

- Clinical document architecture (CDA) implementation guide—provides instructions for developing a Health Level Seven (HL7) CDA Extensible Markup Language (XML) file to transmit the Common Formats patient safety data from the PSO to the PPC using the Common Formats;

- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PPC;

- Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);

- Local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and

- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [e.g., HL-7, International Standards Organization (ISO)].

Commenting on Common Formats Version 1.1

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on healthcare quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats. The NQF also convened an expert panel to review the comments received on Common Formats Version 1.0 and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, has further revised and refined the Common Formats that are now available as Version 1.1.

AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors, particularly from those who use the Common Formats, to guide their improvement. Although AHRQ's Version 1.1 has been developed based on evidence, consensus of the PSWG, public comments and input, and feedback from the NQF expert panel, the formats do not fully reflect the refinement that comes from large-scale use and repeated revision. The process for updating and refining the formats will be an iterative one.

More information on the Common Formats Version 1.1, including the feedback process, can be obtained through AHRQ's PSO Web site: <http://www.PSO.AHRQ.gov/index.html>.

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

FY 2010 Special Diabetes Program for Indians Community-Directed Grant Program

Announcement Type: New/Competing Continuation.

Funding Opportunity Number: HHS-2010-IHS-SDPI-0004.

Catalog of Federal Domestic Assistance Number: 93.237

Key Dates:

Application Deadline: April 30, 2010.

Review Date: June 21–24, 2010.

Earliest Anticipated Start Date: July 15, 2010.

Other information: This announcement will be open throughout Fiscal Year (FY) 2010 based on existing budget cycles. Refer to application instructions for additional details. This current announcement targets grantees that currently operate under a budget cycle that begins on June 1.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting grant applications for the FY 2010 Special Diabetes Program for Indians (SDPI) Community-Directed grant program. This competitive grant announcement is open to all existing SDPI grantees that have an active grant in place and are in compliance with the previous terms and conditions of the grant. This program is authorized under H.R. 6331 "Medicare Improvement for Patients and Providers Act of 2008" (Section 303 of Pub. L. 110-275) and the Snyder Act, 25 U.S.C. 13. The program is described in the Catalog of Federal Domestic Assistance (CFA) under 93.237.

Overview

The SDPI seeks to support diabetes treatment and prevention activities for American Indian/Alaska Native (AI/AN) communities. Grantees will implement programs based on identified diabetes-related community needs. Activities

will be targeted to reduce the risk of diabetes in at-risk individuals, provide services that target those with new onset diabetes, provide high quality care to those with diagnosed diabetes, and/or reduce the complications of diabetes.

The purpose of the FY 2010 SDPI Community-Directed grant program is to support diabetes treatment and prevention programs that have a program plan which integrates at least one IHS Diabetes Best Practice and that have a program evaluation plan in place which includes tracking outcome measures.

This is not an application for continued funding as was previously available for Community-Directed grant programs.

Background

Diabetes Among American Indian/Alaska Native Communities

During the past 50 years, type 2 diabetes has become a major public health issue in many AI/AN communities, and it is increasingly recognized that AI/AN populations have a disproportionate burden of diabetes (Ghodes, 1995). In 2006, 16.1% of AI/ANs age 20 years or older had diagnosed diabetes (unpublished IHS Diabetes Program Statistics, 2006) compared to 7.8% for the non-Hispanic white population (CDC, 2007). In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population (Carter, 1996; Harris, 1995; Gilliland, 1997). Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

Under the Balanced Budget Act of 1997, Congress authorized the IHS to administer the SDPI grant program. SDPI grants are programmatically directed by the IHS Division of Diabetes Treatment and Prevention (DDTP).

Special Diabetes Program for Indians

The SDPI is a \$150 million per year grant program. Over 330 programs have received SDPI Community-Directed grants annually since 1998. In addition, 66 demonstration projects have been funded annually since 2004 to address prevention of type 2 diabetes or cardiovascular disease risk reduction. A Congressional re-authorization in 2008 extended the SDPI through FY 2011.

II. Award Information

Type of Awards

Grants.

Estimated Funds Available

The total amount of funding identified for FY 2010 SDPI

Community-Directed grant program is \$104.8 million. Funds available to each IHS Area and to urban Indian health programs have been determined through Tribal consultation. Within each Area, local Tribal consultation guided IHS decision-making on how much funding is available per eligible applicant. FY 2010 SDPI funding remains unchanged from FY 2009, per Tribal consultation. All 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

Approximately 150 awards will be issued for Budget Cycle IV. Applications will be accepted from grantees whose current SDPI FY 2009 grants end on May 31, 2010. Additionally, applicants from Budget Cycles I, II or III that were deemed ineligible due to incomplete applications or that possessed delinquent OMB A-133 financial audits can resubmit applications under the timelines for Budget Cycle IV.

Project Period

The project period for grants made under this announcement is 24 months, subject to the availability of funds.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include the following:

- *Federally-recognized Tribes operating an Indian health program* operated pursuant to a contract, grant, cooperative agreement, or compact with the IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), (Pub. L. 93-638).
- *Tribal organizations operating an Indian health program* operated pursuant to a contract, grant, cooperative agreement, or compact with the IHS pursuant to the ISDEAA, (Pub. L. 93-638).
- *Urban Indian health programs* that operate a Title V Urban Indian Health Program: This includes programs currently under a grant or contract with the IHS under Title V of the Indian Health Care Improvement Act, (Pub. L. 93-437).
- *Indian Health Service facilities* (refer to paragraph 3 below in this Section).

Current SDPI grantees are eligible to apply for competing continuation funding under this announcement and must demonstrate that they have complied with previous terms and

conditions of the SDPI grant in order to receive funding under this announcement.

Non-profit Tribal organizations and national or regional health boards are not eligible, consistent with past Tribal consultation. Applicants that do not meet these eligibility requirements will have their applications returned without further consideration.

Under this announcement, only one SDPI Community-Directed diabetes grant will be awarded per entity. If a Tribe submits an application, their local IHS facility cannot apply; if the Tribe does not submit an application, the IHS facility can apply. Tribes that are awarded grant funds may sub-contract with local IHS facilities to provide specific clinical services. In this case, the Tribe would be the primary SDPI grantee and the Federal entity would have a sub-contract within the Tribe's SDPI grant.

Collaborative Arrangements

Tribes are encouraged to collaborate with any appropriate local entities including IHS facilities. If a Tribe seeks to provide specific clinical or support services, it may implement sub-contracts with these entities in order to transfer funds. The amount of SDPI funding that the Tribe receives remains the same. The Tribe, as the primary grantee, arranges with the entity to provide specified services that support the program's plan. The entity may request direct costs only.

When a Tribe sub-contracts with the local IHS facility, application requirements for collaborative arrangements include:

- A signed Memorandum of Agreement (MOA) must be submitted with the SDPI application. The MOA must include the scope of work assigned to the sub-contracting IHS facility.
- The IHS Area Director and the Tribal Chairperson must give signed approval of the MOA.
- The Tribe's application must include additional SF-424 and SF-424A forms that are completed by the IHS facility which includes a budget narrative and a face page that is signed by the Chief Executive Officer (CEO).

Applications With Sub-Grants

Programs that submit one application on behalf of multiple organizations (sub-grantees) must submit copies of selected application forms and documents for each of their sub-grantees. (See Section IV, Subsection 2 for specifics.) All sub-grantees must meet the eligibility requirements noted in Subsection 1 above.

2. Cost Sharing or Matching

The FY 2010 Special Diabetes Program for Indians (SDPI) Community-Directed grant program does not require matching funds or cost sharing.

3. Other Requirements

A. Program Coordinator

Provide information about the SDPI Program Coordinator on the "Key Contacts Form" which is included in the application package. The Program Coordinator must meet the following requirements:

- Have relevant health care education and/or experience.
- Have experience with program management and grants program management, including skills in program coordination, budgeting, reporting and supervision of staff.
- Have a working knowledge of diabetes.

B. Documentation of Support

Tribal Organizations

Existing SDPI grantees must submit a current, signed and dated Tribal resolution or Tribal letter of support from all Indian Tribe(s) served by the project. Applications from each Tribal organization must include specific resolutions or letters of support from all Tribes affected by the proposed project activities.

If the Tribal resolution or Tribal letter of support is not submitted with the application, it must be received in the Division of Grants Operations (DGO) by June 15, 2010. This date is prior to the objective review dates, June 21-24, 2010.

Title V Urban Indian Health Programs

Urban Indian health programs must submit a letter of support from the organization's board of directors. Urban Indian health programs are non-profit organizations and must also submit a copy of the 501(c)(3) Certificate. All letters of support must be included in the application or submitted to the DGO by June 15, 2010. This date is prior to the objective review dates, June 21-24, 2010.

IHS Hospitals or Clinics

IHS facilities must submit a letter of support from the CEO. The documentation must be received in the DGO by June 15, 2010. This date is prior to the objective review dates, June 21-24, 2010.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and instructions may be found at www.Grants.gov.

2. Content and Form of Application Submission

Mandatory documents for all applicants include:

- Application forms:
 - SF-424.
 - SF-424A.
 - SF-424B.
- Key Contacts Form.
- Budget Narrative.
- Project Narrative.
- Tribal Resolution or Tribal Letter of Support (Tribal Organizations only).

• Letter of Support from Organization's Board of Directors (Title V Urban Indian Health Programs only).

- 501(c)(3) Certificate (Title V Urban Indian Health Programs only).
- CEO Letters of Support (IHS facilities only).

• 2008 and 2009 IHS Diabetes Care and Outcomes Audit Report.

• Biographical sketches for all Key Personnel.

• Disclosure of Lobbying Activities (SF-LLL) (if applicable).

• Documentation of OMB A-133 required Financial Audit for FY 2007 and FY 2008. 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+Record>.

Mandatory Documents for Programs That Propose Sub-Grantees

The primary grantee for applications that propose sub-grantees must submit all of the mandatory documents listed above. In addition, they must submit the following documents for each sub-grantee:

- SF-424, SF-424A, SF-424B and Key Contacts Form.

- Project Narrative.
- Budget Narrative.

• 2008 and 2009 IHS Diabetes Care and Outcomes Audit Reports.

A separate budget is required for each sub-grantee, but the primary grantee's application must reflect the total budget for the entire cost of the project.

Mandatory Documents for Programs That Propose Sub-Contracts With Local IHS Facilities

Programs that propose sub-contracts with IHS facilities to provide clinical

services must submit the documents noted below for the sub-contractor:

- MOA that is signed by the primary grantee, the sub-contractor, the IHS Area Director and the Tribal Chairperson.

• SF-424 and SF-424A forms completed by the IHS facility (in addition to the primary applicant's SF-424 forms).

A separate budget is required for the sub-contract, but the primary grantee's application must reflect the total budget for the entire cost of the project.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with the 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 13–17 pages (see page limitations for each Part noted below) with consecutively numbered pages. Be sure to place all responses and required information in the correct section or they will not be considered or scored. If the narrative exceeds the page limit, only the first 13–17 pages will be reviewed. There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. A sample project narrative and template are available in the application instructions. See below for additional details about what must be included in the narrative.

Part A: Program Information (no more than 4 pages)

Section 1: Community Needs Assessment

A1.1 Describe the burden of diabetes in your community. Include estimates of the number of people diagnosed with diabetes and the total number of people. Describe how you calculated these estimates.

A1.2 Briefly describe the top diabetes-related health issues in your community.

A1.3 Briefly describe the unique challenges your program experiences related to prevention and treatment of diabetes.

Section 2: Leadership Support

A2.1 Question: Has at least one organization administrator or Tribal leader agreed to be actively involved in your program's work? (Yes or No).

A2.2 Provide the name and role or position that this leader holds.

A2.3 Describe how this leader will be involved with your program.

Section 3: Personnel

Using the table format that is in the application instructions, provide the following information for each person who will be paid with SDPI funds:

A3.1 Name.

A3.2 Title.

A3.3 Brief description of tasks/activities.

A3.4 Is this person already on staff with your SDPI or diabetes program?

A3.5 What percent FTE of this person's salary will be paid using SDPI funds?

Section 4: Diabetes Audit Review

Obtain copies of your local IHS Diabetes Care and Outcomes Audit Reports for 2008 and 2009. Review and compare the results for these two years. Work with your local audit coordinator or Area Diabetes Consultant (ADC) if you need help.

A4.1 Provide a list of results for three to five items/elements (e.g., A1c, eye exam, education, etc.) that improved from 2008 to 2009.

A4.2 Provide a list of three to five items/elements that need to be improved.

A4.3 Describe how your program will address these three to five items/elements that need to be improved or describe how your program will work with your local health care facility to address these areas.

Section 5: Collaboration

A5.1 Describe existing partnerships and collaborations that your program has in place.

A5.2 Describe new partnerships and collaboration that your program is planning to implement.

Part B: Program Planning and Evaluation (no more than 3 pages, with 2 pages for each additional Best Practice)

Section 1: Overview

Each 2009 IHS Diabetes Best Practice includes two specific measures that are called "key measures." Programs may track additional measures based on local priorities. A list of all Best Practices is located in the application instructions. This list provides a short description of the contents and key measures for each Best Practice.

B1.1 List which IHS Diabetes Best Practice(s) your program will implement in order to address the needs that were identified in your community assessment.

Section 2: Program Planning

Provide the information requested below separately for each Best Practice that will be implemented:

B2.1 Target Population: What population will you target?

B2.2 Goal: Describe the goal that your program wants to achieve as a result of implementing the selected Best Practice.

B2.3 Objectives/Measures: List the objective(s) your program will work to accomplish, with at least one measure

identified for each objective. Be sure to include the two key measures for your selected Best Practice and use the Specific, Measurable, Action-oriented, Realistic and Time-bound (SMART) format (see application instructions for additional information). Also, indicate how frequently your program will review data for each measure. (Choose from the following options: weekly, twice a month, monthly, every other month, or quarterly).

B2.4 Activities: List the activities that your program will do to meet the selected Best Practice objectives. These could be events you will organize, services you will offer, materials you will develop and implement, or other activities.

Section 3: Evaluation

B3.1 Describe how your program will track activities for the selected Best Practice(s).

B3.2 Describe how your program will collect and track data on all measures (listed in Section 2 above) for the selected Best Practice(s).

B3.3 Describe how your program will collect stories about individual participants, community events, program staff, and other aspects of your program.

Part C: Program Report (no more than 4 pages)

Section 1: Major Accomplishments and Activities

C1.1 Describe three major accomplishments that your SDPI program achieved in the past 12 months.

C1.2 Describe three to five major accomplishments that your SDPI program has achieved since it began.

C1.3 Describe one story that exemplifies a major program accomplishment from the past year.

C1.4 Describe your SDPI program's primary activities during the past 12 months.

C1.5 Describe your SDPI program's primary activities since it began.

Section 2: Challenges

C2.1 Describe the two or three biggest challenges that your SDPI program encountered in the past 12 months.

C2.2 Describe how your SDPI program addressed these challenges.

C2.3 Indicate if you successfully addressed these challenges. (If so, why; if not, why not.)

Section 3: Dissemination

C3.1 Describe three to five major lessons that your SDPI program has learned since it began.

C3.2 Describe how your SDPI program has shared the lessons that you have learned with other diabetes programs.

C3.3 Describe materials or products your SDPI program has developed.

Section 4: Other Information

C4.1 Provide any additional information about your SDPI program.

B. Budget Narrative (no more than 4 pages)

The budget narrative should explain why each budget item on the SF-424A is necessary and relevant to the proposed project.

3. Submission Dates and Times

Applications are to be submitted electronically through Grants.gov by April 30, 2010 at 12 midnight Eastern Standard Time (EST). Any application received after the application deadline will not be accepted for processing, and it will be returned to the applicant(s) without further consideration for funding.

If technical challenges arise and the applicants need help with the electronic application process, contact Grants.gov Customer Support via e-mail 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 Tammy Bagley, Senior Grants Policy Analyst, IHS Division of Grants Policy (DGP) (tammy.bagley@ihs.gov) at (301) 443-5204 to describe the difficulties being experienced. Be sure to contact Ms. Bagley at least ten days prior to the application deadline. Please do not contact the DGP until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGP as soon as possible.

If an applicant needs to submit a paper application instead of submitting electronically via Grants.gov, prior approval must be requested and obtained (see information under Subsection 6 "Electronic Submission Requirements" for additional information). The waiver must be documented in writing (e-mails are acceptable), before submitting a paper application. After a waiver is received, the application package must be downloaded by the applicant from Grants.gov. Once completed and printed, the original application and two copies must be sent to Denise E. Clark, Division of Grants Operations (DGO) (denise.clark@ihs.gov), 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852. Paper applications that are submitted without a waiver will be returned to the applicant without review or further consideration.

4. Intergovernmental Review

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

5. Funding Restrictions

A. Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR Part 74 and 92, pre-award costs are incurred at the applicant's risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award is less than anticipated.

B. The available funds are inclusive of direct and appropriate indirect costs (see Section VI, Subsection 3).

C. Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

Use the <http://www.Grants.gov> Web site to submit an application electronically; select the "Apply for Grants" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov Web site. Electronic copies of the application may not be submitted as attachments to e-mail messages addressed to IHS employees or offices.

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

Applicants that do not adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Paper applications are not the preferred method for submitting applications.
- If you have problems electronically submitting your application on-line, contact Grants.gov Customer Support via e-mail 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 Tammy Bagley, Senior Grants Policy Analyst, DGP, at (301) 443-5204.
- 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 to submit a paper application must be obtained.

- If it is determined that a waiver is needed, the applicant must submit a request in writing (e-mails are acceptable) to michelle.bulls@ihs.gov that includes a justification for the need to deviate from the standard electronic submission process. If the waiver is approved, the application package must be downloaded by the applicant from Grants.gov. Once completed and printed, it should be sent directly to the DGO by the deadline date of April 30, 2010 (see Section IV, Subsection 3 for details).

- Upon entering the Grants.gov site, there is information that outlines the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation.

- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

- In order to use Grants.gov, the applicant must have a Dun and Bradstreet (DUNS) Number and register in the Central Contractor Registration (CCR). A minimum of ten working days should be allowed to complete CCR registration. See Subsection 8 below for more information.

- All documents must be submitted electronically, including all information typically included on the SF-424 and all necessary assurances and certifications.

- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.

- The application must comply with any page limitation requirements described in the Funding Announcement.

- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGO will download your application from Grants.gov and provide necessary copies to the DDTP. Neither the DGO nor the DDTP will notify applicants that the application has been received.

- You may access the electronic application package and instructions for this Funding Opportunity Announcement on <http://www.Grants.gov>.

- You may search for the application package on Grants.gov either with the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

- The applicant must provide the Funding Opportunity Number: HHS-2010-IHS-SDPI-0004.

DUNS Number

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 nine-digit identification number, which uniquely identifies business entities. Many organizations may already have a DUNS number. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number or to find out if your organization already has a DUNS number, access <http://fedgov.dnb.com/webform>.

Applicants must also be registered with the CCR. A DUNS number is required before an applicant can complete their CCR registration. Registration with the CCR is free of charge. Applicants may register online at <http://www.ccr.gov>. More detailed information regarding the DUNS, CCR, and Grants.gov processes can be found at: <http://www.Grants.gov>.

V. Application Review Information

1. Criteria

Criteria that will be used to evaluate the application are divided into three categories. They include:

- Project Narrative

The project narrative is divided into three parts: Part A—Program Information; Part B—Program Planning/Evaluation; and Part C—Project Report. Required information includes topics such as: Community needs assessment, leadership support, use of Diabetes Audit results, selected Best Practice(s), overall evaluation plan and project accomplishments. For each Best Practice that will be implemented, address: target population, goal, objectives/measures, review of key measures, and activities (see Section IV, Part B, Section 2).

- Budget Narrative

The budget narrative provides additional explanation to support the information provided on the SF-424A form. Budget categories to address include: Personnel, fringe benefits, travel, equipment and supplies, contractual/consultant and constructions/alterations/renovations. In addition to a line item budget, provide a brief justification of each budget item and how they support project objectives.

- Key Contacts Form

This form seeks to obtain contact information about only one person: the project's SDPI Program Coordinator.

Scoring of Applications

Points will be assigned in each category adding up to a total of 100. A minimum score of 60 points is required for funding. Points will be assigned as follows:

- *Project Narrative:* A total of 90 possible points are available for this information. It is divided into two parts: Program Information (20 possible points); Program Planning/Evaluation (60 possible points); and Program Report (10 possible points).

- *Budget Narrative:* A total of 10 possible points are available for this information.

2. Review and Selection Process

Each application will be prescreened by DGO staff for eligibility and completeness as outlined in this Funding Opportunity Announcement. Applications from entities that do not meet eligibility criteria or that are incomplete will not be reviewed. Applicants will be notified by the DGO that their application did not meet minimum requirements.

After being prescreened by the DGO, applications will be reviewed by an Objective Review Committee (ORC) and assigned a score. The ORC is an objective review group that will be convened by the DDTP in consultation with the DGP as required by Department of Health and Human Services (HHS) Grants Policy.

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. (See Section 6 below for application revision guidance). A summary statement outlining the weaknesses of the application will be provided to these applicants. The summary statement will be sent to the Authorized Organizational Representative (AOR) that is identified on the face page of the application.

Review of Applications With Sub-Grants

When an application is submitted on behalf of multiple organizations (sub-grantees), the review score will be a combined score that is based on information provided by all of these organizations.

Programmatic Requirements

Funded applicants (grantees) must meet the following programmatic requirements:

A. Implement an IHS Diabetes Best Practice

Grantees must implement recommended services and activities from at least one 2009 IHS Diabetes Best Practice. They should implement recommendations based on program need, strengths, and resources. Program activities, services and key measures from the selected Best Practice(s) must be documented in the project narrative (see Section IV, Part B, Section 2).

B. Implement Program and Evaluation Plans

Grantees must follow the plans submitted with their application when implementing each selected Best Practice and their evaluation processes. A minimum evaluation requirement is to monitor the key measures over time. Programs may track additional measures based on local priorities.

C. Participate in Training and Peer-to-Peer Learning Sessions

Grantees must participate in SDPI training sessions and peer-to-peer learning activities. Training sessions will be primarily conference calls or combined WebEx/conference calls.

Grantees will be expected to:

- Participate in interactive discussion during conference calls.
- Share activities, tools and results.
- Share problems encountered and how barriers are broken down.
- Share materials presented at conferences and meetings.
- Participate and share in other relevant activities.

Sessions, which will be led by DDTP, DGO, or their agents, will address clinical and other topics. Topics will include: program planning and evaluation, enhancing accountability through data management, and improvement of principles and processes. Grantees will integrate information and ideas in order to enhance effectiveness. Anticipated outcomes from participating in the learning sessions are improved communication and sharing among grantees, increased use of data for improvement, and enhanced accountability.

Application Revisions

If an application does not receive a minimum score for funding from the ORC, the applicant will be informed via a summary statement that will be sent to the AOR via e-mail. The applicant then has two opportunities to submit revisions to their application. Before application revisions can be submitted, the AOR must have received a summary statement from the previous review that

outlines the weaknesses of the initial application.

A. Revision to Initial Application

Applicants will have five business days from the date that the summary statement is sent via e-mail to submit hard copies of their application revisions. Along with the revised application documents, applicants must prepare and submit an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticism and issues raised in the summary statement.

The Introduction and revised application documents must be mailed directly to the DGO to the attention of Denise Clark, Lead Grants Management Specialist (denise.clark@ihs.gov) at: Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852.

Technical assistance will be available to applicants as they prepare resubmission documentation.

An Ad Hoc Review Committee will be convened specifically to review the initial application revisions. If the revised application receives the minimum score for funding or above, the applicant will be informed via a Notice of Award (NoA). If the Review Committee determines that the application with revisions still does not receive a fundable score, the applicant will be informed of their application's deficiencies via a second summary statement that will be e-mailed to the AOR.

B. Second Application Revision

Applicants will have five business days from the date that the second summary statement is sent via e-mail to submit hard copies of their application revisions. Along with the revised application documents, applicants must prepare and submit an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticism and issues raised in the summary statement.

The Introduction and revised application documents must, again, be mailed directly to the DGO to the attention of Denise Clark, Lead Grants Management Specialist (denise.clark@ihs.gov) at: Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852.

A second Ad Hoc Review Committee will be convened to review the second application revisions. If the application

with revisions receives the minimum score for funding or above, the applicant will be informed via a NoA.

If the Review Committee determines that the application with revisions still does not receive a fundable score, applicants will be informed in writing of their application's deficiencies.

Technical Assistance from Area Diabetes Consultants (ADCs) is available to all applicants in all cycles that did not/do not receive fundable scores. These applicants are encouraged to contact the ADC for their area to obtain assistance. Contact information for ADCs can be found on the Division of Diabetes Web site <http://www.diabetes.ihs.gov/index.cfm?module=peopleADCDirectory>.

7. Anticipated Announcement and Award Dates

Grantees that receive a fundable score will be notified of their approval for funding via the NoA.

VI. Award Administration Information

1. Award Notices

The NoA will be prepared by the DGO and sent via postal mail to each applicant that is approved for funding under this announcement. This document will be sent to the person who is listed on the SF-424 as the AOR. The NoA will be signed by the Grants Management Officer. The NoA is the authorizing document for which funds are dispersed to the approved entities. The NoA serves as the official notification of the grant award 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. The NoA is the legally binding document. Applicants who are disapproved based on the ORC score will receive a copy of the summary statement which identifies the weaknesses and strengths of the application submitted. The AOR serves as the business point of contact for all business aspects of the award.

The anticipated NoA date for all applicants that score well in the ORC review for Cycle IV is July 15, 2010.

2. Administrative Requirements

Grants are administered in accordance with the following regulations, policies, and Office of Management and Budget (OMB) cost principles:

A. The criteria as outlined in this Funding Opportunity 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, Other Non-Profit Organizations, and Commercial Organizations.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/2007.

D. Cost Principles:

- OMB Circular A-87—State, Local, and Indian Tribal Governments (Title 2 Part 225).

- OMB Circular A-122—Non-Profit Organizations (Title 2 Part 230).

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 HHS Division of Cost Allocation <http://rates.psc.gov/> and the Department of the Interior (National Business Center) at <http://www.aqd.nbc.gov/indirect/indirect.asp>. If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443-5204.

4. Reporting Requirements

The DDTP and the DGO have requirements for progress reports and financial reports based on the terms and conditions of this grant as noted below.

A. Progress Reports

Program progress reports are required semi-annually. These reports must include at a minimum: Reporting of Best Practice measures; and a brief comparison of actual accomplishments to the goals established for the budget period or provide sound justification for the lack of progress.

B. Financial Status Reports

Annual financial status reports are required until the end of the project period. Reports must be submitted annually no later than 30 days after the end of each specified reporting period. The final financial status report is due within 90 days after the end of the 24 month project period. Standard Form 269 (long form for those reporting program income; short form for all others) will be used for financial reporting.

Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports (FSR). According to SF-269 instructions, the final SF-269 must be verified from the grantee records to support the information outlined in the FSR.

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 applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

C. FY 2007 and FY 2008 Single Audit Reports (OMB A-133)

Applicants who have an active SDPI grant are required to be up-to-date in the submission of required audit reports. These are the annual financial audit reports required by OMB A-133, audits of state, local governments, and non-profit organizations that are submitted. Documentation of (or proof of submission) of current FY 2007 and FY 2008 Financial Audit Reports is mandatory. Acceptable forms of documentation include: e-mail confirmation from FAC that audits were submitted; or face sheets from audit reports. Face sheets can be found on the FAC Web site: <http://harvester.census.gov/fac/dissemin/accessoptions.html?submit=Retrieve+Records>.

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

VII. Agency Contacts

- For Grants Budget Management, contact:

- Denise Clark, Lead Grants Management Specialist, DGO (denise.clark@ihs.gov), Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852, (301) 443-5204.

- For Grants.gov electronic application process, contact:

- Tammy Bagley, Grants Policy, DGP (tammy.bagley@ihs.gov), (301) 443-5204, Grants Policy Web site:http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding.

- For programmatic questions, contact:

- Bonnie Bowekaty, Program Assistant, DDTP (bonnie.bowekaty@ihs.gov), (505) 248-4182;

- Lorraine Valdez, Deputy Director, DDTP (s.lorraine.valdez@ihs.gov), (505) 248-4182;

- Area Diabetes Consultants Web site: <http://www.ihs.gov/MedicalPrograms/diabetes/index.cfm?module=peopleADCDirectory>.

Dated: March 12, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 29, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery,