In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–18987 Filed 8–3–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2390]

Evidentiary Considerations for Integration of Biomarkers in Drug Development; Notice of Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland's Center of Excellence in Regulatory Science and Innovation and the Critical Path Institute, is announcing a public workshop entitled ''Evidentiary Considerations for Integration of Biomarkers in Drug Development.'' The purpose of the meeting is to discuss current scientific approaches to biomarker development, acceptance, and utility in drug and biologic (hereafter referred to as therapeutic product) development programs.

DATES: The meeting will be held on August 21, 2015, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the University of Maryland, Pharmacy Hall, 20 North Pine St., Baltimore, MD 21201. For additional travel and hotel information, please refer to *www.pharmacy.umaryland.edu/cersibiomarkers.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

FOR FURTHER INFORMATION CONTACT: Ann Anonsen, University of Maryland, Fischell Dept. of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301–405–0285, FAX: 304–405–9953, *aanonsen@umd.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this public workshop is to facilitate a unique opportunity for relevant stakeholders from industry, academia, and FDA to discuss biomarker development and provide a framework for evidentiary considerations required for biomarker qualification. The objective of the workshop is to discuss evidentiary considerations for use of clinical safety and enrichment biomarkers in drug development.

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.pharmacy.umaryland.edu/cersibiomarkers.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	$50
Charitable Nonprofit/Academic	50
Government	0

B. Accommodations

Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify all comments with the corresponding 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19037 Filed 8–3–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Funding Announcement Number: HHS–2016–IHS–SDPI–0001; Catalog of Federal Domestic Assistance Number: 93.237]

Special Diabetes Program for Indians; Community-Directed Grant Program; Announcement Type: New and Competing Continuation

Key Dates

Application Deadline Date: October 7, 2015.

Review Date: October 19–November 6, 2015.

Earliest Anticipated Start Date: January 1, 2016.

Signed Tribal Resolution(s) Due Date: October 16, 2015.

Proof of Non-Profit Status Due Date: October 7, 2015.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Special Diabetes Program for Indians (SDPI) is accepting new and competing continuation cooperative agreement applications for the Community-Directed Grant Program. This program is authorized by Section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c–3, as amended, and by the Snyder Act, 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.237.

Background

Diabetes is a complex and costly chronic disease that requires tremendous long-term efforts to prevent and treat. Although diabetes is a nationwide public health problem, American Indian/Alaska Native (AI/AN) people are disproportionately affected. In 2012, 15.9% of AI/AN people aged 20 years or older had diagnosed diabetes, compared to 7.6% of non-Hispanic white people [CDC, 2014 (*http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf*)]. In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population [O'Connell, 2012 (*http://care.diabetesjournals.org/content/33/7/1463.full?sid=f3c75e2c-5b22-479b-ac82-6e96b5f7576c*); Cho, 2014 (*http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2014.301968*)]. Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

In response to the burgeoning diabetes epidemic among AI/AN people, Congress established the SDPI through the Balanced Budget Act of 1997. SDPI is a $150 million per year program that provides grants for diabetes treatment and prevention services. SDPI is administered by IHS, with programmatic oversight provided by the IHS Division of Diabetes Treatment and Prevention (Division of Diabetes).

Over 330 programs have received SDPI Community-Directed grants annually since 1998. A Congressional re-authorization in 2015 extended SDPI through FY 2017.

Purpose

The purpose of this IHS cooperative agreement is to provide diabetes treatment and/or prevention activities and/or services (also referred to as ''activities/services'') for AI/AN communities. Grantees will implement one SDPI Diabetes Best Practice (also referred to as ''Best Practice'') and report data on its Required Key Measure. Grantees may also implement other activities/services based on diabetes-related community needs and develop an evaluation plan. Activities/services will be aimed at reducing the risk of diabetes in at-risk individuals, providing high quality care to those with diagnosed diabetes, and/or reducing the complications of diabetes.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for fiscal year (FY) 2016 is approximately $130.2 million. Individual award amounts are anticipated to be between $12,500 and $6.5 million with an average award amount of approximately $300,000.

The funding formula which determines the funds available to each IHS area has been determined through Tribal consultation. Within each area, grantee Tribes provide input on the formula which determines the amount of funding available for each successful applicant.

- Current SDPI Community-Directed grantees should budget for the same amount as they received in FY 2015. However, funding amounts may change. See the paragraph below for additional information.
- New SDPI Community-Directed grant applicants should apply for a $12,500 base amount.

The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately 325–450 awards will be issued under this program announcement.

Project Period

January 1, 2016 to December 31, 2020.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (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 Involvement

1. IHS Division of Diabetes Treatment and Prevention (Division of Diabetes): The Division of Diabetes will provide general programmatic oversight, coordination, leadership, and resources. Detailed responsibilities include:

a. Communication and technical assistance

i. Maintain a Community-Directed grantee email list and provide updates and announcements via email.

ii. Maintain and update the Division of Diabetes Web site: *www.diabetes.ihs.gov*

iii. Maintain and update SDPI Community-Directed Grant Program Web pages (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=sdpi_hub*), which provide information and resources regarding the cooperative agreement, including:

(1) Information sessions—Recorded webinars available to view on demand and provide a review of the programmatic Terms and Conditions and overview of application or report-specific resources.

(2) Frequently Asked Questions (FAQs)—Updated annually, this Web page provides answers to common questions about SDPI Community-Directed grants.

(3) Additional resources—Documents and links from the Division of Diabetes and the Division of Grants Management (DGM).

(4) New to SDPI—Provides information for new grantees and/or staff.

b. Provide Question and Answer (Q&A) Sessions: The Division of Diabetes will hold regular Q&A sessions regarding application and report processes via live webinars. Sessions will be held regularly one month before the due date for each application and report. These sessions will provide the following:

i. Review of programmatic Terms and Conditions.

ii. Overview of report or application instructions, templates and resources.

iii. Opportunity for attendees to ask questions.

c. Create and provide instructions and templates for the Semi-Annual and Annual Progress Reports.

d. Create and provide instructions and Project Narrative template(s) for continuation applications.

e. Maintain and update the SDPI Diabetes Best Practices.

f. Provide resources, tools, support, and training for facilities to conduct IHS Diabetes Care and Outcomes Audits.

g. Create and provide support for the SDPI Outcomes System (SOS) which grantees will use to track and report on Required Key Measure (RKM) data.

h. Establish SDPI grantee training requirements.

i. Provide or coordinate SDPI grantee training sessions and record them.

2. Area Diabetes Consultant (ADC): Diabetes expert located in each IHS area with the following responsibilities:

a. Serves as the project officer for the SDPI Community-Directed Grant Programs in their IHS area. The project officer is a federal program staff person who is responsible for managing and monitoring the progress of grantees.

b. Serves as a liaison between the SDPI grant programs, Division of Diabetes, and DGM.

c. Helps coordinate an extensive Indian health system diabetes network to facilitate information flow between local and national levels.

d. Provides diabetes training and resources to health care and wellness professionals and paraprofessionals in the Indian health system.

e. Works with the Division of Diabetes to translate and disseminate the latest scientific findings on diabetes treatment and prevention to AI/AN communities.

3. IHS Division of Grants Management: Official grants management office. Provides complete monitoring and oversight for all financial business management and administration for the life cycle of the grant award. First contact for all financial grants operations and policy requirements for compliance of the grant award terms and conditions. Contact office for the Grants Management Specialist (GMS), Grants Management Officer, Chief Grants Management Officer and Acting Director of Grants Management Operations and Policy. Works on a daily basis with all grants award recipients to provide guidance on all grants management questions and concerns.

B. Grantee Cooperative Agreement Award Activities

All awardees (grantees) will need to meet the following requirements. All requirements, including these programmatic requirements, will also be provided as an attachment in the Notice of Award.

1. Diabetes Treatment and Prevention Activities and Services: Grantees must provide activities/services that:

a. Meet the purpose of this FOA (see section I above) which is to provide diabetes treatment and/or prevention services and activities/services for AI/AN communities.

b. Are targeted at reducing risk factors for diabetes and related conditions.

c. Address diabetes-related issues as identified in the grantee's needs assessment.

d. Implement a selected Best Practice and its RKM (see item 2 directly below).

e. Utilize SDPI funds as outlined in the grantee's Budget Narrative.

2. SDPI Diabetes Best Practices (Best Practices): The Best Practices (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedApp*) were updated for FY 2016 to include the latest scientific findings and recommendations. Grantees must select one Best Practice and implement activities/services aimed at improving the RKM from their selected Best Practice. Grantees will report on RKM data via the SDPI Outcomes System.

3. SDPI Outcomes System (SOS): Data for the RKM will be reported using the new SOS. Grantees will enter results for the RKM for their selected Best Practice into this system at the start and end of the budget period, with the option to enter more frequently. The system will generate reports of these results to meet the SDPI outcomes reporting requirements. These results will be stored in the system and accessible to program staff as needed. Grantees will need to appoint at least one person in their program to get access to and add RKM data into the SOS.

4. IHS Diabetes Care and Outcomes Audit (Diabetes Audit): SDPI Community-Directed grantees are required to participate in the Annual Diabetes Audit (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=resourcesAudit*). Grantees must review the results and submit a copy of the Annual Diabetes Audit Report with their continuation applications. Non-clinical or community-based grantees that are not able to directly participate in the Diabetes Audit will need to acquire a copy of the Annual Diabetes Audit Report from their local facility or ADC.

5. Collaboration: Grantee must agree to:

a. Consult with and accept guidance from the Division of Diabetes, the DGM, and their ADC/Federal project officer(s) and/or designated assignee(s). In addition, sub-grantees must agree to consult with and accept guidance from their primary grantee.

b. Respond promptly to requests for information.

c. Attend required meetings and trainings.

d. Provide short presentations on their processes and successes, as requested.

e. Keep the above entities (see item a. above) informed of emerging issues, developments, and challenges that may affect the grantee's ability to comply with the grant Terms and Conditions and/or any requirements.

6. Program Coordinator: Grantees must have an officially approved (by the IHS project officer) program coordinator with the following qualifications:

a. Relevant health or wellness education and/or experience.

b. Experience with grant program management, including skills in program coordination, budgeting, reporting, and supervision of staff.

c. Working knowledge of diabetes.

The program coordinator will also be the primary email contact to entities listed in item B.5. above under ''Collaboration.'' All SDPI grant program staff should be routinely updated by the program coordinator with information and requirements related to their program's activities/services.

7. Hardware/software requirements: The hardware and software items listed below are required in order for grantees to access application and report materials, Web sites, and training forums relevant to this grant:

a. Desktop or laptop computer (recommended: Purchased in 2010 or later).

b. Internet access (recommended: High speed).

c. Internet browser software (recommended: Microsoft® Internet Explorer, version 10.0 or higher).

d. Adobe software compatibility for using Grants.gov. For more information: *http://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html*

e. Adobe Connect webinar capability. For more information: *https://na1cps.adobeconnect.com/common/help/en/support/meeting_test.htm*

In addition to the requirements above, it is recommended that grantees have Microsoft Office software, version 2010 or higher.

8. Semi-Annual Progress Report: Grantees must adhere to reporting

requirements as specified by grants policy. See section VI.4 for details. In addition, a programmatic Semi-Annual Progress Report will be required in the middle of the grantee's budget period. Details, instructions, and a report template will be made available on the following Web page: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedMidReportingReq*

9. Required Trainings: Grantees must participate in SDPI required trainings offered by the Division of Diabetes. Training sessions will be primarily live webinars that will be recorded for those not able to attend the live sessions. Grantees will be expected to:

a. Participate in interactive discussion or chats during conference calls or webinars.

b. Share activities, tools, and results.

c. Share problems encountered and how barriers are overcome.

d. Keep track of participation whether live or recorded.

The SDPI grantee training requirements will be provided on the following Division of Diabetes Web page: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedTraining*

10. Grantees that propose sub-grantees: A sub-grantee is an entity that has an arrangement between a primary grantee institution and one or more participating institutions in support of a project. Primary grantee responsibilities include:

a. Providing oversight and coordination to ensure sub-grantees adhere to the grant requirements as listed in this cooperative agreement.

b. Serving as a liaison between the sub-grantees and the entities provided in item 5.a. above.

I. Eligibility Information

1. Eligibility

To be eligible for this ''New/Competing Continuation Announcement'' under this cooperative agreement announcement, applicants must be one of the following:

i. A Federally-recognized Indian Tribe as defined by 25 U.S.C. 1603(14), operating an Indian health program operated pursuant to a contract, grant, cooperative agreement, or compact with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), (Pub. L. 93–638).

ii. A Tribal organization as defined by 25 U.S.C. 1603(26), 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).

iii. An urban Indian organization, as defined by 25 U.S.C. 1603(29), operating a Title V urban Indian health program that currently has a grant or contract with the IHS under Title V of the Indian Health Care Improvement Act, (Pub. L. 93–437). Applicants must provide proof of non-profit status with the application, *e.g.* 501(c)(3).

iv. Indian Health Service facilities: 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.

Current SDPI Community-Directed 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.

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 DGM of this decision.

Documentation of Support

Tribes and Tribal organizations

These entities must submit documentation of support *from each* of the Indian Tribes served by the project. This documentation of support must be either of the following for each Tribe served:

1. *Tribal Resolution:* Tribes and Tribal organizations should submit an official signed Tribal resolution from each of the Indian Tribes served by the project. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities/services.

Official signed Tribal resolution(s) should be submitted along with the electronic application submission by the Application Deadline Date (see Key Dates). If an official signed Tribal resolution is not available by the Application Deadline Date, a draft Tribal resolution(s) should be submitted along with the electronic application submission by the Application Deadline Date. Then, the official signed Tribal resolution(s) must be received by the Signed Tribal Resolution(s) Due Date (see Key Dates); otherwise, the application will be considered incomplete and ineligible.

2. *Letter of Support:* If it is not possible to obtain a signed official Tribal resolution by the Signed Tribal Resolution(s) Due Date for a Tribe served by the project, then a letter of support signed by a senior Tribal official may be submitted instead of a Tribal resolution for that Tribe. Letter(s) of support must be submitted along with the electronic application submission by the Application Deadline Date (see Key Dates).

Title V Urban Indian Health Programs

These entities must submit a letter of support from their organization's board of directors.

IHS Hospitals and Clinics

These entities must submit a letter of support from their chief executive officer. In addition, letter(s) of support from Tribe(s) served by the IHS SDPI program are highly recommended but not required.

Documentation of support as required above must be submitted with the electronic application.

It is highly recommended that all application materials not submitted via grants.gov be sent by a delivery method that includes confirmation of receipt. Materials should be mailed to 801 Thompson Avenue, TMP Suite 360, Rockville, MD 20852 (attention to the assigned GMS, see section VII). Please contact the assigned GMS by telephone prior to the Review Date (see Key Dates) regarding material submission questions.

Proof of Non-Profit Status

Organizations claiming non-profit status must also 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 the cover page of this announcement.

IHS Diabetes Care and Outcomes Audit

The IHS Diabetes Care and Outcomes Audit is a process to assess care and health outcomes for AI/AN people with diagnosed diabetes. IHS, Tribal, and urban Indian health care facilities nationwide participate in this process each year by auditing medical records for their patients with diabetes. Applicants that are able to must submit copies of their local facility's 2014 and 2015 Annual Diabetes Audit Reports.

1. Most applicants can obtain their 2014 and 2015 Annual Diabetes Audit Reports in one of following ways:

a. Via the WebAudit: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=resourcesAudit.*

b. By requesting these Reports from their local facility.

c. By requesting these Reports from their ADC: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=peopleADC Directory.*

2. If the applicant is unable to obtain their local facility's 2014 and 2015 Annual Diabetes Audit Reports, they must provide an explanation in the Project Narrative (Part B).

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 or (301) 443–5204.

2. Content and Form Application Submission

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

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - SF–424, Application for Federal Assistance.
  - SF–424A, Budget Information—Non-Construction Programs.
  - SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages). See section IV.2.B for details.
- Project Narrative—a PDF-fillable template will be provided. See section [section IV.2.A] for details and a link to the template.
- 2014 and 2015 Annual Diabetes Audit Reports or an explanation as to why these reports cannot be submitted. See section III.3 for details.
- Tribal Resolution(s) (Tribes and/or Tribal organizations). See section III.3 for details.
- Letter(s) of Support (See section III.3) from one of the following:
  - Board of Directors (Title V urban Indian health programs).
  - Chief Executive Officer (IHS facilities).
  - Tribes served (highly recommended for IHS facilities)
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all Key Personnel.
- Key contacts form for diabetes program coordinator.
- Contractor/Consultant resumes or qualifications and scope of work (if applicable).
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost rate (IDC) agreement (not applicable to IHS facilities).
- Organizational chart or written information that shows where the SDPI Program fits into the larger organization.
- Documentation of current Office of Management and Budget (OMB) A–133 required Financial Audit or other required audit for FY 2014 (not applicable to IHS facilities).

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/dissem/accessoptions.html?submit=Go+To+Database.*

Mandatory Documents for Programs That Propose Sub-Grantees

A sub-grantee is an entity that has an arrangement between a grantee institution and one or more participating institutions in support of a project.

A complete application package including all mandatory documents listed above must be completed, signed, and submitted to the primary grantee to be included in their application in response to this announcement. Sub-grantees cannot submit applications directly to Grants.gov.

The primary grantee's application must reflect the total budget for the entire cost of the project. Total budget for the sub-grantees should be accounted for under the contractual/consultant category.

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

A sub-contract is between two entities to provide services or supplies. Programs that propose sub-contracts with IHS facilities to provide clinical services must submit a separate budget for the sub-contract, but the grantee's application must reflect the total budget for the entire cost of the project.

While not required for this grant application, it is highly recommended that the grantee obtain a Memorandum of Agreement that is signed by the grantee, the IHS facility, the IHS area director, and the Tribal chairperson.

Public Policy Requirements

All Federal-wide public policies apply to organizations that receive IHS grants and cooperative agreements with exception of the Discrimination policy: *http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative will be provided using a PDF fillable template that will be available on the SDPI Community-Directed Application Web page at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedApp.*

Be sure to answer succinctly all applicable questions in the Project Narrative, being mindful of the evaluation criteria (see section V.1). The Project Narrative will provide reviewers with critical information about the applicant's resources, capabilities, and proposed activities/services.

There are seven parts to the Project Narrative:

1. Part A—Program Identifiers
2. Part B—Needs Assessment
3. Part C—Program Support
4. Part D—SDPI Diabetes Best Practice
5. Part E—Activities/Services not related to selected Best Practice (Optional)
6. Part F—Additional Information

B. Budget Narrative: The Budget Narrative provides additional explanation to support the information provided on the SF–424A (Budget

Information for Non-Construction Programs). The Budget Narrative consists of two parts:

(1) Budget Line Items.

(2) Budget Justification that provides a brief justification for each budget item, including why it is necessary and relevant to the proposed project and how it supports project activities/services.

The Budget Narrative must include a line item budget with a justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the Project Narrative. Budget should match the scope of work described in the Project Narrative. The page limitation should not exceed five pages.

The list of budget categories and items below is provided for ideas about what might be included in the budget. The applicant does not need to include all the categories and items below and may include others not listed. The budget is specific to the applicant's program, objectives, and activities/services. A sample Budget Narrative is also provided in Appendix 2.

A. Personnel

For each position to be funded by the grant, including program coordinator and others, provide the information below. Include ''in-kind'' positions if applicable.

- Position name.
- Individual's name or enter ''To be named.''
- Brief description of role and/or responsibilities.
- Percentage of annual salary that will be paid for by SDPI funds OR hourly rate and hours worked per year that will be paid for by SDPI funds.

B. Fringe Benefits

List the fringe rate for each position separately. DO NOT list a lump sum fringe benefit amount for all personnel combined.

C. Travel and Training

- Staff travel necessary to provide project activities/services.
- Staff travel to meetings planned during budget period.
- Staff travel for training as needed to provide services related to goals and objectives of the grant, such as continuing clinical education courses, IHS SDPI Meetings, etc.

D. Equipment

- Capital Equipment—Tangible property having a useful life of more than one year and acquisition cost which equals or exceeds $5,000 per item.

E. Supplies

- General office supplies.
- Computers.
- Software purchases or upgrades and other computer supplies.
- Supplies needed for activities/services related to the project.
- File/storage cabinets.

F. Contractual/Consultant

May include partners, collaborators, and/or technical assistance consultants procured to help with project activities/services. Include direct costs and indirect costs for any subcontracts.

G. Alterations and Renovations (A&R)

Major A&R exceeding $150,000 is not allowable under this project without prior approval from the program office.

H. Other

- Participant incentives—list all types of incentives and specify amount per item. See the IHS Grant Programs Incentive Policy at *http://www.ihs.gov/IHM/index.cfm?module=dsp_ihm_circ_main&circ=ihm_circ_0506* for more information including restrictions.
- Marketing, advertising, and promotional items.
- Internet access.
- Medications and lab tests—be specific; list all medications and lab tests.
- Miscellaneous services: rent, telephone, conference calls, computer support, shipping, copying, printing, and equipment maintenance.

I. Indirect Costs

Line item consists of facilities and administrative cost (include IDC agreement computation)

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the application deadline date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov 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 (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Ms. Tammy Bagley, Acting Director of DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Acting Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the application deadline date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

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

5. Funding Restrictions

- Pre-award costs are not allowable.
- 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 above. 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, note the tracking number provided as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver to submit paper application documents 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. DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither DGM nor the Division of Diabetes 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 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 evaluation criteria for reviewing and scoring the application are provided below. Weights assigned to each section are noted in parentheses. Ensure that this Project Narrative and other submitted application documents provide a clear and complete, but succinct, overview of your program. Anticipate that reviewers know nothing about your program and little about IHS and Tribal systems. 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)

(i) Program Identifiers (Project Narrative Part A)

(1) Was the Project Narrative Template used?

(2) Was program identifier information adequately completed?

(3) Was an appropriate abstract provided?

(ii) Needs Assessment (Project Narrative Part B)

(1) Did the applicant adequately describe the key diabetes-related health issues identified by their community/leadership?

(2) Were numbers provided for applicant's local user population and people with diagnosed diabetes?

(3) Was the 2014 Annual Diabetes Audit Report provided? If not, was an adequate statement included regarding why it was not provided?

(4) Was the 2015 Annual Diabetes Audit Report provided? If not, was an adequate statement included regarding why it was not provided?

(5) Did the applicant appropriately identify Diabetes Audit items (or diabetes-related issues if Audit Reports

were not provided) that need to be improved?

(6) Did the applicant adequately describe how they will address the Diabetes Audit items or diabetes-related issues that need to be improved?

(7) Did the applicant adequately describe challenges?

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

(iii) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Did the applicant provide an adequate description of activities/services to improve the RKM?

(2) Are the activities/services proposed appropriate for the selected Best Practice and Target Group?

(3) Are the planned activities/services realistic given the constraints of timeframe, resources, and staff?

(iv) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Do activities/services address diabetes-related issues identified in the needs assessment in Part B?

(2) Are activities/services aimed at reducing risk factors for diabetes and/or related conditions?

(3) Are activities/services adequately described?

(4) Are the planned activities/services realistic given the constraints of timeframe, resources, and staff?

C. Program Evaluation (15 Points)

(v) SDPI Diabetes Best Practice (Project Narrative Part D)

(1) Was one Best Practice selected?

(2) Was the number of patients/participants in the Target Group provided?

(3) Was the Target Group adequately described?

(4) Are the Target Group and number of patients/participants appropriate given the information the applicant provided in their needs assessment and program resources sections?

(vi) If Applicable: Activities/Services Not Related to Selected Best Practice (Project Narrative Part E)

(1) Was an appropriate target group identified for each activity/service?

(2) Did the applicant specify how improvement and reduction in risk factors will be evaluated?

D. Organizational Capabilities, Key Personnel, and Qualifications (20 Points)

(vii) Program Support (Project Narrative Part C)

(1) Was a completed Key Contact form submitted for the program coordinator?

(2) Were appropriate biographical sketches, resumes, or curricula vitae provided for all key personnel?

(3) Was an appropriate organizational chart or description provided?

(4) Were appropriate Tribal Resolution(s) and/or Letter(s) of Support provided?

(5) Did the applicant identify at least one organization administrator or Tribal leader, other than the Program Coordinator, to support their SDPI program?

(6) Did the applicant describe how this leader will be involved with the SDPI Community-Directed grant program?

(7) Did the applicant provide appropriate and adequate information about key personnel in the Project Narrative?

(8) Did the applicant provide appropriate and adequate information about partnerships and collaborations in the Project Narrative?

(viii) Additional Information (Project Narrative Part F)

(1) Did the applicant adequately complete this part of the Project Narrative?

E. Categorical Budget and Budget Justification (20 Points)

(i) Does the budget match the scope of work described in the Project Narrative?

(ii) Was each line item adequately specified and justified?

(iii) Was the Budget Narrative within the five-page limit?

(iv) Do funding totals match between the SF–424A, budget line item, and justification?

(v) Is the budget reasonable and realistic?

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants may be notified by DGM, via email, to provide minor missing components (*e.g.,* fiscal 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 the following 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 receive a score less than the recommended funding level for approval, (60 points), and are deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of the application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be ''Approved.'' but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016, the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

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

2. Administrative Requirements

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

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants:

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

C. Grants policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost principles:

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

E. Audit requirements:

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

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities/services 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 the GMS listed under ''Agency Contacts'' or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities/services. 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, once during the budget period with a due date to be determined by the Division of Diabetes and once within 90 days after the budget period ends. These reports must include a brief summary of progress to date for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final annual report must be submitted within 90 days of expiration of the budget/project period.

For SDPI Community-Directed grant programs, the following programmatic reports will be required:

i. *Semi-Annual Progress Report:* Instructions, templates, and other information will be posted on the Division of Diabetes Web site at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedMidReportingReq.* Report will be submitted by attaching as a ''Grant Note'' in GrantSolutions. The due date will be determined by the Division of Diabetes and will fall within the grant program's budget period.

ii. *Annual Progress Report:* Instructions, template(s), and other information will be posted on the Division of Diabetes Web site at *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=programsSDPIcommunityDirectedReportingReq.* Per DGM policy, the report will be submitted by attaching as a ''Grant Note'' in GrantSolutions within 90 days after the end of the grant program's budget period.

Refer to the SDPI Community-Directed Grant Program Web page (*http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=sdpi_hub*) for the latest information on report templates, due dates, Q&A sessions and submission instructions.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the GMS. 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.

Federal Subaward Reporting System (FSRS)

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

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

sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *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:

- Applicant's Area Diabetes Consultant: *http://www.ihs.gov/MedicalPrograms/Diabetes/index.cfm?module=peopleADCDirectory.*
- IHS Division of Diabetes Treatment and Prevention, 801 Thompson Avenue, Suite 300, Rockville, MD 20852, Phone: 1–844–IHS–DDTP (1–844–447–3387), Fax: 301–594–6213, Email: *IHSDDTPSDPICommunity@ihs.gov*, Division of Diabetes Web site: *www.diabetes.ihs.gov*.

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

For IHS Areas: Albuquerque, Nashville, Navajo, Phoenix, and Tucson GMS: John Hoffman.

Email: *John.Hoffman@ihs.gov,* phone: 301–443–2116.

For IHS Areas: California, Great Plains, Oklahoma City, and Portland GMS: Cherron Smith.

Email: *Cherron.Smith@ihs.gov,* phone: 301–443–2192.

For IHS Areas: Alaska, Bemidji, and Billings GMS: Patience Musikikongo.

Email: *Patience.Musikikongo@ihs.gov,* phone: 301–443–2059.

For urban programs:

GMS: Pallop Chareonvootitam.

Email: *Pallop.Chareonvootitam@ihs.gov,* phone: 301–443–2195, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, Phone: 301–443–5204, Fax: 301–443–9602.

3. Questions on systems matters may be directed to: 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, Pub. L. 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.

Date: July 28, 2015.

Robert G. McSwain,

Deputy Director, Indian Health Service.

VIII. Appendix 1: Commonly Used Abbreviations

ADC = Area Diabetes Consultant
AI/AN = American Indian/Alaska Native
DGM = Division of Grants Management
FOA = Funding Opportunity Announcement
FY = Fiscal Year
GMS = Grants Management Specialist
HHS = Health and Human Services
IHS = Indian Health Service
NOA/NGA = Notice of (Grant) Award
ORC = Objective Review Committee
PDF = Portable Document Format (Access using Adobe Acrobat Reader or Pro)
RKM = Required Key Measure (Pertains to Best Practice requirement)
SDPI = Special Diabetes Program for Indians
SOS = SDPI Outcomes System

IX. Appendix 2: Sample Budget Narrative

Note: This information is included for sample purposes only. Each program's Budget Narrative must include only their budget items and a justification that is relevant to the program's activities/services.

Line Item Budget—SAMPLE

A. Personnel:	
Program Coordinator	40,000
Administrative Assistant	6,373
CNA/Transporter	6,552
Mental Health Counselor	5,769
Total Personnel	58,694
B. Benefits:	
Program Coordinator	14,000
Administrative Assistant\	2,231
CNA/Transporter	2,293
Mental Health Counselor\	2,019
Total Fringe Benefits	20,543
C. Supplies:	
Desk Top Computers and Software (2)	3,000
Exercise Equipment	3,300
Laptop Computer	1,500
LCD Projector	1,200
Educational/Outreach	3,000
Office Supplies	1,200
Food Supplies for Wellness Luncheons	2,400
Medical Supplies (Clinic)	3,000
Total Supplies	18,600
D. Training and Travel:	
Local Mileage	1,350
Staff Training & Travel—Out of State	2,400
Total Travel	3,750
E. Contractual:	
Fiscal Officer	16,640
Consulting Medical Doctor	14,440
Registered Dietitian/Diabetes Educator	18,720
Exercise Therapist	33,250
Total Contractual	83,050
F. Equipment:	
Heavy Duty Printer/Scanner/Copier	9,000
Total Equipment	9,000
G. Other Direct Costs:	
Rent	20,805
Utility	4,000
Postage	500
Telephone	2,611
Audit Fees	2,500
Professional Fees	2,400
Insurance Liability	1,593
Office Cleaning	1,680
Storage Fees	240
Biohazard Disposal	154
Marketing/Advertising	2,010
Total Other Direct Costs	38,493
H. Indirect Costs (15%)	$34,819
TOTAL DIRECT COSTS	$232,130
TOTAL DIRECT COST AND INDIRECT COSTS	$266,949

Budget Justification—SAMPLE

A. Personnel: $58,694.00

Program Coordinator: George Smith

A full-time employee responsible for the implementation of the program goals as well as overseeing financial and grant application aspects of the agency.

(100% Annual Salary = $40,000/year)

Administrative Assistant: Susan Brown

A part-time employee responsible for providing assistance to the Program Coordinator.

(416 hours × $15.32/hour = $6,373.12)

CAN/Transporter/Homemaker: To Be Named

A full-time employee working 8 hours per week on this grant providing transportation services and in-home health care to clients.

(416 hours × $15.75/hour = $6,552.00)

Mental Health Counselor: Lisa Green

A part-time employee works 6 hours per week in the ADAPT/Mental Health Program providing counseling and workshops to clients.

(6 hours × 52 weeks × $18.49/hour = $5,768.88)

B. Fringe Benefits: $20,543.00

Fringe benefits are calculated at 35% for both salaried and hourly employees. Fringe is composed of health, dental, life and vision insurance (20%), FICA/Medicare (7.65%), worker's compensation (1.10%), State

unemployment insurance (1.25%), and retirement (5%).

Program Coordinator: $14,000.
Administrative Assistant: $2,230.59.
CAN/Transporter/Homemaker: $2293.20.
Mental Health Coordinator: $2019.11.

C. Supplies: $18,600.00

Desk Top Computers and Software (2)

Needed by our Diabetes Educator, Exercise Specialist, and Medical Director in order to access and update information on client's records. (2 × $1,500.00 = $3,000.00).

Exercise Equipment

Elliptical cross trainer equipment (creates less impact on the knees), body fat analyzer, 8 dumbbell weights, 4 exercise balls, 4 exercise mats, step stretch, adjustable bench, bow flex plates kit, 2 dance pads, ball stacker set, and exercise video. Total for all exercise equipment is $3,300.00.

Laptop Computer

This type of computer is needed to be used in conjunction with the LCD projector that will be used by the Diabetes Educator for presentations. Cost is $1,500.00.

LCD Projector

This equipment will be used by the Diabetes Educator for presentations. Cost is $1,200.00.

Educational & Outreach Supplies

Various printed literature, books, videos, pamphlets, pens, bottled water, little promotional items will be needed to hand out at various health fairs, events, and to various groups to educate and promote health. Funds allocated are $3,000.00.

Office Supplies

General office supplies are essential in order to properly maintain client records, financial records, and all reporting requirements. General office supplies include file folders, labels, writing pads, pens, paper clips, toner, etc. $1,200.00 will be included in this budget.

Supplies for Monthly Wellness Meetings

An allocation of $200.00 has been made towards teaching tools that will be used by the Diabetes Educator during the monthly wellness classes.

($200.00 × 12 months = $2,400.00)

Medical Supplies—Clinic

An allocation has been made for purchasing medical supplies for our clinic such as alcohol wipes, strips for glucometers, paper sheets, gloves, gowns, etc., in the amount of $3,000.00.

D. Training and Travel: $3,750.00

Local Mileage—Mileage for transportation of clients and outreach services. Estimated at 300 miles/month × 12 months × $0.375 = $1,350.00.

Staff Travel & Training—Expenses in this category are associated with attending conference and seminars associated with diabetes for 2 staff: The budget covers the cost of registration fees ($250 × 2 = $500.00), lodging ($175/night × 2 people × 2 days = $700.00), airfare ($450.00 × 2 people = $900.00), per diem allowance ($50.00 × 2 days × 2 people = $200.00), and ground transportation ($25.00 × 2 × 2 people = $100.00). A total of $2,400.00 for staff travel and training.

E. Contractual: $83,050.00

Fiscal Officer

An independent contractor to perform payroll, accounts payable, financial and grant reporting, and budgetary duties.

(416 hours × $40.00 per hour = $16,640.00)

Consulting Medical Doctor

A medical doctor is contracted to provide medical care to our clients with diabetes.

(12 hours per month × 12 mos. × $100.00 per hour = $14,400.00)

Registered Dietitian/Diabetes Educator

A Registered Dietitian/diabetes educator is contracted to provide diabetes related meal planning and instruction and facilitate one-on-one consultation with clients.

(8 hours per week × 52 weeks × $45 per hour = $18,720.00)

Exercise Specialist

An exercise specialist is contracted to conduct and monitor the exercise program necessary for each client.

(950 hours × $35 per hour = $33,250.00)

F. Equipment: $9,000.00

Heavy Duty Printer/Scanner/Copier

High Performance, high volume printer/scanner/copier to produce materials for diabetes wellness classes. $9,000.00

G. Other Direct Costs: $38,493.00

Rent

This program rents two office locations for a total cost of $83,220.00 per year. Special Diabetes grant program will cover $20,805.00 which is 25% of the rent cost.

Utility

This program will cover 25% of the total utility cost of $16,000.00 per year.

($16,000.00 × 25% = $4,000.00)

Postage

The Diabetes Program postage is estimated at $500.00.

Telephone

This program currently has eight telephone lines at two separate offices as well as pager service and a toll-free number for clients. Diabetes Program will cover $2,611.00 of this expense which is 25% of the annual cost of $10,445.00.

Audit Fees

An annual audit is conducted for this program's financial statements. Funding agencies require audit financial statements of grant funds. Diabetes will cover $2,500.00 of audit expenses which is 25% of the $10,000.00 proposal.

Professional Fees

A computer consultant is needed to fix computer problems. $200.00 per month × 12 mos. = $2,400.00 will cover the expenses.

Insurance Liability

General liability insurance is required to protect the organization against fire and property damage. Diabetes portion of this expense is $1,593.00.

Office Cleaning

Office cleanings are required to keep the agency clean. Diabetes will cover 20% of the contract cost of $8,400.00 = $1,680.00.

Storage Fees

This program stores its records in a storage facility. Diabetes grant will fund $240.00 of this cost.

Biohazard Disposal

A special handling fee for biohazard disposal will cost $154.00 for this program.

Marketing/Advertising

Newspaper advertising will be used to promote Diabetes events. Three (3) ads × $670.00 = $2,010.00

I. Indirect Costs (15%): $34,819

The most recent Indirect Rate Cost Agreement was approved by the Department of the Interior on June 16, 2014. A copy of this agreement is attached separately in the application. The Indirect Rate Cost Agreement for FY2015 will be negotiated after completion of the FY2014 Single Audit.

TOTAL DIRECT COSTS—$232,130.00

TOTAL DIRECT COST AND INDIRECT COSTS—$266,949.00

BILLING CODE 4165–16–P

X. Appendix 3: Sample 2014 Diabetes Audit Report

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	46	124	**37%**	1%	43%
Female	78	124	**63%**	2%	57%
Age					
< 15 years	0	124	**0%**	3%	0%
15-44 years	31	124	**25%**	4%	20%
45-64 years	63	124	**51%**	5%	51%
65 years and older	30	124	**24%**	6%	29%
Diabetes Type					
Type 1	0	124	**0%**	7%	1%
Type 2	124	124	**100%**	8%	99%
Duration of Diabetes					
Less than 1 year	3	124	**2%**	9%	4%
Less than 10 years	54	124	**44%**	10%	47%
10 years or more	69	124	**56%**	11%	40%
Diagnosis date not recorded	1	124	**1%**	12%	13%
Weight Control (BMI)					
Normal (BMI < 25.0)	16	124	**13%**	13%	8%
Overweight (BMI 25.0-29.9)	35	124	**28%**	14%	23%
Obese (BMI 30.0 or above)	73	124	**59%**	15%	67%
Height or weight missing	0	124	**0%**	16%	2%
Blood Sugar Control					
HbA1c < 7.0	20	124	**16%**	17%	36%
HbA1c 7.0-7.9	18	124	**15%**	18%	18%
HbA1c 8.0-8.9	12	124	**10%**	19%	12%
HbA1c 9.0-9.9	19	124	**15%**	20%	9%
HbA1c 10.0-10.9	14	124	**11%**	21%	7%
HbA1c 11.0 or higher	23	124	**19%**	22%	11%
Not tested or no valid result	18	124	**15%**	23%	6%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	79	124	**64%**	24%	67%
140/90 - <160/<95	25	124	**20%**	25%	20%
160/95 or higher	14	124	**11%**	26%	5%
BP category undetermined	6	124	**5%**	75%	8%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Tobacco use					
Current tobacco user	62	124	**50%**	27%	27%
In current users, counseled?					
Yes	46	62	**74%**	28%	62%
No	16	62	**26%**		
Not a current tobacco user	62	124	**50%**	29%	72%
Tobacco use not documented	0	124	**0%**	30%	1%
Diabetes Treatment					
Diet and exercise alone	22	124	**18%**	31%	19%
Diabetes meds currently prescribed, alone or in combination:					
Insulin	47	124	**38%**	32%	33%
Sulfonylurea (glyburide, glipizide, others)	45	124	**36%**	33%	29%
Glinide (Prandin®, Starlix®)	0	124	**0%**	34%	1%
Metformin (Glucophage®, others)	80	124	**65%**	35%	56%
Acarbose (Precose®)/Miglitol (Glyset®)	0	124	**0%**	36%	0%
Pioglitazone (Actos®) or rosiglitazone (Avandia®)	0	124	**0%**	37%	8%
GLP-1 med (Byetta®, Bydureon®, Victoza®)	0	124	**0%**	38%	1%
DPP4 inhibitor (Januvia®, Onglyza®, Tradjenta®)	14	124	**11%**	39%	11%
Amylin analog (Symlin®)	0	124	**0%**	40%	0%
Bromocriptine (Cycloset®)	0	124	**0%**	41%	0%
Colesevelam (Welchol®)	0	124	**0%**	42%	0%
SGLT-2 inhibitor (Invokana®)	0	124	**0%**	43%	0%
Number of diabetes meds currently prescribed:					
One med	40	124	**32%**	44%	38%
Two meds	42	124	**34%**	45%	29%
Three meds	18	124	**15%**	46%	11%
Four or more meds	2	124	**2%**	47%	2%
Ace Inhibitor or ARB Prescribed (See Renal Preservation report for additional info)					
In patients with known hypertension[1]	12	16	**75%**	48%	79%
In patients with increased urine albumin excretion[2]	14	17	**82%**	49%	78%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Aspirin or Other Antiplatelet Therapy Prescribed					
In patients with diagnosed CVD	41	47	**87%**	50%	75%
Lipid Lowering Agent Prescribed					
Single lipid agent	50	124	**40%**	51%	46%
Two or more lipid agents	22	124	**18%**	52%	9%
None	65	124	**52%**	53%	45%
In patients prescribed one or more lipid agents:					
Statin (simvastatin/Zocor®, others)	59	72	**82%**	54%	90%
Statin prescribed in patients with diagnosed CVD:	27	47	**57%**	61%	59%
Fibrate (gemfibrozil/Lopid®, others)	2	72	**3%**	55%	12%
Niacin (Niaspan®, OTC niacin)	4	72	**6%**	56%	3%
Bile Acid Sequestrant (cholestyramine/Questran®, others)	0	72	**0%**	57%	1%
Ezetimibe (Zetia®)	1	72	**1%**	58%	5%
Fish oil	29	72	**40%**	59%	7%
Lovaza®	0	72	**0%**	60%	2%
Exams					
Foot Exam - Neuro & Vasc	77	124	**62%**	62%	59%
Eye Exam - Dilated or Retinal Camera	86	124	**69%**	63%	58%
Dental Exam	42	124	**34%**	64%	40%
Diabetes-Related Education					
Nutrition - by any provider	51	124	**41%**	65%	50%
Nutrition - by RD	39	124	**31%**	66%	23%
Physical activity	90	124	**73%**	67%	54%
Other	90	124	**73%**	68%	65%
Any of above topics	109	124	**88%**	69%	78%
Immunizations					
Flu vaccine during Audit period	70	124	**56%**	70%	62%
Refused - Flu Vaccine	26	124	**21%**	71%	8%
Pneumovax - ever	83	124	**67%**	72%	81%
Refused - Pneumovax	12	124	**10%**	73%	3%
Tetanus/diphtheria - past 10 years	118	124	**95%**	74%	87%
Refused - Tetanus/diphtheria	3	124	**2%**	75%	2%
Hepatitis B 3-dose series complete - ever	22	124	**18%**	76%	22%
Refused - Hepatitis B	2	124	**2%**	77%	1%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Depression An Active Problem					
Yes	25	124	**20%**	78%	22%
No	99	124	**80%**	79%	78%
In patients without active depression, screened for depression during Audit period:					
Screened	94	99	**95%**	80%	80%
Not screened	5	99	**5%**		
Laboratory Exams					
eGFR to assess kidney function (In age 18 and above)	112	124	**90%**	81%	90%
eGFR ≥60 ml/min	95	124	**77%**	82%	73%
eGFR 30-59 ml/min	14	124	**11%**	83%	14%
eGFR 15-29 ml/min	1	124	**1%**	84%	2%
eGFR <15 ml/min	2	124	**2%**	85%	1%
Not tested or no valid result	12	124	**10%**	86%	10%
Non-HDL cholesterol	64	124	**52%**	87%	77%
Non-HDL <130 mg/dl	25	124	**20%**	88%	46%
Non-HDL 130-159 mg/dl	27	124	**22%**	89%	17%
Non-HDL 160-190 mg/dl	8	124	**6%**	90%	9%
Non-HDL >190 mg/dl	4	124	**3%**	91%	5%
Not tested or no valid result	60	124	**48%**	92%	23%
LDL cholesterol	101	124	**81%**	93%	80%
LDL <100 mg/dl	74	124	**60%**	94%	50%
LDL 100-129 mg/dl	17	124	**14%**	95%	20%
LDL 130-160 mg/dl	7	124	**6%**	96%	7%
LDL >160 mg/dl	3	124	**2%**	97%	3%
Not tested or no valid result	23	124	**19%**	98%	20%
HDL cholesterol	66	124	**53%**	99%	78%
In females					
HDL ≤50 mg/dl	31	78	**40%**	100%	53%
HDL >50 mg/dl	7	78	**9%**	101%	25%
Not tested or no valid result	40	78	**51%**	102%	22%
In males					
HDL ≤40 mg/dl	16	46	**35%**	103%	45%
HDL >40 mg/dl	12	46	**26%**	104%	33%
Not tested or no valid result	18	46	**39%**	105%	22%
Triglycerides	66	124	**53%**	106%	78%
TG ≤400 mg/dl	59	124	**48%**	107%	73%
TG >400 mg/dl	7	124	**6%**	108%	5%
Not tested or no valid result	58	124	**47%**	109%	22%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2014 (Audit Period 01/01/2013 - 12/31/2013)
Facility: Test02 (known as Test 02 in 2014)

Annual Audit

124 charts were audited from 130 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Laboratory Exams					
Urine Albumin:Creatinine Ratio (UACR)					
Yes	0	124	**0%**	110%	59%
No	0	124	**0%**	111%	41%
In patients with UACR:					
Urine albumin excretion - Normal: <30 mg/g	0	0	**0%**	112%	62%
Urine albumin excretion - Increased:					
30-300 mg/g	0	0	**0%**	113%	29%
>300 mg/g	0	0	**0%**	114%	8%
In patients age 18 and above with eGFR ≥30, UACR done	0	109	**0%**	115%	64%
Cardiovascular Disease					
Diagnosed CVD	47	124	**38%**	116%	33%
Tuberculosis Status					
TB test +, untreated or tx unknown	10	124	**8%**	118%	9%
TB test +, INH treatment complete	27	124	**22%**	117%	2%
TB test -, placed after DM diagnosis	52	124	**42%**	119%	25%
TB test -, placed before DM diagnosis	13	124	**10%**	120%	12%
TB test -, date of DM Dx or TB test date unknown	0	124	**0%**	122%	3%
TB test status unknown	22	124	**18%**	121%	49%
Combined Outcomes Measures					
Records meeting ALL of the following criteria: A1c <8.0, LDL <100, and mean BP <140/<90	16	124	**13%**	123%	22%
In age 18 and above, records with both an eGFR and a UACR	0	124	**0%**	124%	57%

Definitions

[1]Known hypertension: Has hypertension listed as an active problem, or three visits with a diagnosis of hypertension ever (prior to the end of the Audit period).
[2]Increased urine albumin excretion: UACR≥30 mg/g.

XI. Appendix 4: Sample 2015 Diabetes Audit Report

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	50	125	**40%**	1%	43%
Female	75	125	**60%**	2%	57%
Age					
< 15 years	1	125	**1%**	3%	0%
15-44 years	23	125	**18%**	4%	20%
45-64 years	69	125	**55%**	5%	50%
65 years and older	32	125	**26%**	6%	30%
Diabetes Type					
Type 1	1	125	**1%**	7%	1%
Type 2	124	125	**99%**	8%	99%
Duration of Diabetes					
Less than 1 year	7	125	**6%**	9%	4%
Less than 10 years	56	125	**45%**	10%	48%
10 years or more	67	125	**54%**	11%	40%
Diagnosis date not recorded	2	125	**2%**	12%	12%
BMI Category					
Normal (BMI < 25.0)	6	125	**5%**	13%	8%
Overweight (BMI 25.0-29.9)	23	125	**18%**	14%	22%
Obese (BMI 30.0 or above)	93	125	**74%**	15%	67%
Height or weight missing	3	125	**2%**	16%	3%
Blood Sugar Control					
A1C < 7.0	40	125	**32%**	30%	35%
A1C 7.0-7.9	17	125	**14%**	18%	18%
A1C 8.0-8.9	14	125	**11%**	19%	12%
A1C 9.0-9.9	22	125	**18%**	20%	9%
A1C 10.0-10.9	14	125	**11%**	21%	7%
A1C 11.0 or higher	15	125	**12%**	22%	11%
Not tested or no valid result	3	125	**2%**	23%	8%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	59	125	**47%**	24%	65%
140/90 - <160/<95	39	125	**31%**	25%	21%
160/95 or higher	21	125	**17%**	26%	5%
BP category undetermined	6	125	**5%**	75%	9%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Gender					
Male	50	125	**40%**	1%	43%
Female	75	125	**60%**	2%	57%
Age					
< 15 years	1	125	**1%**	3%	0%
15-44 years	23	125	**18%**	4%	20%
45-64 years	69	125	**55%**	5%	50%
65 years and older	32	125	**26%**	6%	30%
Diabetes Type					
Type 1	1	125	**1%**	7%	1%
Type 2	124	125	**99%**	8%	99%
Duration of Diabetes					
Less than 1 year	7	125	**6%**	9%	4%
Less than 10 years	56	125	**45%**	10%	48%
10 years or more	67	125	**54%**	11%	40%
Diagnosis date not recorded	2	125	**2%**	12%	12%
BMI Category					
Normal (BMI < 25.0)	6	125	**5%**	13%	8%
Overweight (BMI 25.0-29.9)	23	125	**18%**	14%	22%
Obese (BMI 30.0 or above)	93	125	**74%**	15%	67%
Height or weight missing	3	125	**2%**	16%	3%
Blood Sugar Control					
A1C < 7.0	40	125	**32%**	30%	35%
A1C 7.0-7.9	17	125	**14%**	18%	18%
A1C 8.0-8.9	14	125	**11%**	19%	12%
A1C 9.0-9.9	22	125	**18%**	20%	9%
A1C 10.0-10.9	14	125	**11%**	21%	7%
A1C 11.0 or higher	15	125	**12%**	22%	11%
Not tested or no valid result	3	125	**2%**	23%	8%
Mean Blood Pressure (of last 2, or 3 if available)					
<140/<90	59	125	**47%**	24%	65%
140/90 - <160/<95	39	125	**31%**	25%	21%
160/95 or higher	21	125	**17%**	26%	5%
BP category undetermined	6	125	**5%**	75%	9%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Ace Inhibitor or ARB Prescribed (See Renal Preservation report for additional info)					
In patients with known hypertension[1]	62	92	**67%**	50%	78%
In patients with increased urine albumin excretion[2]	35	48	**73%**	51%	78%
Aspirin or Other Antiplatelet Therapy Prescribed					
In patients with diagnosed CVD	17	34	**50%**	52%	72%
Statin Prescribed					
Yes	36	125	**29%**	53%	50%
Allergy or intolerant	0	125	**0%**	54%	3%
In patients with diagnosed CVD:					
Yes	10	34	**29%**	55%	58%
Allergy or intolerant	0	34	**0%**	56%	3%
In patients aged 40-75:					
Yes	32	102	**31%**	57%	53%
Allergy or intolerant	0	102	**0%**	58%	3%
Exams					
Foot Exam - Complete	109	125	**87%**	59%	55%
Eye Exam - Dilated or Retinal Camera	98	125	**78%**	60%	55%
Dental Exam	72	125	**58%**	61%	38%
Diabetes-Related Education					
Nutrition - by any provider	115	125	**92%**	62%	50%
Nutrition - by RD	34	125	**27%**	63%	22%
Physical activity	108	125	**86%**	64%	54%
Other	119	125	**95%**	65%	60%
Any of above topics	121	125	**97%**	66%	77%
Immunizations					
Flu vaccine during Audit period	96	125	**77%**	67%	61%
Refused - Flu Vaccine	9	125	**7%**	68%	8%
Pneumovax - ever	118	125	**94%**	69%	81%
Refused - Pneumovax	1	125	**1%**	70%	4%
Tetanus/diphtheria - past 10 years	121	125	**97%**	71%	89%
Refused - Tetanus/diphtheria	1	125	**1%**	72%	1%
Tdap - ever	120	125	**96%**	73%	84%
Refused - Tdap	1	125	**1%**	74%	2%
Hepatitis B 3-dose series complete - ever	73	124	**59%**	75%	25%
Refused - Hepatitis B	9	124	**7%**	76%	2%
Immune - Hepatitis B	1	125	**1%**	77%	1%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Depression An Active Problem					
Yes	30	125	**24%**	78%	24%
No	95	125	**76%**	79%	76%
In patients without active depression, screened for depression during Audit period:					
Screened	93	95	**98%**	80%	80%
Not screened	2	95	**2%**		
Laboratory Exams					
Non-HDL cholesterol	116	125	**93%**	87%	74%
Non-HDL <130 mg/dl	43	125	**34%**	88%	45%
Non-HDL 130-159 mg/dl	32	125	**26%**	89%	16%
Non-HDL 160-190 mg/dl	22	125	**18%**	90%	8%
Non-HDL >190 mg/dl	19	125	**15%**	91%	5%
Not tested or no valid result	9	125	**7%**	92%	26%
LDL cholesterol	105	125	**84%**	93%	77%
LDL <100 mg/dl	54	125	**43%**	94%	47%
LDL 100-129 mg/dl	30	125	**24%**	95%	19%
LDL 130-160 mg/dl	15	125	**12%**	96%	8%
LDL >160 mg/dl	6	125	**5%**	97%	3%
Not tested or no valid result	20	125	**16%**	98%	23%
HDL cholesterol	116	125	**93%**	99%	75%
In females					
HDL ≤50 mg/dl	53	75	**71%**	100%	50%
HDL >50 mg/dl	17	75	**23%**	101%	25%
Not tested or no valid result	5	75	**7%**	102%	25%
In males					
HDL ≤40 mg/dl	24	50	**48%**	103%	42%
HDL >40 mg/dl	22	50	**44%**	104%	34%
Not tested or no valid result	4	50	**8%**	105%	25%
Triglycerides	116	125	**93%**	106%	75%
TG ≤400 mg/dl	101	125	**81%**	107%	70%
TG >400 mg/dl	15	125	**12%**	108%	5%
Not tested or no valid result	9	125	**7%**	109%	25%
eGFR to assess kidney function (In age 18 and above)	116	124	**94%**	81%	89%
eGFR ≥60 ml/min	94	124	**76%**	82%	72%
eGFR 30-59 ml/min	19	124	**15%**	83%	14%
eGFR 15-29 ml/min	1	124	**1%**	84%	2%
eGFR <15 ml/min	2	124	**2%**	85%	1%
Not tested or no valid result	8	124	**6%**	86%	11%

IHS Diabetes Care and Outcomes Audit - WebAudit
Audit Report for 2015 (Audit Period 01/01/2014 - 12/31/2014)
Facility: Test02

Annual Audit

125 charts were audited from 125 patients on the diabetes registry.

	# of Patients (Numerator)	# Considered (Denominator)	Percent	Area Percent	IHS Percent
Laboratory Exams					
Urine Albumin:Creatinine Ratio (UACR)					
Yes	111	125	**89%**	110%	61%
No	14	125	**11%**	111%	39%
In patients with UACR:					
Urine albumin excretion - Normal: <30 mg/g	63	111	**57%**	112%	63%
Urine albumin excretion - Increased:					
30-300 mg/g	30	111	**27%**	113%	27%
>300 mg/g	18	111	**16%**	114%	9%
In patients age 18 and above with eGFR ≥30, UACR done	108	113	**96%**	115%	68%
Cardiovascular Disease					
Diagnosed CVD	34	125	**27%**	116%	37%
Tuberculosis Status					
TB test done (skin or blood)	102	125	**82%**	117%	49%
If test done, skin test	102	102	**100%**	118%	99%
If test done, blood test	0	102	**0%**	119%	1%
If TB test done, positive result	11	102	**11%**	120%	17%
If positive TB test, treatment completed	2	11	**18%**	121%	25%
If negative TB test, after DM diagnosis	84	91	**92%**	122%	61%
Combined Outcomes Measures					
Patients meeting ALL of the following criteria: A1C <8.0, LDL <100, and mean BP <140/<90	18	125	**14%**	123%	20%
In age 18 and above, patients with both an eGFR and a UACR	109	124	**88%**	124%	59%

Definitions

[1]Known hypertension: Has hypertension listed as an active problem, or three visits with a diagnosis of hypertension ever (prior to the end of the Audit period).
[2]Increased urine albumin excretion: UACR≥30 mg/g.

[FR Doc. 2015–19088 Filed 8–3–15; 8:45 am]
BILLING CODE 4165–16–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute: 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Bench to Bassinet Administrative Coordinating Center.

Date: August 25, 2015.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7182, .Bethesda, MD 20892

Contact Person: Susan Wohler Sunnarborg, Ph.D. Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and