• Determination of COA context of use;

• Practical considerations to develop and implement COAs to document treatment benefit; and

• Description of interagency collaborations and public-private partnerships for COA development.

The Agency encourages patient advocates, health care providers, researchers, regulators, individuals from academia, industry, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm206132.htm* approximately 45 days after the workshop.

The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government Agencies to small businesses.

Dated: July 20, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Direct Service and Contracting Tribes Funding Opportunity

Announcement Type: Limited Competition.

Funding Announcement Number: HHS–2011–IHS–NIHOE–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates:

Application Deadline Date: August 2, 2011.

Review Date: August 8, 2011.

Earliest Anticipated Start Date: August 15, 2011.

I. Funding Opportunity Description

Statutory Authority: The Indian Health Service (IHS) is accepting applications for two limited competition cooperative agreements.

The IHS award includes the following three components, as described in this announcement: ''Retained Tribal Shares of Line Item 128 of the IHS Tribal Shares Table'' (Tribal Shares), ''Health Care Policy Analysis and Review'' and ''Tribal Leaders Diabetes Committee'' (TLDC). The IHS award is authorized under the Snyder Act, codified at 25 U.S.C. 13.

The CMS award, through IHS, includes the following component, as described in this announcement: ''CMS''. The CMS award is authorized under section 1110 of the Social Security Act, codified at 42 U.S.C. 1310, via an Intra-Departmental Delegation of Authority from CMS to IHS dated April 15, 2011 (IDDA–11–92), to permit obligation of funding for CMS for analyses, research and studies to address the potential and actual impact of CMS programs on American Indian/Alaska Native (AI/AN) beneficiaries and the health care system serving these beneficiaries.

IHS will be administering the CMS award pursuant to the Economy Act, codified at 31 U.S.C. 1535. It is the intention of IHS and CMS that one entity will receive both awards. CMS and IHS will concur on the final decision as to who will receive the CMS award. Each award is funded by each respective agency's appropriation. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports (one for each award), as indicated in Section VI. Award Administration Information, Number 4. Reporting Requirements, Item A. Progress Reports and Item B. Financial Reports of this announcement.

This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA).

Background: Outreach and education programs (program) carry out health program objectives in the AI/AN community in the interest of improving Indian health care for all 565 Federally-recognized Tribes, including Tribal governments operating their own health care delivery systems through self-determination contracts with the IHS and Tribes that continue to receive health care directly from the IHS. This program addresses health policy and health programs issues and disseminates educational information to all AI/AN Tribes and villages. These awards require that public forums be held at Tribal educational consumer conferences to disseminate changes and updates in the latest health care information. These awards also require that regional and national meetings be coordinated for information dissemination as well as the inclusion of planning and technical assistance and health care recommendations on behalf of participating Tribes to ultimately inform IHS and CMS based on Tribal input through a broad based consumer network.

Purpose: The purpose of these awards is to further IHS and CMS missions and goals related to providing quality health care to the AI/AN community through outreach and education efforts with the sole outcome of improving Indian health care. The following health services components will be awarded:

IHS Cooperative Agreement Components

1. Tribal Shares
2. Health Care Policy Analysis and Review
3. TLDC

CMS Cooperative Agreement Component

1. CMS

II. Award Information

Type of Award: Cooperative Agreements.

Estimated Funds Available: The total amount of funding identified for fiscal year (FY) 2011 is approximately $1,250,000 to fund the two cooperative agreements for one year. $300,000 is estimated for outreach, education, and support to Tribes who have elected to leave their Tribal Shares with the IHS (this amount could vary based on Tribal Share assumptions; Tribal Shares funding will be awarded in partial increments based on availability and amount of funding); $100,000 for the Health Care Policy Analysis and Review; $250,000 associated with providing legislative education, outreach and communications support to the IHS TLDC and to facilitate Tribal consultation on the Special Diabetes Program for Indians (SDPI); and $600,000 for CMS. The awards under this announcement *are subject to the availability of funds.*

Anticipated Number of Awards: Two awards are anticipated as follows: One IHS award comprised of the following three components: Tribal Shares; Health

Care Policy Analysis and Review; and TLDC; and one CMS award comprised of the following component: CMS.

IHS Award

A. Tribal Shares portion of funding. Tribal Shares dollar amounts available for distribution to the awardee are determined each fiscal year by the IHS Office of Finance and Accounting; *e.g.,* estimated initial set-aside amount and final determination of remaining balances after Tribes and Tribal Organizations (T/TO) have either contracted or compacted Programs, Functions, Services, and Activities from IHS. FY 2011 is estimated at $300,000 total costs which may vary based on Tribal Shares assumption.

B. Health Care Policy Analysis and Review in the amount of $100,000.

C. TLDC in the amount of $250,000.

Project Period: August 15, 2011 with completion by August 14, 2012.

CMS Award

A. CMS in the amount of $600,000.

Project Period: August 15, 2011 with completion by August 14, 2012.

IHS Award Activities

1. Tribal Shares Funding Is Utilized for Outreach, Education, and Support to Tribes

The awardee is expected to:

1. Host an Annual Consumer Conference to disseminate changes and updates on health care information relative to AI/AN.

2. Host mid-year consumer conference(s) as appropriate to disseminate changes and updates on health care information relative to AI/AN.

3. Conduct regional and national meeting coordination as appropriate.

4. Conduct health care information dissemination as appropriate.

5. Coordinate planning and technical assistance needs on behalf of T/TO to IHS and CMS.

6. Convey health care recommendations on behalf of T/TO to IHS and CMS.

2. Health Care Policy Analysis and Review

This funding component requires the awardee to provide IHS with research and analysis of the impact of CMS programs on AI/AN beneficiaries and the health care delivery system that serves these beneficiaries. The awardee will perform in-depth health care policy analysis and review of issues related to CMS rules and regulations and the impact on IHS beneficiaries. This is to include, but not be limited to, a special emphasis and focus on the health care policy issues related to the special provisions for Indians in the Affordable Care Act (ACA).

The awardee will produce measurable outcomes to include:

1. Analytical reports, policy review and recommendation documents—The products will be in the form of written and/or electronic files that contain useful analysis relative to current and proposed health care policy and reform to be reported on a monthly or quarterly basis during the IHS and CMS teleconferences and face-to-face meetings with hard copies submitted to the Director, Office of Resource, Access and Partnerships, IHS.

2. Educational and informational materials to be disseminated by the awardee and communicated to IHS and Tribal health program staff during monthly and quarterly conferences, the Annual Consumer Conference, meetings and training sessions. This can be in the form of power point presentations, informational brochures, and/or handout materials.

3. TLDC and Related Support Activities

A. Coordination of travel and travel/per diem reimbursement of 12 TLDC members and five Technical Advisors to attend four quarterly TLDC meetings in accordance with the approved TLDC charter. Amount: $150,000.

Activities to be performed by the awardee include:

- Communicate directly with TLDC members (and alternates, as necessary) to arrange travel to TLDC meetings in accordance with the approved charter.
- Address and track all inquiries regarding travel arrangements and reimbursements for TLDC members and advisors (and alternates, as necessary) to attend planned TLDC meetings.
- Coordinate sharing of logistical information to TLDC members and advisors for meeting location and lodging with the IHS Division of Diabetes Treatment and Prevention (DDTP) contractor(s).
- Prepare and distribute reimbursement forms with clear instructions, in advance of the meeting and serve as the point of contact for communicating any additional travel information that is required.
- Establish a process to collect reimbursement forms from TLDC members and communicate this process to them.
- Establish and maintain a database on travel reimbursements and related meeting costs.
- Track and report all related travel and per diem costs.
- Coordinate and effect the timely reimbursement of approved participants' expenses within 30 days of the receipt of the claim forms.
- Maintain an active TLDC e-mail directory in order to assist the DDTP and the TLDC with broadcasting related meeting, travel and reimbursement information and soliciting related feedback.
- Include identified DDTP staff on all electronic correspondence to TLDC members.

B. Provide education, outreach and communications support to communicate with Tribal leaders and Indian organizations about the progress of the TLDC and the SDPI grant program. Amount: $70,000.

Activities to be performed by the awardee include:

- Gather and provide information on policy issues that are relevant to diabetes and related conditions in AI/ANs for the purpose of keeping TLDC membership up-to-date on such legislative information.
- Assist the TLDC with communication to Tribes, Tribal leaders, Indian organizations, and others about the success and outcomes of the SDPI and best practice information, to date.
- Coordinate sharing of TLDC information with national non-profit organizations such as the Juvenile Diabetes Research Foundation (JDRF) and the American Diabetes Association (ADA) for improving outreach to Tribes and Tribal communities as well as education and outreach to non-Indian communities in America about AI/ANs living with diabetes.
- Participate in the development of meeting agendas for face-to-face and conference call meetings under the direction of the TLDC and DDTP.
- Support the DDTP activities at mid-year meetings and the Annual Consumer Conference, which will include a plenary presentation on diabetes and up to four workshops through the payment of presenter fees, registration fees and exhibit fees.
- Support presentations that address diabetes and related chronic disease issues among AI/ANs at national Tribal health care conferences through payment of presenter fees and costs for no more than three separate trips.

C. Support collaborative efforts aimed at addressing obesity and AI/AN youth Annual Amount: $30,000.

Activities to be performed by the awardee include:

- Address the findings in the report generated at the National Indian Health Board (NIHB)/IHS Obesity Prevention and Strategies in Native Youth Meeting held December 1, 2009 (contact DDTP for this report).

○ Reconvene childhood obesity workgroup to review report cited above, review action steps and begin planning process.

CMS Award Activities

1. Centers for Medicare and Medicaid Services (CMS) in the amount of $600,000.

CMS Research Projects

CMS is funding five research activities/projects for FY 2011 in the amount of $600,000, subject to the availability of funding.

The research projects are as follows:

(1) *CMS Regulations/Initiatives Impact Analysis Project Objective: $200,000*—Assess the impact of the ACA through an analysis of CMS regulations and CMS initiatives that have a potential impact or effect on IHS, Tribal and Urban (I/T/U) providers and AI/AN beneficiaries. The objective is to determine and monitor the level of AI/AN participation in the CMS regulatory process and assess whether such participation contributes to the understanding of how CMS-related provisions in the ACA impact the financing and delivery of health care in the Indian health care system. Specific tasks include:

- Review the **Federal Register** to identify ACA CMS-related regulations and policies impacting I/T/U providers and prepare factual analysis on the potential impact on I/T/U providers and AI/AN beneficiaries.
- Analyze the impact of CMS regulations and CMS health reform initiatives on AI/AN access to Medicare, Medicaid and CHIP programs.
- Submit to the CMS Tribal Technical Advisory Group (TTAG) a bi-weekly status report of regulations and policies reviewed and commented on; such status report shall include a brief summary of the regulation, and a concise description of the impact of the regulation on I/T/U providers and AI/AN beneficiaries.
- Prepare for the CMS Tribal Affairs Group/Office of Public Engagement quarterly reports and an annual report which summarizes the impacts of the ACA CMS-related regulations and initiatives on provision of health care in the I/T/U system and AI/AN beneficiaries.

(2) *Data Research and Analysis Project Objective: $250,000*—Refine inventory and analysis of AI/AN demographic, enrollment, and utilization data through coordinated review of CMS, IHS, Social Security Administration (SSA), Census and other data resources to develop strategies that make CMS data systems capable of reporting AI/AN enrollment, service utilization, health status and payment data from the Medicare, Medicaid and CHIP programs to facilitate program planning and evaluation, performance measurement, health status monitoring, and targeted enrollment efforts. Coordinate and perform data analysis activities consistent with Health Insurance Portability and Accountability Act rules. Specific tasks include:

- Refine understanding of current data collection and reporting requirements and capabilities of the Medicare system and develop proposals for additional data collection and/or coordination of current efforts to ensure that the data accurately reflects enrollment and utilization of program services, and propose system changes to improve analytic capabilities.
- Refine proposals for protocols that accurately reflect appropriate collection of ethnicity data on national basis.
- Develop research protocols to determine rates of racial misclassification in current Medicaid data, determine difference in rates of Medicaid enrollment and services utilization between Medicaid racially identified AI/ANs and IHS AI/AN Active Users and other recipients, and analyze determinants which may cause differences in Medicaid use and payments for Medicaid racially identified AI/ANs and IHS AI/AN Active Users and other recipients.
- Prepare Medicare and Medicaid/CHIP annual reports that include findings from the analysis of the Medicare, Medicaid, and CHIP data, identifies gaps in data collection, identifies shortcomings in system interactions, proposes CMS/IHS/SSA data interface protocols, and makes specific recommendations on additional data systems improvements.
- Propose and analyze approaches necessary to change and augment data collection systems and other information needed to support all reporting required under the ACA, Children's Health Insurance Program Reauthorization Act (CHIPRA) and American Recovery and Reinvestment Act (ARRA), and propose reporting mechanisms and protocols for such reporting.

(3) *CMS Day and other Research Education Activities Project Objective: $100,000*—Provide a national forum and educational opportunity for sharing the results of CMS-sponsored research and education and outreach efforts with Tribal leadership, Tribal program directors and staff, Tribal beneficiaries and IHS leadership and program staff to enhance information sharing between CMS and the Indian health care system. Specific tasks include:

- Within 30 business days after the effective date of the CMS cooperative agreement award, participate in a conference call or meeting with CMS and IHS to clarify the goals and objectives of a CMS Day during the Annual Consumer Conference and to discuss the agenda for CMS Day.
- Within ten business days after initial meeting, forward to the IHS and CMS Project Officers for approval a preliminary plan that includes methodology for surveying Tribes or other methodologies to determine the most appropriate ways to share CMS information and make use of CMS Day and a preliminary plan for meeting logistics.
- Collaborate with the TTAG throughout the planning phase to ensure their input is obtained on the agenda and other meeting developments.
- Make all necessary arrangements with the convention site to acquire and ensure ample conference rooms, audio-visual equipment, and appropriate room set-ups for this one day CMS meeting.
- Extend the invitation to any Tribal participants who are identified as part of the survey/information gathering process to determine who should participate in the CMS Day and the best methods for further information sharing.
- Meet periodically with CMS and IHS to discuss progress for the CMS Day and incorporate all changes recommended by the agencies.
- Provide periodic progress updates.
- Prepare the final draft CMS Day agenda that incorporates recommendations from CMS, IHS and the TTAG.
- Include up to 40 CMS staff and presenters to permit key staff to participate in the Conference and present on research findings and conduct outreach related activities on CMS Day.
- Develop and disseminate evaluation forms after each session to permit CMS, IHS and the TTAG to determine how to improve current practices and identify other areas where training is needed to determine other areas for research and outreach.

(4) *Strategic Plan Development and Analysis Project Objective: $25,000*—Revise and update the current TTAG Strategic Plan (currently for the years 2010–2015) to include recent new authorities in the ACA and other changes as they have developed through CHIPRA and ARRA. With the recent statutory authorization for a permanent TTAG, this plan reflects the commitment of CMS to ongoing input from the TTAG on the administration of

CMS programs in Indian Country. Specific tasks include:

- Revise and update the current strategic plan to include the years 2012–2018.
- Review objectives stated in the plan for current relevance and update and propose new objectives as appropriate in line with current program status.
- Review and propose new action steps in the plan as appropriate.
- Review and propose new budget categories and priorities to align the plan with the CMS budget process and funding mechanisms.
- Coordinate at least one in-person meeting of the Strategic Plan Subcommittee and conduct in-person interviews with CMS Baltimore headquarters staff as part of the process of updating objectives, action steps and budget alignment.

(5) *Consultation Policy Development Project Objective: $25,000*—Provide research support and approaches/options for the development of a CMS specific Tribal consultation policy. CMS currently does not have an agency specific policy and needs to develop a policy consonant with the recently revised HHS policy. Specific tasks include:

- Review the newly developed HHS policy for impact on individual agencies.
- Review the CMS draft plan developed in 2008 for consonance with the new HHS policy.
- Review all other currently approved HHS Operating Divisions' policies for potential impact and inclusion of approaches in a new CMS policy.
- Survey Tribal leadership for input on how to develop an effective CMS policy.
- Coordinate at least one in-person meeting of the Tribal Consultation Subcommittee and participate in in-person interviews with CMS Baltimore headquarters staff on specific areas such as budget and regulation development to ensure full understanding of all CMS perspectives.
- Prepare an options paper and specific language for all aspects of the proposed CMS Consultation policy.
- Provide ongoing review and updates as CMS policy becomes operational.

Roles of Involvement: In accordance with the Federal Grant and Cooperative Agreement Act of 1977, two cooperative agreements will be awarded, as IHS and CMS will have substantial programmatic involvement as applicable with the awardee in carrying out each of the two awards as noted in the following delineated roles of involvement to further IHS and CMS health program objectives in the AI/AN community with outreach and education efforts in the interest of improving Indian health care.

Cooperative Agreements—Involvement of Parties: The awardee is responsible for the following in addition to fulfilling all requirements noted for each award component: Tribal Shares, Health Care Policy Analysis and Review, TLDC, and CMS:

(1) To facilitate a forum or forums where concerns can be heard that are representative of all Tribal Governments in the area of health care policy analysis and program development for each of the four components listed above;

(2) To assure that health care outreach and education is based on Tribal input through a broad-based consumer network involving the Area Indian Health Boards or Health Board Representatives from each of the twelve IHS Areas;

(3) To establish relationships with other national Indian organizations, with professional groups and with Federal, State and local entities supportive of AI/AN health programs;

(4) To improve and expand access for AI/AN Tribal Governments to all available programs within the HHS;

(5) To disseminate timely health care information to Tribal Governments, AI/AN Health Boards, other national Indian organizations, professional groups, Federal, State, and local entities;

(6) To provide an opportunity for Tribal Government officials to share their concerns, challenges, and recommendations for improving health care delivery through the IHS in forums designed to provide training, technical assistance and appropriate policy discussions; and

(7) To provide periodic dissemination of health care information, including publication of a newsletter four times a year that features articles on health promotion/disease prevention activities and models of best or improving practices, health policy and funding information relevant to AI/AN, *etc.*

Programmatic involvement of IHS staff in IHS and CMS awards: (IHS will be administering the CMS award pursuant to the Economy Act, codified at 31 U.S.C. 1535):

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

(2) The IHS assigned program official will monitor the overall progress of the awardee's execution of the requirements of the IHS award and the CMS award noted above, as well as their adherence to the terms and conditions of the cooperative agreements. This includes providing guidance for required reports, development of tools, and other products, interpreting program findings and assistance with evaluation and overcoming any slippages encountered.

(3) The IHS assigned program official will work closely with CMS and all participating IHS health services/programs as appropriate per their requirements noted in each of their respective sections.

(4) The IHS assigned program official will coordinate the following for CMS and the participating IHS program offices and staff:

- Discussion and release of any and all special grant conditions upon fulfillment.
- Monthly scheduled conference calls.
- Appropriate dissemination of required reports to each participating program.

(5) IHS will jointly with the awardee plan and set an agenda for the Annual Consumer Conference that:

- Shares the training and/or accomplishments.
- Fosters collaboration among the participating program offices, agencies and/or departments.
- Increases visibility for the partnerships between the awardee IHS, and CMS.

(6) IHS will provide guidance in addressing deliverables and requirements.

(7) IHS will provide guidance in preparing articles for publication and/or presentations of program successes, lessons learned and new findings.

(8) IHS staff will review articles concerning the HHS for accuracy and may, if requested by the awardee, provide relevant articles.

(9) IHS will communicate via monthly conference calls, individual or collective site visits, and monthly meetings.

(10) IHS will provide technical assistance to the awardee as requested.

(11) IHS staff may, at the request of the entity's board, participate on study groups, in board meetings, and may recommend topics for analysis and discussion.

III. Eligibility

1. Eligible Applicants

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

Eligible entities must have demonstrated expertise in the following areas:

- Representing all Tribal governments and providing a variety of services to Tribes, Area Health Boards, Tribal organizations, and Federal agencies, and playing a major role in focusing attention on Indian health care needs, resulting in progress for Tribes.
- Promotion and support of Indian education, and coordinating efforts to inform AI/AN of Federal decisions that affect Tribal government interests including the improvement of Indian health care.
- National health policy and health programs administration.
- Have a national AI/AN constituency and clearly support critical services and activities within the IHS mission of improving the quality of health care for AI/AN people.
- Portray evidence of their solid support of improved healthcare in Indian Country.

IHS will be available to provide technical assistance to eligible applicants that meet the above criteria.

2. Limited Competition Announcement

This is a Limited Competition announcement. The funding levels noted include both direct and indirect costs. Applicant must address both projects. Applicants must provide a separate budget for each award and each budget may not exceed the maximum funding level from each agency. Limited competition refers to a funding opportunity that limits the eligibility to compete to more than one entity but less than all entities.

3. Other Required Information

(1) *Cost Sharing or Matching*—The IHS and CMS awards do not require matching funds or cost sharing.

(2) *Other Requirements*

- If the budgets submitted in the applications exceed the stated dollar amounts outlined within this announcement, the applications will not be considered for funding.
- Applications proposing other projects will be considered ineligible and will be returned to the applicant.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and instructions may be located at *http://www.Grants.gov* or *http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding.*

2. Content and Form of Application Submission

Mandatory documents for both the IHS award and the CMS award include:

- SF–424 Application for Federal Assistance.
- SF–424A Budget Information—Non-Construction Programs.
- SF–424B Assurances—Non-Construction Programs.
- Four separate budget narratives, one for each of the four components (not to exceed 2 single-spaced pages each). Four separate project narratives, one for each of the four components (not to exceed 10 single-spaced pages each)
- Health Board resolution (if applicable).
- 501(c)(3) Non-Profit Certification.
- Resumes for all key personnel.
- Position descriptions.
- Disclosure of Lobbying Activities (SF LLL) (if applicable).
- Copy of current negotiated indirect cost (IDC) rate agreement (if applicable).
- Documentation of current OMB A–133 required financial audit, (if applicable). Acceptable forms of documentation include:
  - E-mail confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
  - Face sheets from audit reports. These can be found on the FAC Web site.

Public Policy Requirements

All Federal-wide public policies apply to IHS grantees with the exception of the Discrimination policy. All guidelines provided in this announcement apply to both the IHS and CMS awards.

Requirements for Project and Budget Narratives

A. *Project Narratives for each of the four components:* This announcement is for two cooperative agreements; the narrative should be a separate Word document that is no longer than ten pages for each component: IHS will have 30 pages for three components and CMS will have ten pages for one component (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 limits noted above, only the first 30 pages of the IHS submission and only the first ten pages of the CMS submission 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. See below for additional details about what must be included in the narrative:

Page Limitations for Narrative for Each of the Four Components Submission:
Part A: Program Information (2 page limitation)
Section 1: Needs
Part B: Program Planning and Evaluation (6 page limitation)
Section 1: Program Plans
Section 2: Program Evaluation
Part C: Program Report (2 page limitation)
Section 1: Describe major accomplishments over the last 24 months.
Section 2: Describe major activities over the last 24 months.

B. *Narratives:* A separate budget narrative is required for each component. Each narrative must describe the budget amount(s) requested and match the corresponding scopes of work described in the project narrative. The page limitation should not exceed six pages for the IHS submission and two pages for the CMS submission—two pages per each of the four health services/programs components described in this announcement.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by August 2, 2011 at 12 midnight Eastern Time (ET). Any application received after the application deadline will not be accepted for processing.

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.
- Other Limitations—A current recipient cannot be awarded a new, renewal, or competing continuation grant for any of the following reasons:

—The current project is not progressing in a satisfactory manner;
—The current project is not in compliance with program and financial reporting requirements; or
—The applicant has an outstanding delinquent Federal debt. No award shall be made until either:
  - The delinquent account is paid in full; or
  - A negotiated repayment schedule is established and at least one payment is received.

6. Electronic Submission Requirements

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 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 of the requirement to submit electronic applications must follow the rules and timelines noted below when they submit a paper application. The applicant must request a waiver, if needed, 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. Refer to the CCR Section below for further information.

Please be aware of the following:

- Please search for the application package in Grants.gov by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header 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 CCR 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 Division of Grants Management (DGM).
- Page limitation requirements equally apply to paper and electronic applications. After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download your application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Office of Direct Service and Contracting Tribes (ODSCT) will notify applicants that the application has been received.

Technical Challenges

- If technical challenges arise and assistance is required with the electronic application process, contact Grants.gov Customer Support via e-mail at *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). 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 waiver from the agency must be obtained.
- If problems persist, contact Paul Gettys, DGM, (*Paul.Gettys@ihs.gov*) at (301) 443–5204.
- Waiver requests must be submitted in writing to *GrantsPolicy@ihs.gov* with a copy to *Tammy.Bagley@ihs.gov.* Please include a clear justification for the need to deviate from our standard electronic submission process. If the waiver is approved, the application should be sent directly to the DGM by the deadline date of August 2, 2011. A copy of the approved waiver must be submitted along with the paper application that is mailed to the DGM (Refer to Section VII to obtain the mailing address). Paper applications that are submitted without a waiver will be returned to the applicant without review or further consideration. Late applications will not be accepted for processing or considered for funding and will be returned to the applicant.

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 CCR database. Additionally, 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. These requirements will ensure use of a universal identifier to enhance the quality of information available to the public. Effective October 1, 2010, all HHS recipients were asked to start reporting information on subawards, as required by the Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''). The DUNS number is a unique nine-digit identification number provided by D&B, which uniquely identifies your entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, you may access it through the following Web site *http://fedgov.dnb.com/webform* or to expedite the process, call (866) 705–5711.

Central Contractor Registry

Organizations that have not registered with CCR will need to obtain a DUNS number first and then access the CCR online registration through the CCR home page at *https://www.bpn.gov/ccr/default.aspx* (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 your CCR registration will take approximately 3–5 business days to process. Registration with the CCR is free of charge.

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and CCR, can be found on the IHS DGM Web site: *http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_policy_topics.*

V. Application Review/Information

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:

Evaluation Criteria

Part A: Program Information—Needs (15 points)
Part B: Program Planning and Evaluation
Program Plans—(40 points)
Program Evaluation—(20 points)
Part C: Program Report (15 points)
Budget Narratives (10 points)

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. Points will be assigned to each evaluation criteria adding up to a total of 100 points.

Part A: Program Information

Project Narrative

A. Abstract—One page summarizing project (narrative).

B. Criteria.

(1) INTRODUCTION AND NEED FOR ASSISTANCE (15 points)

(a) Describe the organization's current health, education and technical assistance operations as related to the broad spectrum of health needs of the AI/AN community. Include what programs and services are currently provided (*i.e.,* Federally-funded, State-funded, *etc.*), any memorandums of agreement with other National, Area or local Indian health board organizations. This could also include HHS' agencies that rely on the applicant as the primary gateway organization that is capable of providing the dissemination of health information. Include information regarding technologies currently used (*i.e.,* hardware, software, services, Web

sites, *etc.*), and identify the source(s) of technical support for those technologies (*i.e.,* in-house staff, contractors, vendors, *etc.*). Include information regarding how long the applicant has been operating and its length of association/partnerships with Area health boards, *etc.* [historical collaboration].

(b) Describe the organization's current technical assistance ability. Include what programs and services are currently provided, programs and services projected to be provided, memorandums of agreement with other national Indian organizations that deem the applicant as the primary source of health policy information for AI/AN, memorandums of agreement with other Area Indian health boards, *etc.*

(c) Describe the population to be served by the proposed projects. Are they hard to reach? Are there barriers? Include a description of the number of Tribes who currently benefit from the technical assistance provided by the applicant.

(d) Describe the geographic location of the proposed projects including any geographic barriers experienced by the recipients of the technical assistance to the health care information provided.

(e) Identify all previous IHS cooperative agreement awards received, dates of funding and summaries of the projects' accomplishments. State how previous cooperative agreement funds facilitated education, training and technical assistance nation-wide for AI/ANs and relate the progression of health care information delivery and development relative to the current proposed projects. (Copies of reports will not be accepted.)

(f) Describe collaborative and supportive efforts with national, Area and local Indian health boards.

(g) Explain the need/reason for your proposed projects by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed projects. Explain how these gaps/weaknesses were discovered. If the proposed projects include information technology (*i.e.,* hardware, software, *etc.*), provide further information regarding measures taken or to be taken that ensure the proposed projects will not create other gaps in services or infrastructure (*i.e.,* IHS interface capability, Government Performance Results Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, *etc.*), if applicable.

(h) Describe the effect of the proposed projects on current programs (*i.e.,* Federally-funded, State-funded, *etc.*) and, if applicable, on current equipment (*i.e.,* hardware, software, services, *etc.*). Include the effect of the proposed projects on planned/anticipated programs and/or equipment.

(i) Describe how the projects relate to the purpose of the cooperative agreement by addressing the following: Identify how the proposed projects will address outreach and education regarding various health data listed, *e.g.,* Health Care Policy Analysis and Review, TLDC, and CMS, *etc.,* dissemination, training, and technical assistance.

Part B: Program Planning and Evaluation

Section 1: Program Plans

(2) PROJECT OBJECTIVE(S), WORKPLAN AND CONSULTANTS (40 points)

(a) Identify the proposed objective(s) for each of the four projects, as applicable, addressing the following:

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

Example: Issue four quarterly newsletters, provide alerts and quantify number of contacts with Tribes.

Goals must be clear and concise. Objectives must be measurable, feasible and attainable for each of the selected projects.

(b) Address how the proposed projects will result in change or improvement in program operations or processes for each proposed project objective for all of the selected projects. Also address what tangible products, if any, are expected from the projects, (*i.e.,* legislative analysis, policy analysis, Annual Consumer Conference, mid-year conferences, summits, *etc.*).

(c) Address the extent to which the proposed projects will provide, improve, or expand services that address the need(s) of the target population. Include a strategic plan and business plan currently in place and that are being used that will include the expanded services. Include the plan(s) with the application submission.

(d) Submit a work plan in the appendix which includes the following information:

- Provide the action steps on a timeline for accomplishing each of the projects' proposed objective(s).
- Identify who will perform the action steps.
- Identify who will supervise the action steps.
- Identify what tangible products will be produced during and at the end of the proposed projects' objective(s).
- Identify who will accept and/or approve work products during the duration of the proposed projects and at the end of the proposed projects.
- Include any training that will take place during the proposed projects and who will be attending the training.
- Include evaluation activities planned in the work plans.

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

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products to be delivered on a timeline.

If a potential consultant/contractor has already been identified, please include a resume in the Appendix.

(f) Describe what updates will be required for the continued success of the proposed projects. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

Section 2: Program Evaluation

PROJECT EVALUATION (20 points)

Each proposed objective requires an evaluation component to assess its progression and ensure its completion. Also, include the evaluation activities in the work plan.

Describe the proposed plan to evaluate both outcomes and process. Outcome evaluation relates to the results identified in the objectives, and process evaluation relates to the work plan and activities of the project.

a. For outcome evaluation, describe:

- What will the criteria be for determining success of each objective?
- What data will be collected to determine whether the objective was met?
- At what intervals will data be collected?
- Who will collect the data and their qualifications?
- How will the data be analyzed?
- How will the results be used?

b. For process evaluation, describe:

- How will each project be monitored and assessed for potential problems and needed quality improvements?
- Who will be responsible for monitoring and managing each project's improvements based on results of ongoing process improvements and their qualifications?
- How will ongoing monitoring be used to improve the projects?
- Describe any products, such as manuals or policies, that might be developed and how they might lend themselves to replication by others.

• How will the organization document what is learned throughout each of the projects' periods?

c. Describe any evaluation efforts planned after the grant period has ended.

d. Describe the ultimate benefit to the AI/AN population that the applicant organization serves that will be derived from these projects.

Part C: Program Report

Section 1: Describe Major Accomplishments Over the Last 24 Months

Section 2: Describe Major Activities Over the Last 24 Months

ORGANIZATIONAL CAPABILITIES AND QUALIFICATIONS (15 points)

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

(a) Describe the organizational structure of the organization beyond health care activities, if applicable.

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

(c) Describe what equipment (*i.e.*, fax machine, phone, computer, *etc.*) and facility space (*i.e.*, office space) will be available for use during the proposed projects. Include information about any equipment not currently available that will be purchased through the cooperative agreement/grant.

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

(e) If personnel are to be only partially funded by this cooperative agreement, indicate the percentage of time to be allocated to the projects and identify the resources used to fund the remainder of the individual's salary.

Budget Narratives:

CATEGORICAL BUDGET AND BUDGET JUSTIFICATION (10 points)

This section should provide a clear estimate of the projects' program costs and justification for expenses for the entire cooperative agreement periods. The budgets and budget justifications should be consistent with the tasks identified in the work plans. Because each of the two awards included in this announcement are funded through separate funding streams, the applicant must provide a separate budget and budget narrative for each of the four components and must account for costs separately.

(a) Provide a categorical budget for each of the 12-month budget periods requested for each of the four projects.

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

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

Appendix Items

(1) Resolutions from Health Board of Directors (if applicable).

(2) Work plan for proposed objectives.

(3) Position descriptions for key staff.

(4) Resumes of key staff that reflect current duties.

(5) Consultant proposed scope of work (if applicable).

(6) Indirect Cost Rate Agreement (if applicable).

(7) Organizational chart.

Review and Selection Process

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Incomplete applications and applications that are non-responsive to the eligibility criteria may not be referred to the Objective Review Committee (ORC). Applicants will be notified by DGM, via e-mail or letter, to outline minor missing components (*i.e.,* signature on the SF–424, 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 e-mail 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. Applicants that receive less than a minimum score will be considered to be ''Disapproved'' and will be informed via e-mail or regular mail by the ODSCT of their application's deficiencies. A summary statement outlining the strengths and weaknesses of the application will be provided to each disapproved applicant. The summary statement will be sent to the Authorized Organizational Representative (AOR) that is identified on the face page (SF424), of the application within 60 days of the completion of the Objective Review.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by DGM and will be e-mailed or mailed via postal mail to the entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer as the authorizing document for which funds are disbursed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is a legally binding document.

2. Administrative Requirements

Grants are administrated in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this Announcement.

B. Administrative Regulations for Grants:

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

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

C. Grants Policy:

• HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

• Title 2: Grant and Agreements, part 225–Cost Principles for State, Local, and Indian Tribal Governments (OMB Circular A–87).

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

E. Audit Requirements:

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

3. Indirect Costs

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

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation *http://rates.psc.gov/* and the Department of Interior National Business Center *http://www.aqd.nbc.gov/services/ICS.aspx.* If your organization has questions regarding the indirect cost policy, please call Mr. Andrew Diggs, DGM, at (301) 443–5204 to request assistance.

4. Reporting Requirements

The awardee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. The reporting requirements for this program are noted below.

A. Progress Reports

Semi-annual progress report must be submitted within 30 days of the conclusion of the first six months of the budget period and a final within 90 days of the expiration of the budget period for each award. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. Final reports must be submitted within 90 days of expiration of the budget/project periods. Separate progress reports are required for the IHS award and the CMS award.

B. Financial Reports

SF 425 Federal Financial Reports, Cash Transaction and Expenditure Reports are due 30 days after the close of every calendar quarter to the Division of Payment Management, HHS at: *http://www.dpm.gov* for each award. It is recommended that you also send a copy of your SF 425 reports to your Grants Management Specialists. Failure to submit timely reports may cause a disruption in timely payments to your organization. Separate financial reports are required for the IHS award and the CMS award. The awardee is responsible for accounting for each award separately.

Awardees are responsible and accountable for accurate information being reported on all required reports: the Progress Reports and Federal Financial Reports.

C. Federal Subaward Reporting System (FSRS)

These awards may be subject to the Transparency Act subaward and executive compensation reporting requirements of 2 CFR part 170. The Transparency Act requires 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.

Effective October 1, 2010, IHS was instructed by HHS to implement a new Term and Condition into all new NoA, regarding the requirements for use and reporting of Federal subaward data. Although required to be referenced in all Funding Opportunity Announcements, this IHS Term of Award is applicable to all New (Type 1) IHS grants and cooperative agreement awards issued after October 1, 2010. Additionally, all IHS Renewal (Type 2) grant and cooperative agreement awards and Competing Revision awards (Competing T–3s) issued on or after October 1, 2010, may also be subject to the following award term. Further guidance on Renewal and Competing Revision award requirements to report subaward data is expected to be provided as it becomes available.

For the full IHS award term and condition implementing this requirement and additional award applicability information please visit the Grants Policy Web site at: *http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_policy_topics.*

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

VII. Agency Contact(s)

Grants (Business)

Mr. Andrew Diggs, DGM, Grants Management Specialist, 801 Thompson Avenue, TMP Suite 360, Rockville, Maryland 20852. *Telephone:* (301) 443–5204. *Fax:* (301) 443–9602. *E-Mail: Andrew.Diggs@ihs.gov.*

Program (Programmatic/Technical)

Ms. Roselyn Tso, Acting Director, ODSCT, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852. *Telephone:* (301) 443–1104. *Fax:* (301) 443–4666. *E-Mail: Roselyn.Tso@ihs.gov.*

VIII. Other Information

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

Dated: July 15, 2011.

Randy Grinnell,

Deputy Director, Indian Health Service.

[FR Doc. 2011–19144 Filed 7–27–11; 8:45 am]

BILLING CODE 4165–16–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of ACHP Quarterly Business Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will meet Thursday, August 11, 2011. The meeting will be held in the Plymouth Room of the Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.