

Consolidated Continuing Appropriations Act, 2013, and Section 119 of the Continuing Appropriations Act, 2014; *Office of Management and Budget Memorandum M-12-12*: All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences. Specifically: The total amount of funds provided in this award/cooperative agreement that were spent for "Conference X", must be reported in final detailed actual costs *within 15 days of the completion of the conference*. Cost categories to address should be: (1) *Contract/Planner*, (2) *Meeting Space/Venue*, (3) *Registration Web site*, (4) *Audio Visual*, (5) *Speakers Fees*, (6) *Non-Federal Attendee Travel*, (7) *Registration Fees*, (8) *Other*.

D. Federal Subaward Reporting System (FSRS)

This award may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR Part 170.

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

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the Grants Management Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

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

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to:

Mr. Chris Buchanan, Director, 801 Thompson Avenue, Suite 220, Rockville, MD 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, E-Mail: Chris.Buchanan@ihs.gov.

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

Mr. John Hoffman, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Telephone: (301) 443-5204, Fax: (301) 443-9602, Email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to:

Mr. Paul Gettys, Grant Systems Coordinator, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, 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: August 19, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014-20113 Filed 8-22-14; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

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

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on August 6, 2014 for the FY 2014 National Indian Health Outreach and Education II—Methamphetamine

Suicide Prevention Intervention/ Domestic Violence Prevention Initiative Program Announcement and Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome. The notice contained incorrect dates.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Buchanan, Director, Office of Direct Service and Contracting Tribes, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, MD 20852, Telephone (301) 443-1104. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 6, 2014, in FR Doc. 2014-18531, on page 45817, in the first column, under the heading Key Dates, the correct dates should read as follows:

Application Deadline Date:

September 6, 2014.

Review Date: September 8, 2014.

Earliest Anticipated Start Date:

September 15, 2014.

Proof of Non-Profit Status Due Date:

September 6, 2014.

Dated: August 16, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014-20108 Filed 8-22-14; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

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

Announcement Type: New Limited Competition.

Funding Announcement Number: HHS-2014-IHS-NIHOE-0003.

Catalog of Federal Domestic Assistance Number: 93.933

Key Dates

Application Deadline Date:

September 25, 2014.

Review Date: September 26, 2014.

Earliest Anticipated Start Date:

September 30, 2014.

Proof of Non-Profit Status Due Date:

September 25, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Direct Service and Contracting Tribes (ODSCT) and the Office of Resource Access and Partnerships (ORAP) is accepting cooperative

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

Background

The NIHOE III programs carry out health program objectives in the American Indian/Alaska Native (AI/AN) community in the interest of improving the quality of and access to health care for all 566 Federally-recognized Tribes including Tribal governments operating their own health care delivery systems through self-determination contracts and compacts with the IHS and Tribes that continue to receive health care directly from the IHS, 25 U.S.C. 1603(29), which is not limited to organizations that are receiving funding from the IHS under the IHCIA. This program addresses health policy and health program issues and disseminates educational information to all AI/AN Tribes and villages. These awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates on the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as for the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and the Department of Health and Human Services (HHS) based on Tribal input through a broad based consumer network.

Purpose

The purpose of this IHS cooperative agreement announcement is to encourage national Indian organizations, IHS, and Tribal partners to work together to conduct ACA/IHCIA training and technical assistance throughout Indian Country. Under the Limited Competition NIHOE Cooperative Agreement program, the overall program objective is to improve Indian health care by conducting

training and technical assistance across AI/AN communities to ensure that the Indian health care system and all AI/ANs are prepared to take advantage of the new health insurance coverage options which will improve the quality of and access to health care services, and increase resources for AI/AN health care. The goal of this program announcement is to coordinate and conduct training and technical assistance on a national scale for the 566 Federally-recognized Tribes and Tribal organizations on the changes, improvements and authorities of the ACA and IHCIA and the health insurance options available to AI/AN through the Health Insurance Marketplace.

Limited Competition Justification

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

II. Award Information

Type of Award

Cooperative Agreement.

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

A. Two entities collaborating and applying as one entity.

B. Two entities applying separately to accomplish appropriately divided program activities.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2014 is approximately \$600,000. Individual award amounts are anticipated to be \$400,000 and \$200,000, respectively if awarded to two entities applying separately; \$600,000 if awarded to two entities applying as one entity. Further details are provided in the applicable section components. The amount of funding available for both competing and continuation awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Optional approach allowed for applying for the \$600,000:

1. First Option: If two entities are collaborating to apply for \$600,000 as one entity, then funding will be divided as follows: One entity will be allowed \$400,000. The second entity will be allowed \$200,000 for carrying out the remainder of the activities.

2. Second Option: If two entities are applying separately, then one entity will apply for \$400,000. The second entity will apply for the remaining \$200,000.

Anticipated Number of Awards

Approximately one to two awards will be issued under this program announcement.

Project Period

The project period will be for one year and will run consecutively from September 30, 2014 to September 29, 2015.

Cooperative Agreement

Cooperative agreements awarded by HHS are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be

responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) The IHS assigned program official will work in partnership with the awardee in all decisions involving strategy, hiring of consultants, deployment of resources, release of public information materials, quality assurance, coordination of activities, any training activities, reports, budget and evaluation. Collaboration includes data analysis, interpretation of findings and reporting.

(2) The IHS assigned program official will approve the training curriculum content, facts, delivery mode, pre- and post-assessments, and evaluation before any materials are printed and the training is conducted.

(3) The IHS assigned program official will review and approve all of the final draft products before they are published and distributed.

B. Grantee Cooperative Agreement Award Activities

The awardee must comply with relevant Office of Management and Budget (OMB) Circular provisions regarding lobbying, any applicable lobbying restrictions provided under other law, and any applicable restriction on the use of appropriated funds for lobbying activities.

(1) Foster collaboration across the Indian health care system to encourage and facilitate an open exchange of ideas and open communication regarding training and technical assistance on the ACA and IHCA provisions.

(2) Conduct training and technical assistance on the ACA and IHCA and the changes and requirements that will affect AI/ANs either independently or jointly via a partnership as described previously. The purpose of this IHS cooperative agreement announcement is to encourage national and regional Indian organizations and IHS and Tribal (I/T) partners to work together to conduct ACA/IHCA training and technical assistance throughout Indian Country. The project goals are three-fold for the IHS and the selected entities:

(i) Materials—Develop and disseminate (upon IHS approval) training materials about the ACA/IHCA impact on the Indian health care system including: Educating consumers on the health care insurance options available, educating the I/T system on the process for enrollment (with a special focus on the Certified Application Counselor (CAC) and Hardship Waiver

requirements) and eligibility determinations, and maximizing revenue opportunities.

(ii) Training—Develop and implement an ACA/IHCA implementation training plan and individual training sessions aimed at educating all Indian health care system stakeholders on health care system impact and changes, specifically implementation in the different types of Marketplaces, the role of Health Insurance Marketplace assisters (special emphasis on CAC), and the Hardship Waiver for AI/ANs. Collaborate and partner with other national organizations to identify ways to take full advantage of the health care coverage options offered through the Health Insurance Marketplace.

(iii) Technical Assistance—Provide technical assistance to I/T on the ACA/IHCA implementation. Work with these entities to assess the training needs, identify innovations in ACA/IHCA implementation, and promote the dissemination and replication of solutions to the challenges faced by I/T in implementing the ACA/IHCA.

Summary of Tasks To Be Performed

The project will conduct the following major activities:

1. Develop a national coordination strategy for the project to ensure a shared vision and mission amongst all partners and convene partners on a regular basis;

2. Develop and implement a communications strategy to:

a. Educate AI/ANs on the available health coverage options under the ACA;

b. Educate Tribal leaders and Tribal employers on the health insurance options under the ACA including the Small Business Health Options Program (SHOP) and tribal self-insurance; and

c. Focus on the needs of Direct Services Tribes, including: Providing policy review and analysis of health care issues, training Tribal leaders on the health insurance options available under the ACA and sharing outreach and education best practices among Direct Services Tribes.

3. Develop a technical assistance plan and provide technical assistance to NIHOE partners, Tribal leaders, Tribal employers and Direct Services Tribes on ACA/IHCA implementation across the Indian health care system.

4. Work with NIHOE partners and Direct Service Tribes to achieve economies of scale and reduce duplication of AI/AN training and outreach and education materials, including the development of cross-cutting ACA/IHCA content specific to the Indian health care system.

5. Work with NIHOE partners and Direct Service Tribes to enhance collaboration with other Federal agency programs, local, state, Tribal and national partners.

The following key components need to be addressed in the work plan: Develop a national coordination strategy for the project to ensure a shared vision and mission amongst all partners and convene partners on a regular basis.

Applicants should describe plans for addressing the following:

Outreach and Education

- The awardee shall coordinate and develop a multiple strategy education and outreach training approach for I/T that reaches the widest audience possible in a timely fashion, appropriately tailored to the needs of AI/AN communities.

- The awardee shall conduct regional and national ACA/IHCA education and outreach focusing on four consumer groups: (1) Consumers; (2) Tribal Leadership and Membership; (3) Tribal Employers; and (4) Indian Health Facility Administrators.

- The awardee shall provide measurable outcomes and performance improvement activities for ACA/IHCA outreach and education actions.

- The awardee shall share information, innovative ideas, challenges and solutions, and provide progress reports.

Policy Analysis

- The awardee shall monitor and review ACA review metrics that provide indicators of AI/AN participation in Marketplace plans and I/T participation as network providers in the Marketplace and disseminate ACA policy information at National Conferences and through IHS Advisory Committees.

- The awardee shall review and coordinate ACA/IHCA policy recommendations and strategies by the I/T.

- The awardee shall ensure the training curriculum content addresses all new regulations and operations for implementing the ACA/IHCA requirements.

Information Sharing and Technical Assistance

- The awardee shall collaborate and coordinate to ensure training and educational materials are widely distributed for Tribal Leaders and frontline enrollment personnel.

- The awardee shall conduct and record monthly meetings with NIHOE national and regional principals to share information and provide progress reports.

- The awardee shall plan communication around key moments or events through the grant period to increase education efforts.

- The awardees shall identify I/T audiences that may have challenges with enrollments and tailor outreach efforts accordingly.

- The awardees shall develop communications vehicles to showcase positive impact stories of I/T with ACA/IHCIA.

- The awardee shall develop and provide templates for tribal, IHS, and community outreach and education.

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

- The awardee will provide postings on ACA/IHCIA outreach and education related information for appropriate Web site.

- The awardee will develop and/or maintain a comprehensive list of ACA/IHCIA outreach and education program development and business practice guidelines for use by I/T programs.

- The awardee shall act as a resource broker and identify subject matter experts to conduct trainings and technical assistance for implementation of the ACA enrollments.

- The awardee shall provide quarterly articles for I/T newsletters focusing on the successful impact and outcomes of ACA/IHCIA in Tribal communities, available resources, and funding opportunities.

- The awardee shall meet with stakeholders to identify their needs from a community level and access to education and outreach materials (i.e., pharmacy bags, palm cards, posters, payroll inserts, etc.).

Training

- The awardee shall re-evaluate all ACA/IHCIA training material available for AI/AN, shall present findings to IHS, and mutually decide on new materials.

- The awardee shall record training sessions and make available to the I/T and AI/AN community on the Web sites of the national Indian organizations and partners.

- The awardee shall provide focused ACA/IHCIA education that translates in everyday language explaining the benefits of the laws. The awardee, because involvement of community based partners and local leadership from all I/T levels is an important factor in the success of any enrollment

process, shall develop modified training briefs for Tribal Health Directors, Chief Executive Officers, Health care professionals, and Tribal Leaders to assist with outreach efforts.

- The awardee shall provide ongoing AI/AN consumers training on tools developed for state Marketplace implementation.

Reporting

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

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

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

- The awardee shall conduct and record monthly meetings with NIHOE national and regional principals to share information and provide progress reports.

- The awardee shall assess and provide measurable outcomes and performance improvement activities for ACA/IHCIA outreach and education actions both quantitative and qualitative.

1. The awardee shall monitor and track I/T facility enrollment data and identify challenges and opportunities for outreach and education activities.

2. Identify successes and gaps in enrollment and develop future enrollment campaigns.

Deliverables

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

2. Participation on outreach and education conference calls identified by the IHS assigned program official, evidenced by meeting agenda and minutes as needed.

3. Report of outcomes at conferences (meeting booths, workshops and/or presentations provided):

- (a) National Advisory Committee conference calls and meetings

- (b) IHS Area conference calls

- (c) IHS Area and national webinars

- (d) Other AI/AN national conferences

4. Completed programmatic reviews of semi and annual progress reports of Outreach and Education projects, in order to identify projects that require technical assistance. [**Note:** This review is not to replace IHS review of Outreach and Education programs. The programmatic reviews to be conducted by grantee are secondary reviews intended solely to identify programs in need of technical assistance.]

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

5. Copies of educational and practice-based information provided to I/T programs (electronic form and one hard copy).

6. Copies of all promotional and educational materials provided to I/T programs and other projects (electronic form and one hard copy).

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

8. Copies of all articles published (electronic form and one hard copy). Submit semi-annual and annual progress reports to ORAP and ODSCT, due no later than 30 days after the reporting cycle, attaching any necessary documentation. For example: Meeting minutes, correspondence with I/T/U programs, samples of all written materials developed including brochures, news articles, videos, and radio and television ads to adequately document accomplishments.

9. The awardee will submit a deliverable schedule to the program official not later than 30 days after the start date.

The IHS will provide guidance and assistance as needed. Copies of all deliverables must be submitted to the IHS ODSCT; IHS ORAP; and IHS Senior Advisor to the Director.

A. Collaboration and Coordination To Ensure Training and Materials Are Widely Distributed

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

2. Record, track, and coordination information sharing activities (enrollments, trainings, information shared, meetings, updates, etc.) with IHS Offices: ODSCT, ORAP and 11 IHS

Area Offices including Albuquerque Area, Bemidji Area, Billings Area, California Area, Great Plains Area, Nashville Area, Navajo Area, Oklahoma Area, Phoenix Area, Portland Area and Tucson Area.

3. Record training sessions and describe how they will be made available on the Web sites of the national Indian organizations and partners.

4. Describe how to ensure the training curriculum content addresses all new regulations implementing the ACA and IHCA requirements.

5. Participate in monthly meetings with NIHOE national and regional principals to share information and provide progress reports.

6. Provide ongoing training on tools developed for state Marketplace implementation.

7. Because involvement of community based partners and local leadership from all I/T levels is an important factor in the success of any enrollment process, develop modified training briefs for, and other community leaders to assist with outreach efforts.

B. Work Plan

1. Provide a Work Plan that describes the sequence of specific activities and steps that will be used to carry out each of the objectives, including updates about progress implementing the ACA.

2. Report the number of CAC staff trained and employed, network contracts, additional consumers enrolled in Medicaid, CHIP or Marketplace plan, and in network contracts with a QHP in the Marketplace using the QHP addendum. Describe outreach and enrollment activities, partnerships, and planning.

3. Include a detailed time line that links activities to project objectives for the 12-month budget period.

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

5. Describe communication methods with partners.

C. Evaluation

1. Provide a plan for assessing the achievement of the project's objectives and for evaluating changes in the specific problems and contributing factors.

2. Identify performance measures by which the project will track its progress over time.

D. Budget

Provide a functional categorically itemized budget and program narrative

justification that supports accomplishing the program objectives, activities, and outcomes within the timeframes specified.

III. Eligibility Information

1. Eligibility

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

Eligible applicants that can apply for this funding opportunity are national Indian organizations.

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

Eligible entities must have demonstrated expertise in the following areas:

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

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

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

- Supporting improved health care in Indian Country.

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

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

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

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If

deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Proof of Non-Profit Status

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

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

IV. Application and Submission Information

1. Obtaining Application Materials

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

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

2. Content and Form Application Submission

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
 - SF-424, Application for Federal Assistance.
 - SF-424A, Budget Information—Non-Construction Programs.
 - SF-424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed ten pages for each of the two components).
 - 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 Letters of Support (Optional).
- Letter of Support from Organization's Board of Directors.
- 501(c)(3) Certificate (if applicable).

- Position Descriptions of Key Personnel.
- Resumes of Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation of current OMB A–133 required Financial Audit (if applicable).

Acceptable forms of documentation include:

- Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- Face sheets from audit reports. These can be found on the FAC Web site: <http://harvester.census.gov/sac/dissemin/accessoptions.html?submit=Go+To+Database>

Public Policy Requirements

All Federal-wide public policies apply to IHS grants 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 ten pages for each of the two components for a total of 20 pages: \$600,000 to conduct ACA/IHCLIA Education and Outreach Training and Technical Assistance. Project narrative 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" by 11" paper.

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

There are three parts to the narrative: Part A—Program Information; Part B—

Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Part A: Program Information (4 Page Limit for Each Component)

Section 1: Needs

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

Part B: Program Planning and Evaluation (4 Page Limit for Each Component)

Section 1: Program Plans

Describe fully and clearly the direction the national Indian organization plans to address the NIHOE III requirements, including how the national Indian organization plans to demonstrate improved health education and outreach services to all 566 Federally-recognized Tribes. Include proposed timelines as appropriate and applicable.

Section 2: Program Evaluation

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

Part C: Program Report (2 Page Limit for Each Component)

Section 1: Describe major accomplishments over the last 24 months. Identify and describe significant program achievements associated with the delivery of quality health outreach and education. Provide a comparison of the actual accomplishments to the goals established for the project period, or if applicable, provide justification for the lack of progress.

Section 2: Describe major activities over the last 24 months. Please provide an overview of significant program activities and impacts (meaningful changes made), associated with the delivery of quality health outreach and education. This section should address significant program activities and impacts including those related to the accomplishments listed in the previous section.

B. Budget Narrative: This narrative must describe the budget requested and match the scope of work described in

the project narrative. The page limitation should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12:00 a.m. 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 will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via email to support@grants.gov or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys, DGM (Paul.Gettys@ihs.gov) at (301) 443–2114. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically via 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 a clear justification for the need to deviate from the required electronic grants submission process. Written waiver request can be sent to Tammy.Bagley@ihs.gov. Once the waiver request has been approved, the applicant will receive a confirmation of approval and the mailing address to submit the application. Paper applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed or considered further for funding. The applicant will be notified via email of this decision by the Grants Management Officer of 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.
- 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 receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

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

Please be aware of the following:

- Please search for the application package in <http://www.Grants.gov> by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: support@grants.gov or (800) 518-4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a

request in writing (emails are acceptable) to GrantsPolicy@ihs.gov with a copy to Tammy.Bagley@ihs.gov. Please include a clear justification for the need to deviate from the standard electronic submission process.

- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the ODSCT will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

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

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

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on subawards. Accordingly, all IHS grantees must notify potential first-tier subrecipients that no entity may receive a first-tier subaward unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to

enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

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

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

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten page narrative for each component should include only one year of activities. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 60 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (15 Points)

1. Describe the individual entity's and/or partnering entities' (as applicable) current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (i.e., Federally funded, State funded, etc.), any memorandums of agreement with other

National, Area or local Indian health board organizations, HHS' agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information, information regarding technologies currently used (i.e., hardware, software, services, etc.), and identify the source(s) of technical support for those technologies (i.e., in-house staff, contractors, vendors, etc.). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area health boards, etc. [historical collaboration].

2. Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, etc.

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

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

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

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

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

1. Proposed project objectives must be:

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

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

- a. Provide the action steps on a timeline for accomplishing the proposed project objective(s).
- b. Identify who will perform the action steps.
- c. Identify who will supervise the action steps taken.
- d. Identify what tangible products will be produced during and at the end of the proposed project objective(s).
- e. Identify who will accept and/or approve work products during the duration of the proposed project and at the end of the proposed project.

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

g. Include evaluation activities planned.

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

- a. Educational requirements.
- b. Desired qualifications and work experience.
- c. Expected work products to be delivered on a timeline.
- d. If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

C. Program Evaluation (15 Points)

Each proposed objective requires an evaluation component to assess its progression and ensure its completion. Also, include the evaluation activities in the workplan. Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work-plan and activities of the project.

1. For outcome evaluation, describe:

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

c. At what intervals will data be collected.

d. Who will collect the data and their qualifications.

e. How the data will be analyzed.

f. How the results will be used.

2. For process evaluation, describe:

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

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

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

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

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

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

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

1. Describe the organizational structure of the organization.

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

3. Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed project.

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

E. Categorical Budget and Budget Justification (10 Points)

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

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

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

Appendix Items

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- 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. Applicants will be notified by DGM, via email, to outline minor missing components (i.e., budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

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

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (<https://www.grantsolutions.gov>). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

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

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved", but were not funded due to lack of funding, will have their applications held by DGM for a period of 1 year. If additional funding becomes available during the course of FY 2015, the approved application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the Project Director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

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

A. The criteria as outlined in this Program Announcement.

B. Administrative Regulations for Grants:

- 45 CFR Part 92, Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments.

- 45 CFR Part 74, Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and other Non-profit Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- 2 CFR Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A-87).

- 2 CFR Part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).

E. Audit Requirements:

- OMB Circular A-133, Audits of States, Local Governments, and Non-profit Organizations.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current

rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <https://rates.psc.gov/> and the Department of Interior (Interior Business Center) http://www.doi.gov/ibc/services/Indirect_Cost_Services/index.cfm. For questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

4. Reporting Requirements

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

The reporting requirements for this program are noted below.

A. Progress Reports

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

B. Financial Reports

Federal Financial Report FFR (SF-425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management

Service, HHS at: <http://www.dpm.psc.gov>. It is recommended that the applicant also send a copy of the FFR (SF-425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

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

C. Federal Subaward Reporting System (FSRS)

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

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

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a \$25,000 subaward obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) the project period start date was October 1, 2010 or after and (2) the primary awardee will have a \$25,000 subaward obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the Grants Management Grants Policy Web site at: https://www.ihs.gov/dgm/index.cfm?module=dsp_dgm_policy_topics.

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

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Mr. Chris Buchanan, Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, Telephone: (301) 443-1104, Fax: (301) 443-4666, email: Chris.Buchanan@ihs.gov.

2. Questions on grants management and fiscal matters may be directed to: Mr. John Hoffman, Grants Management Specialist, DGM, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852, Telephone: (301) 443-5204, Fax: (301) 443-9602, email: John.Hoffman@ihs.gov.

3. Questions on systems matters may be directed to: Mr. Paul Gettys, Grant Systems Coordinator, DGM, 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852, Phone: (301) 443-2114; or the DGM main line (301) 443-5204, Fax: (301) 443-9602, 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: August 19, 2014.

Yvette Roubideaux,

Acting Director, Indian Health Service.

[FR Doc. 2014-20109 Filed 8-22-14; 8:45 am]

BILLING CODE 4165-16-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

AGENCY: Eunice Kennedy Shriver

National Institute of Child Health and Human Development (NICHD), National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) hereby announces the Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics for 2014. The BPCA, reauthorized in 2012 as part of the Food and Drug Safety and Innovation Act, seeks to improve the level of information on the safe and effective use of pharmaceuticals used to treat children. The BPCA requires that the NIH identify the drugs of highest priority for study in pediatric

populations and publish a list of drugs/needs in pediatric therapeutics. This notice fulfills the requirement to publish that list.

SUPPLEMENTARY INFORMATION: The pediatric medical community, the public health community, and government agencies have recognized multiple gaps in knowledge regarding the use of therapeutics in children, including the correct dose, appropriate indications, side effects, and safety concerns of pharmaceuticals in the short and long term. These gaps have frequently resulted in inadequate labeling for pediatric use and in wide-spread off-label use of prescription drugs in children. Off-label use of a drug substantially limits the ability to gain clinical information of the drug product, such as appropriate dosing of a drug, changes in drug metabolism and response during growth and development, and important short- and long-term effects.

The NICHD is working with the Food and Drug Administration (FDA), other federal agencies, and various nonprofit and commercial organizations to address the knowledge gaps that exist in pediatric therapeutics and to promote an increase in evidence-based data about medications used in children.

Update on BPCA Prioritization

The BPCA requires that the NIH, in consultation with the FDA and experts in pediatric research, identify the drugs and therapeutic areas of highest priority for study in pediatric populations. The BPCA authorizes the NIH to establish a program for pediatric drug testing and development and to publish a list of drugs/needs in pediatric therapeutics. The BPCA program consists of a series of clinical trials in various therapeutic areas, which may be based on proposed pediatric study requests (PPSRs) submitted to the FDA and/or on written requests (WR) received from the FDA. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents that need further study. It is organized by therapeutic areas, which are general categories of conditions, diseases, settings of care, or populations with multiple therapeutic needs. The first priority list of off-patent drugs needing further study under the 2002 BPCA legislation was published in January 2003 in the **Federal Register** (FR Vol. 68, No. 13; Tuesday, January 21, 2003; 2789-2790). The most recent priority list was published October 24, 2012; all **Federal Register** Notices can be found on the BPCA Web site: <http://bpca.nichd.nih.gov/prioritization/>