

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific guidances available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a revised draft guidance for generic rifaximin oral tablets.

FDA initially approved new drug application (NDA) 021361 for XIFAXAN (rifaximin oral tablets) 200 milligram (mg) in May 2004 and NDA 022554 for XIFAXAN (rixaximin oral tablets) 550 mg in March 2010. In November 2011, FDA issued a draft guidance for

industry on generic 200 mg rifaximin oral tablets; in February 2012, FDA issued a draft guidance for industry on generic 550 mg rifaximin oral tablets. We are now consolidating these two guidances and issuing a single revised draft guidance for industry on generic rifaximin oral tablets ("Draft Guidance on Rifaximin").

In May 2008, Salix Pharmaceuticals, Inc. (Salix), manufacturer of the reference listed drugs XIFAXAN 200 mg and XIFAXAN 550 mg, submitted a citizen petition requesting that FDA refrain from approving any ANDA referencing XIFAXAN 200 mg unless certain conditions were satisfied, including conditions related to demonstrating BE. In October 2016, Baker & Hostetler LLP submitted a citizen petition on behalf of Salix requesting that FDA refrain from approving any ANDA referencing XIFAXAN 200 mg or XIFAXAN 550 mg unless certain conditions were satisfied, including conditions related to demonstrating BE. FDA has reviewed the issues raised in these citizen petitions and is responding to the citizen petitions separately in the dockets for those citizen petitions (Docket Nos. FDA-2008-P-0300 and FDA-2016-P-3418, available at <https://www.regulations.gov>).

The revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on "Draft Guidance on Rifaximin." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidances at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS-2017-IHS-HLY-0001; Catalog of Federal Domestic Assistance Number: 93.933]

Healthy Lifestyles in Youth Project; Proposed Single Source Competing Continuation Cooperative Agreement with National Congress of American Indians

Key Dates

Application Deadline Date: May 15, 2017

Review Date: May 22-26, 2017

Earliest Anticipated Start Date: September 1, 2017

Proof of Non-Profit Status Due Date: May 15, 2017

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventive Services, Division of Diabetes Treatment and Prevention, is accepting applications for a single source competing continuation cooperative agreement with the National Congress of American Indians (NCAI) for the purpose of continued implementation of the Healthy Lifestyles in Youth Project in selected Native American Boys and Girls Clubs of America. This program is authorized under the authority of the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001; and the Public Health Service Act, as amended, 42 U.S.C. 241(a). This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.933.

Background

This program promotes healthy lifestyles among American Indian and Alaska Native (AI/AN) youth using the curriculum "Together Raising Awareness for Indian Life" (TRAIL) among selected Boys and Girls Club sites. Under this cooperative agreement, IHS proposes to enter into a collaborative effort/initiative with NCAI, because of their unique experience partnering with the IHS and Boys and Girls Clubs of America (BGCA) in successfully establishing this program, as well as, their overall expertise and experience in addressing and evaluating healthy lifestyle techniques in AI/AN youth.

Purpose

This work will continue to support the IHS mission to improve the health of AI/AN youth through health

promotion and health education programs. The purpose of this IHS cooperative agreement is to focus on addressing healthy lifestyle development, emphasizing nutrition and physical activity for AI/AN children and youth 7 through 11 years of age. The long term goal is to prevent or delay the onset of obesity and related diseases such as type 2 diabetes. NCAI will continue partnering work with selected Native American Boys and Girls Club sites to: (a) Provide health and physical education programs; (b) help youth achieve and maintain healthy lifestyles through participation in fitness programs; (c) help youth to acquire a range of physical skills; and (d) help youth develop a sense of teamwork and cooperation.

These early intervention strategies provide evidence based opportunities to reduce and/or halt the increasing trend of obesity and diabetes among youth and young adults. Clubs that develop a health promotion program that includes the TRAIL curriculum may help curtail the effects of unhealthy eating behaviors and lack of physical activity that can lead to obesity, diabetes, and other chronic diseases later in life. The TRAIL curriculum was developed to provide information on good nutrition and to promote physical activity among youth participating in Native American Boys and Girls Clubs. TRAIL is a three month (12 lessons) program that provides youth with a comprehensive understanding of healthy lifestyles in order to prevent diabetes. Woven throughout the program are self-esteem and prevention activities. Participants

draw from Tribal traditions and history to learn about nutrition, healthy food choices, media influences, and the impact of diabetes. Clubs also implement the Nike Let Me Play and SPARK physical activity programs to foster Club-wide participation in fun activities and games for 60 minutes every day. TRAIL emphasizes the importance of teamwork and community service. Members engage in service projects to improve healthy lifestyles in their communities, including starting community gardens to connect youth to their food source and organizing community-wide physical fitness events.

Since the inception of the program in 2003, TRAIL has been implemented at over 79 Native American Boys and Girls Club of America sites located in 17 states. There are currently over 50 sites in more than 15 states participating in the program.

The overall results show improvement in participant knowledge of diabetes, health, and healthy food choices, as well as, improved fitness and level of physical activity. To support this project, NCAI will select and assist at least 50 Native American Boys and Girls Club sites to establish and implement this curriculum project. Boys and Girl Club sites that are located outside of Tribal communities will not be considered by the grantee. The Boys and Girls Club sites selected by the grantee may use IHS grant funds to provide services to eligible IHS beneficiaries only. The grantee will be expected to: Provide technical consultation; train; monitor; evaluate; as

well as provide funds to support these activities.

Single Source Justification

NCAI is identified as the single source for the award, based on their successful record of performance with this project, their unique relationship and work in developing and maintaining: (1) Relationships with the Boys and Girls Clubs organization and staff, (2) being able to successfully implement the TRAIL program curriculum, (3) the project Web site information, and (4) the project data and evaluation systems. The award is for a continuation of activities identified. These activities, the collaboration with the network of Native American Boys and Girls Clubs, and the evaluation process have been effectively undertaken by NCAI for the past 13 years. The process, as well as the outcomes, have been deemed very successful and clearly supportive of Agency initiatives for youth.

The grantee has documented success in (1) recruiting and working with sites, (2) developing and implementing the TRAIL curriculum at the sites, (3) implementing a method for collecting data from the sites, (4) fostering collaboration between sites and their communities, and (5) collecting and reporting data that demonstrates participant increases in health and food choice knowledge and increases in participant physical activity and level of fitness. Some of the data for the most recent years of the current 5 year cooperative agreement (2013–2016) are as follows:

2013–2014 Data

Number of AI/AN Children Participating in the Curriculum, Training, and Strength and Endurance Challenges.	1,403 (610 males/716 females—77 gender not identified).
Age Range of Children Participating	ages 4–14 (representing grades 2–6, with 96% of children in grades 2–5).
Achieving Goal of 60 Minutes/Day of Physical Activity—Club Wide (Children in TRAIL plus Other Boys and Girls Club Children).	Average of 2,970 Children at 54 Sites Performed an Average of 74.15 Minutes/Day of Physical Activity = 3,683 hours of Physical Activity/Day Nationwide (128 Days in the Reporting Period).
Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores—82% of Clubs had post test scores of >70% compared to 3% with pre-test scores >70%).	

2014–2015 Data

Number of AI/AN Children Participating in the Curriculum, Training, and Strength and Endurance Challenges.	1332 (590 males/669 females—63 gender not identified).
Age Range of Children Participating	ages 6–11 (representing grades K–6, with 89% of children in grades 2–5).
Achieving Goal of 60 Minutes/Day of Physical Activity—Club Wide (Children in TRAIL plus Other Boys and Girls Club Children).	Average of 2,450 Children at 50 sites Performed an Average of 74.15 Minutes/Day of Physical Activity = 3,038 hours of Physical Activity/Day Nationwide (128 Days in the Reporting Period).
Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores—85% of Clubs had post test scores of >70% compared to 9% with pre-test scores >70%).	

2015–2016 Data

Number of AI/AN Children Participating in the Curriculum, Training, and Strength and Endurance Challenges.	1,256 Children (606 boys, 627 girls, 23 gender not identified).
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Age Range of Children Participating	6–12 years (representing grades K–6 with 87% of children in grades 2–5).
Achieving Goal of 60 Minutes/Day of Physical Activity—Club Wide (Children in TRAIL plus Other Boys and Girls Club Children).	Average of 2,907 Children Performed an Average of 63.9 Minutes/Day of Physical Activity = 3,038 hours of Physical Activity/Day Nationwide (128 Days in the Reporting Period).

Program test scores indicate: (a) Increased knowledge about diabetes, (b) increased physical activity, and (c) increased ability to identify healthier food options (increase in post test scores vs. pre test scores—82% of Clubs had post test scores of >70% compared to 18% with pre-test scores >70%).

The TRAIL curriculum and subsequent revision were developed by the grantee as a part of earlier agreements. If there is a need to update the curriculum and subsequently implement the revised curriculum, it will be more efficiently and cost effectively performed as the grantee is very familiar with the existing curriculum and the implementation.

The grantee uses a sub-contractor (First Pic) to develop and implement the evaluation and reporting process for individual sites and for analysis and reporting of aggregated data. This unique and program specific evaluation system has been beneficial to sites and to IHS. All of the tools for using this system have been made available via the Native American Boys and Girls Clubs Web site—<http://www.naclubs.org/index.php/club-programs/trail-diabetes-prevention>.

The grantee (NCAI) has been effective, timely, and cooperative, and has consistently achieved or exceeded requirements of the previous agreement. NCAI and First Pic are uniquely qualified to continue to receive the award and provide the identified program activities based on their history with this project and project sites, their evaluation system, their knowledge of the curriculum, and their documented performance achievements with the sites under the previous agreement.

All Department of Health and Human Services (HHS) and IHS policies, regulations, grants management and programmatic reporting requirements from the prior funding segment remain in effect under this renewal announcement unless otherwise stated or modified in the terms and conditions of the new Notice of Award.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2017 is \$1,250,000. The average award amount will be \$1,250,000 annually. 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

One award will be issued under this program announcement.

Project Period

The project period is for five years and will run consecutively from September 1, 2017 to August 31, 2022.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. However, 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

- (1) Identify a core group of IHS staff to work with the grantee in providing technical assistance and guidance.
- (2) Meet with the grantee to review grantee work plan and provide guidance on implementation and data collection tools.
- (3) Participate in quarterly conference calls. Work with the grantee to showcase the results of this project by publishing on shared Web sites as well as in jointly authored publications.

B. Grantee Cooperative Agreement Award Activities

- (1) Develop a written plan for the planning, implementation, and evaluation of this project to include selecting at least 50 sites as agreed upon with the IHS. This task will be completed within 30 days from award and approved by the IHS.
- (2) Develop selection criteria for new sites, announce, evaluate, and select sites. Sites must submit documentation verifying they serve only AI/AN youth

from eligible IHS beneficiaries as a requirement for selection by the grantee. A start-up planning meeting with new sites will be conducted within two months of each site’s initial selection and award.

(3) Plan and facilitate an orientation and training meeting for new sites within two months of selection. Submit agenda, training goals and objectives, and participant list to IHS within one month of completion of each orientation session.

(4) Update TRAIL curriculum as needed/directed and implement use.

(5) Develop, in consultation with the IHS, the implementation and technical assistance plan for the coordination of the selected Boys and Girls Club sites. Submit criteria to the IHS for approval. Grantee will continue work with sites to develop and report measurements for assessment of physical activity and nutrition behaviors among club participants.

(6) Each site will implement the TRAIL program, emphasizing healthy behaviors such as physical activity and nutrition. Each program plan will also include a parent component describing approaches for involving the families of participants.

(7) Each site will implement Physical Activity Strength and Endurance Challenges three times, six to eight weeks apart. Physical activity data will be collected and summarized.

(8) Grantee will promote and facilitate local, state, and national partnerships for the purpose of establishing or enhancing program support that involves increasing physical activity and good nutrition for the Tribally-managed Boys and Girls Club sites. This includes but is not limited to establishing other partners such as American Indian-Alaska Native Program Branch (AI-ANPB) of Head Start Programs, Wings of America, United National Indian Tribal Youth, Inc. (UNITY), Tribal colleges, BGCA, Tribal organizations, local community health providers and other private organizations as appropriate.

(9) Grantee will continue to implement current evaluation processes in consultation for the TRAIL project. At a minimum, the evaluation will include:

(a) Training attendance (gender, age, grade level);

(b) pre- and post- tests to assess participant knowledge;

(c) monthly activity logs from each site on the physical activity portion of their program. Daily data to be collected includes the date, number of minutes of physical activity, and number of children participating; and

(d) information/log on parent and family participation in education and activity programs, community involvement and partnerships.

(10) Submit collated and summarized data to the IHS. Work with the IHS in drafting an evaluation summary at the end of the project period for publication. Submit collated and summarized data and project evaluation summaries to all sites. Provide a minimum of annual reports (feedback) to each site on how their data compare to data (mean, median, and range) from other selected sites.

(11) Provide ongoing technical support to the sites for the duration of the initiative. Provide training and technical assistance in all forms, *i.e.*, on-site, on-line, by phone, and mail. The planning, design and delivery of training and technical assistance will support the local organization's long-term planning and outreach efforts. The training will be customized based on sites' capability and experience. Technical assistance will also be provided on program planning and implementation. Collaborate with IHS to provide services to club sites. Maintain records and reports.

(12) Provide technical consultation to the sites in developing a written work plan, with measurable goals, objectives and activities.

(13) Establish a formal agreement with Native American Boys and Girls Club sites which involves minimal fiscal assistance but substantial technical support to make sure clubs successfully implement the TRAIL program.

(14) Submit to the IHS a written work plan and report describing each site's demographics, information on the number of youth in the eligible age range in the catchment area, the number that attend the Boys and Girls Clubs regularly, and the number served by this project, goals, objectives, activities, partnerships, and proposed outcomes.

(15) Provide IHS written quarterly reports on the evaluation outcomes, activity reports at each site, any parent involvement activities and other participation, description of the community partnerships, and other activities as appropriate

(16) Conduct quarterly conference calls with IHS to review project status.

III. Eligibility Information

1. Eligibility

The award is offered as a single source competing continuation cooperative agreement with the NCAI. NCAI is identified as the single source for the award, based on their successful record of performance with this project, their unique relationship and work in developing and maintaining: (1) Relationships with the Boys and Girls Clubs organization and staff, (2) being able to successfully implement the TRAIL program curriculum, (3) the project Web site information, and (4) the project data and evaluation systems. The award is for a continuation of activities identified. NCAI is the sole organization eligible to apply for competing continuation funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the Healthy Lifestyles in Youth grant in order to receive funding under this announcement.

2. Cost Sharing or Matching

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

3. Other Requirements

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

Proof of Non-Profit Status

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

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

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can

be found at <http://www.Grants.gov> or <http://www.ihs.gov/dgm/funding/>.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443-2114 or (301) 443-5204.

2. Content and Form Application Submission

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

- 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 30 pages).
 - Project Narrative (must be single-spaced and not exceed 30 pages).
 - Background information on the organization.
 - Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
 - 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).
 - Documentation of current Office of Management and Budget (OMB) Financial Audit (if applicable).
- Acceptable forms of documentation include:
- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
 - Face sheets from audit reports. These can be found on the FAC Web site: <https://harvester.census.gov/facdissem/Main.aspx>.
- #### Public Policy Requirements
- All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.
- #### Requirements for Project and Budget Narratives
- A. Project Narrative:* This narrative should be a separate Word document

that is no longer than 30 pages and must: Be single-spaced, 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 familiar with the applicant's activities and accomplishments prior to this possible cooperative agreement award. If the narrative exceeds the page limit, only the first 30 pages will be reviewed. The 30 page limit for the narrative does not include the work plan, standard forms, Tribal resolutions, table of contents, budget, budget justifications, narratives, and/or other appendix items.

There are three parts to the narrative: Part A—Introduction and Need for Assistance; Part B—Work Plan; and Part C—Organizational Capabilities. See below for additional details about what must be included in the narrative.

Part A: Introduction and Need for Assistance 10 Page Limitation

Please provide description of the need for assistance with offering this program. Applicant should demonstrate knowledge of: Health concerns for AI/AN youth; health promotion activities in Tribal communities such as BGCA; and working with Tribes and Tribal organizations.

Part B: Work Plan 10 Page Limitation Section 1: Program Plans

This section should demonstrate the soundness and effectiveness of the proposal. The work plan should be designed to describe how and when the sites will be selected; describe how the sites will be trained on the curriculum and provided technical assistance; and describe how sites will be supported for a physical activity program with the equipment and participant incentives.

Section 2: Program Evaluation

Describe the plan for collecting data, monitoring, and assuring quality and quantity of data and the plan for evaluating and reporting program results.

Part C: Organizational Capabilities 10 Page Limitation

Describe the broader capacity of the organization to complete the project

outlined in the work plan, including (1) identification and bios for key personnel responsible for completing tasks; (2) description of the structure of the organization and chain of responsibility for successful completion of the project outline in the work plan; (3) description of financial and project management capacity, including information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed; (4) description of national experience in providing administrative and support services to Tribal youth organizations, education agencies and other Tribal programs for the benefit of AI/AN children and youth and Tribal communities. Indicate experience in national partnerships or national support efforts on behalf of AI/AN communities especially as it pertains to health concerns; (5) description of equipment and space available for use during the proposed project; and (6) description of specialized experience working with Tribal Boys and Girls Club sites and the TRAIL curriculum program.

B. Budget Narrative: 30 Page Limit

This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable allowable, allocable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. This section should provide a clear estimate of the project program costs and justification for expenses for the entire cooperative agreement period. The budget and budget justification should be consistent with the tasks identified in the work plan.

3. Submission Dates and Times

Applications must be submitted electronically through *Grants.gov* by 11:59 p.m. Daylight Saving Time (DST), on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact *Grants.gov* Customer Support via email to support@grants.gov or at (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If

problems persist, contact Mr. Gettys (Paul.Gettys@ihs.gov), DGM Grant Systems Coordinator, by telephone at (301) 443-2114 or (301) 443-5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

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.

If the applicant needs to submit a paper application instead of submitting electronically through *Grants.gov*, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). A written waiver request must be sent to GrantsPolicy@ihs.gov with a copy to Robert.Tarwater@ihs.gov. The waiver must (1) be documented in writing (emails are acceptable) before submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process.

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 Mr. Tarwater 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., DST 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. Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or <http://www.Grants.gov> registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact *Grants.gov* Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting *Grants.gov*, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to fifteen working days.
- Please use the optional attachment feature in *Grants.gov* to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this funding announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The DGM will download the application from *Grants.gov* and provide necessary copies to the appropriate agency officials. Neither the DGM nor IHS Office of Clinical and Preventive Services, Division of Diabetes Treatment and Prevention 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, you may 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 sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at <https://www.sam.gov> (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at <https://www.sam.gov>.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: <http://www.ihs.gov/dgm/policytopics/>.

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 30 page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance 20 points

This section should demonstrate knowledges of health concerns and issues regarding AI/AN youth, health promotion activities in Tribal communities, and working with Tribes and Tribal organizations.

B. Work Plan 30 points

This section should demonstrate a sound and effective annual work plan that will support accomplishment of deliverables and milestones of the TRAIL project. The work plan should be designed to:

- Describe how and when the sites will be selected;
- Describe how the sites will be trained on the curriculum and provided technical assistance;
- Describe the plan for collecting data, monitoring, and assuring quality and quantity of data;
- Describe the plan for evaluating and reporting;
- Describe how sites will be supported for a physical activity program.

C. Organizational Capabilities 40 points

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

- Describe the structure of the organization.
- Describe the ability of the organization to manage the proposed project and include information

regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

- Describe what equipment (*i.e.*, phone, Web sites, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased throughout the agreement.

- List and provide bios for key personnel who will work on the project. The section should demonstrate knowledge in:

- Financial and project management.
- Nationwide experience in providing administrative and support services to Tribal youth organizations, education agencies and other Tribal programs for the benefit of children and youth.

- AI/AN youth and Tribal communities and indicate experience in national partnerships or national support efforts on behalf of AI/AN communities especially as it pertains to health concerns.

- Experience working with Tribal Boys and Girls Club sites and the TRAIL curriculum program.

D. Categorical Budget and Budget Justification 10 points

This section should provide a clear estimate of the project program costs and justification for expenses for the entire cooperative agreement period. The budget and budget justification should be consistent with the tasks identified in the work plan.

- Categorical budget (Form SF 424A, Budget Information Non Construction Programs) completing each of the budget periods requested.

- Narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allow ability.

- Indication of any special start-up costs.

- Budget justification should include a brief program narrative for the third and fourth years.

- 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.

Multi-Year Project Requirements (if applicable)

Projects requiring a second, third, fourth, and/or fifth year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans 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.

- Map of area identifying project location(s).

- Additional documents to support narrative (*i.e.*, data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.*, budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

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

is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval (60), 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 submitted. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page (SF-424) of the application. 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 2017 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

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

2. Administrative Requirements

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

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

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

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

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

E. Audit Requirements:

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

3. Indirect Costs

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

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

4. Reporting Requirements

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

The reporting requirements for this program are noted below.

A. Progress Reports

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

B. Financial Reports

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

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

C. Federal Sub-Award Reporting System (FSRS)

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

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

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

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

D. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

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

The HHS Office for Civil Rights (OCR) also provides guidance on complying with civil rights laws enforced by HHS. Please see <http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html>; and <http://www.hhs.gov/civil-rights/index.html>. Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/civil-rights/for-individuals/disability/index.html>. Please contact the HHS OCR for more information about obligations and prohibitions under Federal civil rights laws at <http://www.hhs.gov/ocr/about-us/contact-us/headquarters-and-regional-addresses/index.html> or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

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

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

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

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

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

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

Submission is required for all applicants and recipients, in writing, to

the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

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

AND

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

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

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Ms. Carmen Licavoli Hardin, Deputy Director, Division of Diabetes Treatment and Prevention, Indian Health Service (HQ), 5600 Fishers Lane, Mail Stop: 08N34 A&B, Rockville, MD 20857, Telephone: 1-844-IHS-DDTP (1-844-447-3387), Fax: 301-594-6213, Email address: diabetesprogram@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Donald Gooding, Senior Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Telephone: 301-443-2298, Fax: 301-594-0899, Email address: Donald.Gooding@ihs.gov.

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Phone: 301-443-2114; or the DGM main line 301-443-5204, Fax: 301-594-0899, Email: Paul.Gettys@ihs.gov.

VIII. Other Information

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

Dated: March 6, 2017.

RADM Chris Buchanan,

Assistant Surgeon General, USPHS, Acting Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS-2017-IHS-PHN-0001: Catalog of Federal Domestic Assistance Number: 93.933]

Community Based Model of PHN Case Management Services (Behavioral Health)

AGENCY: Division of Nursing, Public Health Nursing, Indian Health Service, HHS.

Key Dates

Application Deadline Date: May 15, 2017

Review Date: May 26-June 5, 2017

Earliest Anticipated Start Date: June 15, 2017

Proof of Non-Profit Due Date: May 15, 2017

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Clinical and Preventive Services (OCPS), Division of Nursing Services/Public Health Nursing (PHN), is accepting applications for grant awards for the Community Based Model of PHN Case Management Services (Behavioral Health). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2011; the Public Health Service Act, as amended, 42 U.S.C. 241; and the Indian Health Care Improvement Act, as amended, (IHCIA), 25 U.S.C. 1653(c). This program is described in the Catalog