I/T/U) dental programs.

Proposed programs focused at one locale or on clinical or preventive care alone, with no concomitant focus on a regional or area support-oriented component for the dental program, while well-intentioned and of potential value, are not responsive to this announcement or to the support center project.

*Purpose*

The purpose of this IHS grant program is to combine existing resources and infrastructure with IHS Headquarters (HQ) and IHS area resources in order to address the broad challenges and opportunities associated with IHS preventive and clinical dental programs. In accordance with the recently stated priorities of the Department of Health and Human Services (HHS) Secretary on the need to achieve "higher value" health care services, the dental support centers will address two priority goals: (1) Provide support, guidance, training, and enhancement of I/T/U dental programs within their area; and (2) ensure that the services of the support centers and the I/T/U/dental programs result in measurable improvements in the oral health status of the American Indian/Alaska Native (AI/AN) patients served. In order to address these two goals, a strong collaborative working relation with the IHS HQ Division of Oral Health (DOH) and the Area Dental Director or Area Dental Officer should be maintained. In short, support centers will empower the dental programs they serve and impact oral health outcomes through the guidance and services they provide. Improvements to oral health must be documented.

**II. Award Information**

*Type of Award*

Grant.

*Estimated Funds Available*

The total amount of funding identified for the current fiscal year (FY) 2015 is approximately \$1,000,000. Individual award amounts are anticipated to be \$250,000. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The

IHS is under no obligation to make awards that are selected for funding under this announcement.

#### *Anticipated Number of Awards*

Approximately four awards will be issued under this program announcement.

#### *Project Period*

The project period is for five years, and will run consecutively from September 30, 2015 to September 29, 2020.

### III. Eligibility Information

#### *1. Eligible Applicants*

Eligible applicants include:

- Urban Indian organizations as defined by the IHClA, amended 2010. "Urban Indian organization" means a non-profit corporate body situated in an urban center governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities. 25 U.S.C. 1603(29).

- Tribal organizations.

"Tribal organization" means the elected governing body of any Indian Tribe or any legally established organization of Indians which is controlled by one or more such bodies or by a board of directors elected or selected by one or more such bodies (or elected by the Indian population to be served by such organization) and which includes the maximum participation of Indians in all phases of its activities. 25 U.S.C. 1603(26), referencing 25 U.S.C. 450b(1).

All organizations claiming non-profit status must provide proof with the application (a current valid IRS tax exemption certificate or a copy of 501(c)(3) form).

While multiple submissions from the same area or region will be reviewed, only one submission from any urban Indian organization or Tribal organization will be accepted, and only one award will be made to any one area or region. Organizations in the same area are encouraged to share resources in order to produce one collaborative proposal, rather than competing with each other.

All of the individual I/T/U hospital- or clinic-based dental programs to be served must be listed in the proposal. All programs within the defined area or region that will not be served must be listed also.

**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 Requirements*

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

#### *3. Other Requirements*

- If the application budget exceeds 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 for this or other reasons, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

- Continuation awards will be issued annually based on satisfactory performance evaluated and documented as described herein, documented progress toward goals and objectives, availability of funding, and the evolving needs of the IHS.

#### *Proof of Non-Profit Status*

Nonprofit urban organizations must submit a copy of the 501(c)(3) certificate as proof of non-profit status. 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.

**Signed Tribal resolution**—A signed Tribal resolution from each of the Indian Tribes served by the project must accompany the electronic application submission. An Indian Tribe or Tribal organization that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities.

**Draft Tribal resolutions** are acceptable in lieu of an official signed resolution and *must* be submitted along with the electronic application submission prior to the official application deadline date or prior to the start of the Objective Review Committee (ORC) date. However, an official signed Tribal resolution must be received by the DGM prior to the beginning of the Objective Review. If an official signed resolution

is not received by the Review Date listed under the Key Dates section on page one of this announcement, the application will be considered incomplete and ineligible.

The official signed resolution can be mailed to the DGM, Attn: Mr. John Hoffman, Grants Management Specialist (GMS), 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852. Applicants submitting Tribal resolutions after or aside from the required online electronic application submission must ensure that the information is received by the IHS/ DGM. It is highly recommended that the documentation be sent by a delivery method that includes delivery confirmation and tracking. Please contact Mr. Hoffman GMS, by telephone at (301) 443-2116 prior to the review date regarding submission questions.

Files illustrating a limited selection of work products such as pamphlets or handouts produced by existing support centers or through similar initiatives can be appended.

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 instruction for this announcement can be found at <http://www.grants.gov> or [https://www.ihs.gov/dgm/index.cfm?module=dsp\\_dgm\\_funding](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 of Application Submission*

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms
  - SF-424, Application for Federal Assistance.
  - SF-424A, Budget Information—Non-Construction Programs.
  - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).

- Project Narrative (must be single spaced and not exceed 7 pages for each of the four components listed).
    - 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.
    - Tribal Resolution or Tribal Letter of Support (Tribal Organizations only).
    - 501(c)(3) Certificate (if applicable).
    - Biographical sketches for all Key Personnel.
    - Contractor/Consultant resumes or qualifications and scope of work.
    - Disclosure of Lobbying Activities (SF-LLL).
    - Certification Regarding Lobbying (GG-Lobbying Form).
    - Copy of current Negotiated Indirect Cost rate (IDC) agreement, required in order to receive IDC.
    - Organizational chart (optional).
    - 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:** The project narrative should be a separate Word document that is no longer than seven 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 each part of the narrative and place all responses and required information under the correct sections (noted below), or they shall not be considered or scored. This project narrative will assist the ORC in becoming familiar with the applicant's activities and accomplishments prior to this grant award. If the narrative exceeds the page limit, only the first seven pages will be reviewed. The seven page limit for the narrative does not include the standard forms, abstract, Tribal resolutions, table

of contents, budget, budget justifications, biographical sketches of key personnel, 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.

The project narrative is limited to 7 pages total.

#### Part A: Program Information (2 Pages Maximum)

##### Section 1: Needs

Describe the needs of both the field programs you propose to serve, and the patients these programs served. Upon what information do you base these observations?

Describe how you will monitor these evolving needs in the future. Briefly describe the current structure and resources of your current program. If you are proposing the creation of a new support center, briefly describe the envisioned structure and resources.

#### Part B: Program Planning and Evaluation (3 Pages Maximum)

##### Section 1: Program Plans

Describe the direction your proposed support center plans to take, including how significant services will be provided to the dental field programs, and how you plan to improve the oral health of American Indians/Alaska Natives (AI/ANs) through the guidance and services you offer. State your overarching goals for the five-year funding period. Include a summary of timelines for proposed key services and anticipated measurable improvements to oral health.

##### Section 2: Program Evaluation

Describe how you will monitor the continuing appropriateness and evaluate the effectiveness of services provided relative to the evolving needs of the field dental programs. Describe how you will evaluate and document improvements to the oral health of AI/ANs associated with the guidance and services you provide to field programs.

#### Part C: Program Report (2 Pages Maximum)

##### Section 1: Major accomplishments

Describe significant accomplishments with respect to oral health outcomes or other outcomes over the past 24 months.

##### Section 2: Major activities

Describe significant accomplishments with respect to services provided over the past 24 months. If you are proposing the creation of a new support center, and hence have no history of recent accomplishments, so state.

**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. The budget narrative should match the scope of work described in the project narrative. The page limitation should not exceed five pages.

To these three sections the applicant is encouraged to add a brief budget narrative. The budget narrative is not considered part of the project narrative, and is not counted toward the seven page maximum length of the latter. It too is in the form of an overview for the reviewers. A budget outline or spreadsheet in conjunction with a brief narrative documents anticipated expenditures in detail sufficient for reviewers to match significant line items to project activities and goals. While there is no firm maximum allowable length to this presentation, a budget spreadsheet accompanied by approximately one or two pages of narrative or justification is envisioned.

#### Additional Information

Provide a cover page that labels the submission as a "Proposed Dental Preventive and Clinical Support Center" for one or more identified IHS areas or a defined geographic region. Include contact information for one primary author or contact, and contact information for one alternate contact.

Provide a project abstract (not to exceed one page), providing the synopsis of "who, what, when, where, why, and a general description of total associated costs."

Provide a table of contents to correspond with numbered pages of the narrative and attachments. Format outlined in the table of contents and used for the proposal is discretionary. However, a format for the application narrative similar to the outline of the scoring criteria herein utilizing labels or "signposts" that enable reviewers to easily locate the sections of the proposal being evaluated and scored is suggested.

Content of the application should relate directly to the overarching emphasis of the support center project, to improve the oral health of AI/AN people, and to provide support and technical assistance to I/T/U dental programs for:

- Clinical dental programs
- community-based preventive initiatives
- clinic-based preventive programs
- regional and national initiatives.

Applications proposing services to proportionately greater numbers of

I/T/U dental programs within an area or region will gain a competitive advantage over proposals outlining services to relatively few I/T/U dental programs per Area or region. Applicants should strive to provide services to all individual dental programs within a defined area or region.

Technical information regarding the support centers project, including clarification of any unclear information herein, may be obtained from the program official: Dr. Patrick Blahut, Division of Oral Health, (301) 443-4323, or email him at [patrick.blahut@ihs.gov](mailto:patrick.blahut@ihs.gov).

### 3. Submission Dates and Times

Applications must be submitted electronically through [Grants.gov](http://www.Grants.gov) by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. [Grants.gov](http://www.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](http://www.Grants.gov) Customer Support via email to [support@grants.gov](mailto: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 ([Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov)), DGM Grant Systems Coordinator, by telephone 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](http://www.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](http://www.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](mailto:GrantsPolicy@ihs.gov) with a copy to [Tammy.Bagley@ihs.gov](mailto: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., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

### 4. Intergovernmental Review

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

### 5. Funding Restrictions

- Pre-award costs are not allowable in conjunction with this grant application.
- 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.
- Funds may be used for new activities to accomplish the objectives of your support center.
- Funds may be used to pay for consultants, materials, resources, travel, and associated expenses to implement and evaluate intervention activities outlined in your proposal.
- Funds may not be used for diagnostic testing, patient rehabilitation, pharmaceutical purchases, facilities construction, lobbying, or routinely for direct patient care.
- Each dental support center grant or award shall not exceed \$250,000 per year, or a total of \$1,250,000 for five years.
- While support centers are encouraged to collaborate with each other, no more than one grant will be awarded to each area or geographic locale, and no area or geographic locale will be directly served by more than one support center.

### 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://](http://www.Grants.gov)

[www.Grants.gov](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 Catalog of Federal Domestic Assistance 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](mailto:Grants.gov) Support directly at: [support@grants.gov](mailto: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](http://www.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](mailto:GrantsPolicy@ihs.gov) with a copy to [Tammy.Bagley@ihs.gov](mailto: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](http://www.Grants.gov) as the registration process for SAM and [Grants.gov](http://www.Grants.gov) could take up to fifteen working days.
- Please use the optional attachment feature in [Grants.gov](http://www.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 DOH will notify the applicant that the application has been received.

- Email applications will not be accepted under this announcement.

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

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

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act") to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its UEI 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 to 5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3 to 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](https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics).

#### **V. Application Review and Selection Information**

The application narrative expands upon the project narrative, telling your reviewers in detail what you propose to do and accomplish. The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each of the five sections are noted in parentheses. The seven page project narrative allowed per each of the four components page narrative should include only the first year of activities. This application narrative is limited to the first nineteen pages maximum. If an application narrative exceeds twenty-six pages (seven for the project narrative and nineteen for the application narrative), only the first twenty-six pages will be reviewed and scored. 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 65 points is required for funding.

The IHS DOH considers the criteria, comments and scores of reviewers very carefully. The IHS DOH makes final decisions concerning awarding grants based on geographic balance and diversity of services and interventions throughout the nationwide program.

For applicant organizations that have been direct or indirect recipients of prior dental support centers funding, DOH will evaluate the level of correspondence between actual achievements and the specific strategies and deliverables described in the previously funded proposals.

Throughout the narrative, maintain a focus on the two primary goals of the support centers:

(1) Provide support and technical assistance to Area and field programs for:

- Clinical dental programs
- community-based preventive initiatives
- clinic-based preventive programs, and
- regional and national initiatives.

(2) Improve the oral health of AI/ANs. Document these improvements.

#### *1. Criteria*

A. Introduction and Need for Assistance (2 Pages Maximum, 10 Points Maximum)

Applicants will justify the need for a support center. Applicants will discuss needs in their area or region not likely to be addressed, and oral health outcomes not likely to be attained, if not for the services and guidance of a support center.

Centers will periodically assess the needs of the dental programs served. In order to be responsive to the perceived needs of the dental personnel throughout an area or region, perceived needs must be systematically assessed. Initial and periodic recurring structured needs assessments or other appraisals of perceived needs of the dental personnel to be served are essential. Successful proposals will either document the assessed and perceived needs of area dental personnel, or outline how area needs will be assessed.

a. Proposed new centers and existing centers without a comprehensive assessment of needs less than three years old will outline a plan for an assessment to be completed within the first nine months of the grant funding period, by July 1, 2016.

b. Proposed continuing or currently existing centers with a comprehensive assessment of perceived needs less than three years old will summarize the results of that survey, and outline a plan for a future assessment to be completed within the first three years of the five-year funding cycle, by October 1, 2018.

c. Ongoing, frequent assessment of perceived needs through feedback from a steering committee or other means is highly recommended.

B. Project Objective(s), Work Plan and Approach (5 Pages Maximum, 30 Points Maximum)

Centers will provide technical assistance and resources for local and area clinic-based and community-based oral health promotion/disease prevention initiatives.

Centers will produce and document positive health outcomes. Consistent with the HHS Secretary's emphasis upon funding tied to value and outcomes, the activities, guidance, and services provided by the support centers to area dental programs will be

structured such that they lead to meaningful and measurable improvements in the oral health status of AI/AN patients. Proposals must describe practical and feasible plans that will foster improved health outcomes, and will include specific plans for periodic objective evaluation of the outcomes of these efforts by objective reviewers with no conflict of interest. The dental support centers will improve the oral health of AI/ANs through their services, guidance, and collaboration with the IHS dental program.

Consistent with the HHS Secretary's emphasis upon funding tied to value and outcomes, proposals are strongly encouraged, but not required, to include as part of their strategy an evaluation of the oral health outcomes of IHS dental program practices and initiatives from recent years. Proposals including such evaluation will enjoy a competitive advantage. This assessment of outcomes could include any of several measures of value obtained for services delivered, including actual patient outcomes. Examples of patient outcomes include but are not limited to measurable improvements to oral health or an assessment of the need for additional restorative care within an intermediate time frame following the initial provision of care.

Centers will send an appropriate representative or representatives to national support centers project meetings convened by IHS HQ DOH. Such meetings will be convened periodically, approximately once every three years, as deemed necessary by IHS HQ DOH. The DOH will communicate closely with all centers about the perceived need for any meeting. All centers are expected to reserve sufficient funds to send a representative or representatives to these meetings.

Centers will promote the coordination of research, demonstration projects, and studies relating to the causes, diagnosis, treatment, control, and prevention of oral disease. This may be addressed through the collection, analysis, and dissemination of data or other methodology deemed appropriate by the IHS HQ DOH. This may also be addressed through support given to field programs engaged in demonstration projects.

Centers are encouraged to collaborate with IHS HQ DOH on national initiatives such as efforts to reduce Early Childhood Caries, promoting and facilitating the annual Basic Screening Surveys (BSS), promotion of the goals of the Government Performance and Results Act (GPRA) and achieving

annual GPRA targets, or other national initiatives.

Centers will share information and work products proactively with other areas and other support centers. Large quantities of work products need not be provided free of charge, but examples of work products will be shared widely.

Centers are encouraged to provide technical assistance and resources for local and area clinical programs.

Centers are encouraged to communicate frequently with their Area Dental Officer (ADO), in order to coordinate activities and initiatives closely. Centers are encouraged to amplify impact and increase effectiveness through detailed communication and coordinated efforts with the ADO.

Centers are encouraged to provide technical assistance and resources for continuing education opportunities, including but not limited to, annual area-wide meetings for area dental personnel.

Centers are encouraged to address Early Childhood Caries on a local level, area-wide level, or regional basis. Interventions must include an evaluation process assessing outcomes in addition to process (that is, an assessment of actual prevalence of disease over the course of the intervention, in addition to counts or assessments of activities or services and products provided to clientele). Such evaluation does not require original data, if appropriate other data such as, for example, BSS data are available.

#### C. Program Evaluation (5 Pages Maximum, 30 Points Maximum)

Centers will evaluate their ongoing efforts and progression toward goals and objectives in an objective manner, utilizing reviewers without conflicts of interest.

Centers will assess and document changes to selected oral health outcomes over time.

Centers will adhere to an annual reporting cycle, providing three quarterly reports and one annual report at the end of the fourth quarter to the project officer. Annual reports from the support centers must describe: (1) Services and support provided to the dental program; (2) the methods used to influence oral health; (3) details of the evaluative methodology; and (4) progress toward goals and objectives, and (5) the oral health outcomes status. Funding beyond year one of the five year noncompetitive renewal cycle will be contingent upon documentation provided by an objective evaluator of ongoing evaluation and progress

deemed suitable by the DOH program official.

Centers funded via grants will meet any additional reporting requirements of the IHS Grants Management Office.

#### D. Organizational Capabilities, Key Personnel and Qualifications (2 Pages Maximum, 10 Points Maximum)

Centers will document organizational capabilities, and how these capabilities will be used to address program goals and objectives.

Centers will list key personnel, and describe their qualifications. If a key position is not currently occupied, a description of key desired qualifications of the individual to be recruited will suffice.

#### E. Categorical Budget and Budget Justification (5 Pages Maximum, 20 Points Maximum)

Centers will provide a detailed proposed budget for the initial year of operation.

Centers will justify all line items or categories of proposed expenditures within their proposed budgets by providing a line item budget justification and narrative relating to the attainment of specific goals and objectives.

Centers will justify all proposed expenditures that relate to the attainment of specific goals and objectives of their grant project. If the application requests indirect costs, applicants are required to submit their current Indirect Costs Rate Agreement and explain briefly what these funds are used for.

#### *Multi-Year Project Requirements (If Applicable)*

The application narrative should focus on the first year of activities, services, and outcomes. Projects requiring a second, third, fourth, and/or fifth year must include a brief project narrative and budget (a maximum of one additional page total per year) addressing the developmental plans and evolving goals for each additional year of the project.

#### *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 (see Section VI-3, "indirect costs").

- Organizational chart.
- Map 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 Federal and non-Federal reviewers appointed by the IHS DOH to review, score, and make recommendations concerning 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 may be notified by DGM, via email, to outline minor missing components such as audit documentation or key contacts needed for an otherwise complete application. All missing information or documentation must be provided to DGM on or before the due date listed in the email of notification of missing required documents.

## 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 is initiated by the DGM in the grants 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 receive a score less than the recommended funding level for approval, 65, 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 strengths and weaknesses of their application. The IHS program office will also provide contact information as requested 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 1 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

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

- The criteria as outlined in this program announcement.
- Administrative Regulations for Grants:
  - Uniform Administrative Requirements HHS Awards, located at 45 C.F.R Part 75.
  - C. Grants Policy:
    - HHS Grants Policy Statement, Revised 01/07.
  - D. Cost Principles:
    - Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.
  - E. Audit Requirements:
    - Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

### 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 budget period. If the current rate is not on file with the DGM at the time of the 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](http://www.doi.gov/ibc/services/Indirect_Cost_Services/index/cfm). For questions regarding the indirect cost policy, 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; or (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. Annual reports must be submitted electronically via GrantSolutions; quarterly progress reports are submitted to the program official. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. See the "Agency Contacts" list for the systems contact information.

#### A. Progress and Annual Reports

Program progress reports are required quarterly, by December 31, March 31, and June 30 each year. These deadlines may be revised by consensus of all grantees and the program official. Progress reports must be submitted via Grant Notes in GrantSolutions, with an email notifying the program official they have been submitted. 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. An annual report must be submitted within

90 days of expiration of the annual 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 reported on all required reports.

#### 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. The IHS Term of Award is applicable to all IHS grants and cooperative agreements issued on or after October 1, 2010, with a \$25,000 subaward obligation dollar threshold for any specific reporting period. Additionally, all new discretionary IHS awards where the project period is made up of more than one budget period, the project period state date was October 1, 2010 or after, and 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 requirement. 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](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 programmatic issues may be directed to:

Patrick Blahut, DDS, MPH, Deputy Director, IHS DOH, 801 Thompson Ave., Suite 332, Rockville, MD 20852, Phone: (301) 443-4323, Email: [patrick.blahut@ihs.gov](mailto:patrick.blahut@ihs.gov).

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

John Hoffman, Senior Grants Management Specialist, 801 Thompson Ave., Suite TMP 360, Rockville, MD 20852, Phone: (301) 443-2116, Fax: (301) 443-9602, Email: [john.hoffman@ihs.gov](mailto:john.hoffman@ihs.gov).

3. Questions on systems matters may be directed to:

Paul Gettys, Grant Systems Coordinator, 801 Thompson, Suite TMP 360, Rockville, MD 20852, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, Email: [paul.gettys@ihs.gov](mailto: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: May 22, 2015.

**Robert G. McSwain,**

*Acting Director, Indian Health Service.*

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**BILLING CODE 4165-16-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Indian Health Service

##### Notice of Request for Information

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The Indian Health Service (IHS) is seeking broad public input as it begins efforts to advance and promote the health needs of the American Indian/Alaska Native (AI/AN) Lesbian, Gay, Bisexual, and Transgender (LGBT) community.

**DATES:** To be assured consideration, comments must be received at one of

the addresses provided below, no later than 5:00 p.m. Eastern Daylight Time on July 6, 2015.

**ADDRESSES:** Electronic responses are encouraged and may be addressed to [lisa.neel@ihs.gov](mailto:lisa.neel@ihs.gov). Written responses should be addressed to: Indian Health Service, 801 Thompson Avenue, Suite 300, Rockville, MD 20852. Attention: LGBT Feedback.

**FOR FURTHER INFORMATION CONTACT:** Lisa Neel, MPH, Indian Health Service HIV/AIDS Program, (301) 443-4305.

**SUPPLEMENTARY INFORMATION:** In the summer of 2015, the IHS will hold a public meeting to garner information from individuals on AI/AN LGBT health issues. The goal of this meeting will be to gain a better understanding of the health care needs of AI/AN LGBT individuals so that IHS can implement health policy and health care delivery changes to advance the health care needs of the AI/AN LGBT community. The agency is seeking to increase community access to and engagement with IHS leadership and secure a legacy of transparent, accountable, fair, and inclusive decision-making specific to AI/AN LGBT people.

This request for information seeks public comment on several key dimensions of the health needs of the AI/AN LGBT community, including but not limited to the following questions:

a. Are there effective models and best practices surrounding the health care of the LGBT community that should be considered for replication? Please include rationale for their use in the IHS service population.

b. What are the specific measures that could be used to track progress in improving the health of LGBT persons?

c. How can IHS better engage with stakeholders around the implementation of improvements?

d. Are there gaps or disparities in existing IHS services offered to LGBT persons?

e. What additional information should the agency consider while developing plans to improve health care for the LGBT community?

Dated: May 22, 2015.

**Robert G. McSwain,**

*Acting Director, Indian Health Service.*

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