

Protect Children and Adolescents,” at 21 CFR part 1140. The final regulations apply to manufacturers, distributors, and retailers who make, distribute, or sell cigarettes or smokeless tobacco products.

Beginning on June 22, 2010, these Federal regulations will prohibit retailers from selling cigarettes, cigarette tobacco, or smokeless tobacco to persons under the age of 18, and will require retailers to verify the age of all customers under the age of 27 by checking a photographic identification that includes the bearer's date of birth.

FDA is announcing the availability of a draft guidance document, which is intended to help small businesses comply with the requirements of the new regulations. FDA is soliciting comments on the draft guidance document and may amend the guidance document periodically as a result of comments received.

## II. Significance of Guidance

FDA is issuing this draft guidance document consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on “Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents.” It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IV. Electronic Access

An electronic version of the guidance document is available on the Internet at <http://www.regulations.gov> and <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: June 7, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-13922 Filed 6-7-10; 11:15 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Office of Public Health Support; Division of Planning, Evaluation & Research Native American Research Centers for Health (NARCH) V Evidence-Based Interventions for Tribal Communities Against AIDS and STDs

*Announcement Type:* Competitive Supplements.

*Funding Announcement Number:* HHS-2010-IHS-NARCH-0001.

*Catalog of Federal Domestic Assistance Number:* 93.933.

#### Key Dates

*Application Deadline Date:* June 30, 2010.

*Review Date:* July 15, 2010.

*Earliest Anticipated Start Date:* September 1, 2010.

#### I. Funding Opportunity Description

##### Statutory Authority

The Indian Health Service (IHS) is accepting competitive supplemental grant applications from existing Native American Research Centers for Health (NARCH) V grantees to establish and test Evidence-Based Interventions for Tribal Communities Against Acquired Immune Deficiency Syndrome (AIDS) and sexually transmitted diseases (STDs). This program is authorized under: the Snyder Act, 25 U.S.C. 13, the Public Health Service Act, 42 U.S.C. 241 as amended, and the Indian Health Care Improvement Act, 25 U.S.C. 1602(a)(b)(16). This program is described in the Catalog of Federal Domestic Assistance under 93.933.

##### Background

The NARCH V program supports partnerships between Federally recognized American Indian and Alaska Native (AI/AN) Tribes or Tribal organizations (including national and area Indian health boards, and Tribal colleges meeting the definition of a Tribal organization as defined by 25 U.S.C. 1603(d) or (e)) and institutions that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH). Due to the

complexity of factors contributing to the health and disease of AI/ANs, and to their health disparities compared with other Americans, the collaborative efforts of the agencies of the Department of Health and Human Services (HHS) and the collaboration of academic researchers and AI/AN communities are needed to achieve significant improvements in the health status of AI/AN people. To accomplish this goal, in addition to objectives set by the Tribes, Tribal organizations or Indian health boards, the IHS NARCH program pursues the following program objectives:

To develop a cadre of AI/AN scientists and health professionals—Opportunities are needed to develop more AI/AN scientists and health professionals engaged in research, and to conduct biomedical, clinical, behavioral and health services research that is responsive to the needs of the AI/AN community and the goals of this initiative. Faculty/researchers and students at each proposed NARCH develop investigator-initiated, scientifically meritorious research projects, including pilot research projects, and will be supported through science education projects designed to increase the numbers of, and to improve the research skills of, AI/AN investigators and investigators involved with AI/ANs.

To enhance partnerships and reduce distrust of research by AI/AN communities—Recent community-based participatory research suggests that AI/AN communities can work collaboratively in partnership with health researchers to further the research needs of AI/ANs. Fully utilizing all cultural and scientific knowledge, strengths, and competencies, such partnerships can lead to better understanding of the biological, genetic, behavioral, psychological, cultural, social, and economic factors either promoting or hindering improved health status of AI/ANs, and generate the development and evaluation of interventions to improve their health status. Community distrust of research and researchers will be reduced by offering the Tribe greater control over the research process.

##### Purpose

The purpose of this opportunity for supplementing the existing NARCH V program is to determine the feasibility of adapting and implementing HIV evidence based interventions (EBI)(s) supported by the CDC for effective use within AI/AN communities, and to contribute to, and document, a successful adaptation and implementation

in this new population and setting. Baseline and ongoing data will be collected and analyzed to help determine future effectiveness of the adapted EBI(s).

While new treatments continue to offer hope for individuals infected with HIV, behavioral interventions shown to reduce HIV risk behaviors remain one of the most powerful tools in curbing the AIDS epidemic. Health departments (HDs) and community-based organizations (CBOs) increasingly are required to implement EBI(s) or public health strategies (PHSs) that have been shown to be efficacious for HIV prevention in rigorous controlled trials. Unfortunately, the development of new EBI(s) is a resource-intensive process that has not progressed as quickly as the epidemiology of the disease. One method to accelerate this process is by adapting existing EBI(s) supported by CDC's previous Prevention Research Synthesis (PRS), Replicating Effective Programs (REP), and Diffusion of Effective Behavioral Interventions (DEBI) projects for new populations or settings. This announcement responds to concerns from the field and many AI/AN communities that existing EBI(s) do not address the focused HIV prevention needs of AI/ANs due, at least in part, to lack of cultural relevance and to the absence of effectiveness data for these interventions with respect to Tribal communities.

These supplements will facilitate the creation and testing of culturally adapted and evidence based interventions against AIDS and STDs. The methodology of Tribal or community based participatory research (T/CBPR) is expected to be the most effective approach to selecting, adapting and testing an existing EBI for deployment and maximal effectiveness in a given Tribal community. Effective T/CBPR partnerships can take years to develop, but the need for culturally relevant EBI(s) is urgent. Fortunately, a number of such partnerships have already been created under the NARCH program. These partnerships are an already existing T/CBPR infrastructure whose core purposes include the ability to help the Tribes respond to urgent research needs and opportunities, such as the object of this announcement.

Grantees will test the use of a T/CBPR adaptation model to assist agencies with the process of tailoring an existing prevention intervention, previously shown to be effective and catalogued by CDC, for use in different small or hard-to-access AI/AN population at risk for HIV infection. When adapting the EBI, the core elements that contributed to the efficacy of the original intervention will

be maintained, which will increase efficiency of adaptation. Each grantee's ability to successfully adapt, tailor, and implement their chosen intervention will be monitored and evaluated, and all operational processes will be documented.

*The nature of these projects will require collaboration to:* (1) Coordinate activities with the IHS Research Program and IHS National HIV Program and (2) acquire technical assistance from the IHS Research Program and the Capacity Building Branch (CBB) of the Division of HIV/AIDS Prevention (DHAP) at CDC.

Proposed activities that cover large populations and/or geographical areas that do not necessarily correspond with current IHS administrative areas are allowed. In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under: 1. *Recipient Activities*, and HHS will be responsible for conducting activities under 2. *HHS Activities*.

#### 1. Recipient Activities

- Conduct targeted research and literature review on the question of whether any of the existing EBI supported by CDC can be successfully adapted to an AI/AN population at risk.
- Identify the unique risk behaviors and contextual factors that lead to an increased risk of HIV acquisition or transmission.
- Conduct pre-implementation phases of assessment, adaptation, tailoring of intervention, and IRB submission.
- Assess EBI(s) to determine their compatibility with the needs of the community and IHS capacity and resources. No EBI(s) are capable of addressing all of the identified risk behaviors and contextual factors in the selected population. NARCH partners will select those most suitable for adaptation and implementation (*i.e.*, the EBI that can be adapted to be most responsive to identified risk behaviors, contextual factors, and circumstances).
- Review adaptations to determine cultural proficiency.
- Conduct process evaluation to document an evidence base for the adaptations.
- Adapt and tailor selected interventions to meet the needs of the AI/AN population identified.
- Implement the adapted and tailored interventions.
- Evaluate the utility and effectiveness of the adaptation and tailoring of the intervention.
- Evaluate the effectiveness of the adapted and tailored intervention.

Compare the magnitude of behavioral/biologic change in the original and adapted interventions using measures from the original intervention with as little modification as possible (*i.e.* unprotected sex, condom negotiation, numbers of sex partners, etc).

- Collaborate with IHS national programs (IHS Research Program and IHS National HIV Program) per quarterly meetings (including use of telecommunications) and by providing data on a bi-annual basis, identifying and documenting best practices for developing and implementing interventions.
- Document the operational processes used during adaptation, tailoring, implementation and evaluation.
- Report to IHS Research Program. A three page mid-year progress report and no more than a ten-page summary annual assessment and evaluation at the end of each project year. The report should establish the impact and outcomes of various methods of adapting, tailoring and implementing the intervention.

#### 2. HHS Activities (IHS Research and HIV Programs and CDC)

- Provide funded NARCH with ongoing consultation and technical assistance to plan, implement, and evaluate each component of the comprehensive program as described under *Recipient Activities* above. Consultation and technical assistance will include, but not be limited to, the following areas:
  - (a) CDC will train grantee(s) to deliver the original intervention. Grantees trained in the original intervention will develop an adapted and tailored intervention training curriculum based on the original intervention training included in the REP intervention package. Grantees will train local staff.
  - (b) Provide oversight and technical assistance throughout adaptation, tailoring, implementation and evaluation. Awardees will implement the adapted intervention tailored to address the AI/AN population and locale.
  - (c) Analyze Data: Participate in analysis of data gathered from project activities; assist in reporting and disseminating results.
  - (d) Provide overall operational planning and program management.
    - Conduct site visits to assess program progress and mutually resolve problems, as needed.
    - Coordinate these activities with all IHS HIV activities on a national basis.
    - Coordinate with the CBB of DHAP at CDC to provide technical assistance related to the selection of the

appropriate EBI or PHS, cultural and linguistic adaptation of the intervention and supporting materials, and training of facilitators.

## II. Award Information

### Type of Awards

Competitive supplemental revisions to existing NARCH V awards.

### Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2010 is approximately \$1,800,000. Competing and continuation awards issued under this announcement are subject to the availability of funds. In the absence of funding, the agency is under no obligation to make awards funded under this announcement.

### Anticipated Number of Awards

Three supplements of \$600,000 per grantee are anticipated in FY 2010 under the existing NARCH V awards. Additional NARCH awards may be supplemented, if additional funds become available.

### Project Period

Projects will be funded for one annual budget period. There will be yearly continuation applications required. The continuation years will be pending funding and based on the following:

- Satisfactory progress.
- Availability of funds and agency capacity to sustain program(s).
- Continuing need for IHS to support the program (program priorities).

Awardees will be required to submit semi-annual cumulative progress reports, as described within this announcement and existing NARCH V Notices of Grant Award (NoA), as well as the Standard Form (SF) 2590 and a Progress Report, annually and financial statements as required in the PHS Grants Policy Statement, revised 0107. Forms are available at the following Web site <http://grants.nih.gov/grants/funding/2590/2590.htm>. The progress report should provide information about changes in the program and a summary report of any evaluations. These bi-annual reports will be closely monitored by the IHS staff to ensure that the grant is achieving the goals of the Office of HIV/AIDS Policy (OHAP) and the NARCH program.

## III. Eligibility Information

### 1. Eligibility

Eligible applicants are limited to current NARCH grantees with at least two years remaining of their current NARCH project period. Proof of eligibility status will be confirmed by

the IHS Research Program. No current grantees other than existing NARCH V grantees are expected to meet this remaining project period requirement.

### 2. Cost Sharing or Matching

The NARCH Program does not require matching funds or cost sharing.

### 3. Other Requirements

Letters of intent are not required under this announcement.

## IV. Application and Submission Information

### 1. Obtaining Application Materials

1. The application package and instructions can be requested from the NARCH Program Official, Reyes Building, 801 Thompson Avenue, Rockville, MD 20852 or by e-mail to [narch@ihs.gov](mailto:narch@ihs.gov). The National Institutes of Health (NIH) PHS 398 application instructions are available in an interactive format at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. Applicants must use the currently approved version of the PHS 398. For further assistance contact Mr. Paul Gettys Telephone (301) 443-2114, E-mail: [Paul.Gettys@ihs.gov](mailto:Paul.Gettys@ihs.gov). In any instance where the PHS 398 instructions are contradicted by this announcement, the instructions in this announcement must be followed. PHS 398 page limits should be followed as for NIH activity Code R21.

### 2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Application forms;
- PHS-398 Package <http://grants.nih.gov/grants/funding/phs398/phs398.html>;
- Documentation of current OMB A-133 required Financial Audit, if applicable. Acceptable forms of documentation include:

- E-mail 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/fac/dissemin/accessoptions.html?submit=Retrieve+Records>.
- Disclosure of Lobbying Activities (SF-LLL) (if applicable).

### Public Policy Requirements

All Federal-wide public policies apply to IHS grants with exception of the Discrimination policy.

### 3. Submission Dates and Times

Submit a typed and signed original application, including the Checklist,

and five (5) single-sided photocopies of the entire application (including Appendices and supporting documents) in one package to: Division of Grants Operations, Indian Health Service, Reyes Building, 801 Thompson Avenue, TMP 360, Rockville, MD 20852-1627 Attn: Mr. Roscoe Brunson, (zip code is unchanged for express/courier services), Telephone: (301) 443-5204 by no later than 5pm EDT on June 30, 2010.

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

### 4. Intergovernmental Review

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

### 5. Funding Restrictions

- Pre-award costs are not allowable under this announcement.
- 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. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

Applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a unique nine-digit identification number provided by D&B, which uniquely identifies business entities. The DUNS number is site specific; therefore each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://fedgov.dnb.com/webform> or by phone (866) 705-5711.

## V. Application Review Information

Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 65 points is required for funding. Points are assigned as follows:

### 1. Evaluation Criteria

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The narrative should include all prior years of activity; information for multi-year projects should be included as an appendix (see E. "Categorical Budget and Budget Justification") at the end of this section for more information. It should be well organized, succinct, and contain all

information necessary for reviewers to understand the project fully. You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified research objectives of the grant. Measures of effectiveness must relate to the purpose and goal stated in the "Funding Description" section of this announcement. Measures should include process and outcome information and contain both quantitative and qualitative data that measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation. The goals of this IHS-supported research are to advance the understanding of HIV/AIDS-related behavior and biological systems, improve the control and prevention of HIV/AIDS, and enhance community health and wellness. In the written comments, reviewers will be asked to evaluate the application and the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

#### A. Significance (10 Points)

a. Is the proposed selection process of the specific EBI to be implemented justified in terms of AI/AN risk, AI/AN behavior, and HIV or STD epidemiology? Are the proposed interventions and populations realistically matched in terms of behavioral determinants and risk behaviors? Is the applicant's selected AI/AN population either small with high HIV incidence or harder to gain access to (e.g. male-to-female transgender, men who have sex with other men, rural communities with high stigma, etc.)? Is the selected population HIV positive? If HIV has not yet been detected in the population, are there existing STD or blood-borne disease problems that suggest a fertile field for HIV dissemination if the virus were to enter the community?

b. If the aims of the application are achieved, how will scientific knowledge in AI/AN be advanced? What will be the effect of these studies on AI/AN communities and what will be the benefits to service providers and/or communities?

c. Define the project target population, identify their unique characteristics, and describe the impact of HIV and/or other STDs or blood-borne diseases on the population.

#### B. Research Objectives and Approach (40 Points)

Applicants should address the following research objectives in their application:

a. Process of selection, adaptation, tailoring and implementation of the EBI. One potential EBI may be selected to use as a tentative example in the application, to illustrate the approach that is planned by the applicant. However, if used, the example EBI should be justified for the anticipated population, either in terms of relevant theory or based on preliminary, preparatory T/CBPR activity such as meetings with Tribal officials, groups, Community Advisory Boards of the existing NARCH, or focus groups. Use of a specific EBI as an example as described above is not required in the application and is only one of various different ways the applicant may choose to describe their approach. If an example EBI is chosen for use in the application, it will not necessarily be the EBI finally chosen by the grantee's full eventual process if the grant is funded.

b. Refinement of adaptation and tailoring guidance.

c. Research plan should address activities to be conducted over the entire project period. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

d. How will grantee gain access to and rapidly assess the specific population(s) (i.e., via community planning groups, community advisory boards, focus groups)? Has the applicant used local data to inform the current RFA? Are there existing relationships between the applicant and local/Tribal public health authorities and/or Tribal or IHS medical providers? Is the plan to obtain appropriate Tribal and/or Board approval(s) to test the intervention adequately described?

e. Has the applicant demonstrated how they will establish and maintain collaboration with universities, research partners, IHS national programs, etc.?

f. Has the applicant chosen an adequate sample size and demonstrated access to at least that many members of the target population who are not currently receiving intervention, particularly if the population is small or hard-to-reach?

g. Has the applicant included a relative timeline or action plan for each phase of activities (selection, assessment, adaptation, tailoring, implementation, and evaluation including milestones; costs; development of materials (i.e., adapted and tailored training curriculum, evaluation tools, checklists) and required reports? Absolute timelines

and dates will not be required.

However, each necessary step should be described, in logical order, to complete the project within the total budget amount allowed (\$600,000).

h. Has the applicant demonstrated sufficient understanding of EBI(s) as set forth by the CDC?

i. Describe how the program will ensure that the intervention services and analyses will be culturally sensitive and relevant.

#### C. Innovation (10 Points)

a. Does the project employ concepts, approaches or methods novel to standard biomedical science?

b. Does the project challenge existing paradigms or develop new methodologies or technologies?

c. Is the target sub-population one that is not typically targeted for behavioral intervention research (e.g. AI/AN transgender, AI/AN men who have sex with other men, AI/AN communities, etc)?

#### D. Project Evaluation and Reporting (20 Points)

a. Does the grantee provide a clear and organized plan for monitoring and evaluating each phase of the project through implementation, and to identify best practices?

b. Has the applicant provided a quality assurance plan that addresses all phases of adaptation, tailoring, implementation and evaluation and included personnel responsible for ensuring quality? Has the applicant provided a plan for documenting process measures including who is responsible, processes to be measured, and sample tools that might be used?

c. Do the outcomes and performance measures described in the evaluation include both quantitative and qualitative approaches?

d. Reporting Requirements. Does application provide a clear and organized plan to strictly adhere to reporting requirements set forth in section VI.4.?

e. Based on the plans for monitoring, evaluation through each phase, and reporting, does the grantee demonstrate obvious understanding of the evaluation and reporting processes and requirements?

#### E. Organizational Capacity (10 Points)

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

a. Describe the ability of the organization to manage the proposed

research project and the quality of the established NARCH partnership(s).

b. Include information regarding any similarly sized projects in scope and financial assistance as well as any other similar projects successfully completed and/or under way.

c. Note who will be writing the required reports.

#### F. Categorical Budget and Budget Justification (10 Points)

Is the proposed budget reasonable in relation to the proposed work and research? Applicants must provide an itemized budget to complete the project in one year and budget justification for direct and indirect costs.

a. Narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project.

b. Budget justification should include a brief program narrative for the second and third years, in the event that the project is not completed in the first year.

#### 2. Review and Selection

Each application will be prescreened by the DGO staff for eligibility and completeness as outlined in the funding announcement. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the Objective Review Committee. Applicants will be notified by DGO, via letter, to outline the missing components of the application.

To obtain a minimum score for funding, applicants must address all program requirements and provide all required documentation. Applicants that receive less than a minimum score will be informed via e-mail of their application's deficiencies. A summary statement outlining the strengths and weaknesses of the application will be provided to these applicants. The summary statement will be sent to the Authorized Organizational Representative that is identified on the face page of the application.

### VI. Award Administration Information

#### 1. Award Notices

The Notice of Award (NoA) will be initiated by the DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer and this is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect 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. The NoA is the legally binding document and is signed by an authorized grants official within the IHS.

#### 2. Administrative Requirements

Grants 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 Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-profit Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Title 2: Grant and Agreements, Part 225—Cost Principles for State, Local, and Indian Tribal Governments (OMB A-87).

- Title 2: Grant and Agreements, Part 230—Cost Principles for Non-Profit Organizations (OMB Circular A-122).

E. Audit Requirements:

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

#### 3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II-27, IHS requires applicants to obtain a current indirect cost 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 DGO at the time of award, the indirect cost portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <http://rates.psc.gov/> and the Department of Interior (National Business Center) <http://www.aqd.nbc.gov/indirect/indirect.asp>. If your organization has questions regarding the indirect cost policy, please call (301) 443-5204 to request assistance.

#### 4. Reporting Requirements

The reporting requirements for this program are noted below.

##### A. Progress Reports

Program progress reports are required semi-annually. These reports will 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

Semi-annual Financial Status Reports (FSR) reports must be submitted within 30 days after the budget period ends. Final FSRs are due within 90 days of expiration of the project period. Standard Form 269 (long form for those reporting on program income; short form for all others) will be used for financial reporting.

Federal Cash Transaction Reports are due every calendar quarter to the Division of Payment Management, Payment Management Branch at: [www.dpm.gov](http://www.dpm.gov). Failure to submit timely reports may cause a disruption in timely payments to your organization.

Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due semi-annually. Financial Status Reports (SF-269) are due 90 days after each budget period and the final SF-269 must be verified from the grantee records on how the value was derived.

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.

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

**VII. Agency Contacts**

Grants (Business): For specific grant-related and business management information:

Roscoe Brunson, Grants Management Specialist, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852, (301) 443-5204 or [roscoe.brunson@ihs.gov](mailto:roscoe.brunson@ihs.gov).

Program (Programmatic/Technical): For program-related and general information regarding this announcement:

Alan Trachtenberg, MD, MPH, IHS Research Program, 801 Thompson Ave, TMP Suite 450, Rockville, MD 20852, (301) 443-0578 or [narch@ihs.gov](mailto:narch@ihs.gov).

Dated: June 2, 2010.

**Yvette Roubideaux**,  
Director, Indian Health Service.

[FR Doc. 2010-13852 Filed 6-8-10; 8:45 am]

**BILLING CODE 4165-16-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Health Center Program**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Noncompetitive Replacement Awards to Albany Area Primary Health Care, Inc.

**SUMMARY:** The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) Community Health Center (CHC), Increased Demand for Services (IDS), and Capital Improvement Program (CIP) funds originally awarded to Unadilla Health Care Center, Inc., to Albany Area Primary Health Care, Inc., to ensure the provision of critical primary health care services to underserved populations in Dooly County, Georgia.

**SUPPLEMENTARY INFORMATION:**

*Former Grantee of Record:* Unadilla Health Care Center, Inc.

*Original Period of Grant Support:* December 1, 2008, to November 30, 2010 (CHC); March 27, 2009, to March 26, 2011 (IDS); and June 29, 2009, to June 28, 2011 (CIP).

*Replacement Awardee:* Albany Area Primary Health Care, Inc.

*Amount of Replacement Awards:* The current awards for Unadilla Health Care Center, Inc., were issued at \$678,041 (CHC); \$126,411 (IDS); and \$316,325 (CIP). The amounts transferred will be

the remaining funds from those most recent awards.

*Period of Replacement Awards:* The period of support for the replacement awards is the remaining time in the Health Center project period ending on November 30, 2010 (CHC); March 26, 2011 (IDS); and June 28, 2011 (CIP).

**Authority:** Section 330 of the Public Health Service Act, 42 U.S.C. 254b.

*CFDA Numbers:* 93.224 and 93.703

**Justification for the Exception to Competition**

The former grantee, Unadilla Health Care Center, Inc. (UnaHealth), notified HRSA that it was unable to carry out the administrative and programmatic requirements to appropriately manage the grant funds and indicated that it would be relinquishing the grant funds. UnaHealth is unable to provide the necessary primary health care services in Dooly County, Georgia, to the more than 3,000 low income, underserved and uninsured individuals in the service area.

Albany Area Primary Health Care, Inc. (AAPHC) is an experienced provider of care and has a demonstrated record of compliance with the Health Center Program statutory and regulatory requirements and is located in the same geographical area. AAPHC will provide services to the residents of Dooly County at a site proximate to UnaHealth's current location. Community support for this transfer is demonstrated by letters of support from three other existing section 330 grantees in the service area, as well as a letter of support from the local Primary Care Association.

This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay or disruption of services caused by a competition. As a result, in order to ensure that critical primary health care services remain available to the original target population without disruption, this replacement award will not be competed.

**FOR FURTHER INFORMATION CONTACT:**

Lynn Spector via e-mail at [lspector@hrsa.gov](mailto:lspector@hrsa.gov) or 301-594-4300.

Dated: June 3, 2010.

**Mary K. Wakefield**,  
Administrator.

[FR Doc. 2010-13865 Filed 6-8-10; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Environmental Health Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special Emphasis Panel; Conferences and Scientific Meetings Support.

*Date:* June 30, 2010.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call)

*Contact Person:* Leroy Worth, PhD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, (919) 541-0670, [worth@niehs.nih.gov](mailto:worth@niehs.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: June 2, 2010.

**Jennifer Spaeth**,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-13842 Filed 6-8-10; 8:45 am]

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