

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry and review staff entitled "Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information." This guidance is intended to help applicants and CDER's review staff determine when a drug belongs to an established pharmacologic class as well as how to select the appropriate word or phrase (term) that describes the pharmacologic class for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling, as required by § 201.57(a)(6) (21 CFR 201.57(a)(6)).

In January 2006, FDA published a final rule that amended the requirements for the content and format of labeling for human prescription drug and biological products.¹ The new labeling format is intended to make it easier for health care professionals to access, read, and use the information in prescription drug labeling, thereby facilitating professionals' use of labeling to make prescribing decisions.

The rule requires that the following statement appear under the *Indications and Usage* section of *Highlights* if a drug is a member of an established pharmacologic class:²

"(Drug) is a (name of class) indicated for (indication(s))."

If the drug is not a member of an established pharmacologic class, the statement must be omitted.

Knowing the established pharmacologic class can provide health care professionals with important information about what to expect from a drug and how it relates to other therapeutic options. Such information can also help reduce the risk of duplicative therapy and drug interactions. This draft guidance provides recommendations for identifying the established pharmacologic class and its appropriate term for inclusion in the *Indications and Usage* section of *Highlights*.

¹See "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (71 FR 3922, January 24, 2006; 21 CFR parts 201, 314, and 601).

²See § 201.57(a)(6).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-9347 Filed 5-15-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Indian Health Service****Tribal Management Grant Program**

Announcement Type: New and Competing Continuation Discretionary Funding Cycle for Fiscal Year 2008.

Funding Announcement Number: HHS-2008-IHS-TMD-0001.

Catalog of Federal Domestic Assistance Number(s): 93.228.

Key Dates: Training: Application Requirements Session: May 8-9, May 23-24, and June 13-14, 2007; Grant Writing Session: June 4-8, 2007.

Application Deadline Date: August 3, 2007.

Receipt Date for Final Tribal Resolution: September 28, 2007.

Review Date: October 1-5, 2007.

Application Notification Date: November 12, 2007.

Earliest Anticipated Start Date: January 1, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Tribal Management Grant (TMG) Program. This program is authorized under Section 103(b)(2) and Section 103(e) of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended. This program is described at 93.228 in the Catalog of Federal Domestic Assistance.

The TMG Program is a national competitive discretionary grant program pursuant to 45 CFR 75 and 45 CFR 92 established to assist Federally-recognized Tribes and Tribally-sanctioned Tribal organizations in assuming all or part of existing IHS programs, services, functions, and activities (PSFA) through a Title I contract and to assist established Title I contractors and Title V compactors to further develop and improve their management capability. In addition, TMGs are available to Tribes/Tribal organizations under the authority of Public Law (Pub. L.) 93-638 section 103(e) for (1) obtaining technical assistance from providers designated by the Tribe/Tribal organization (including Tribes/Tribal organizations that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management and the development of cost allocation plans for indirect cost rates; and (2) planning, designing and evaluating Federal health programs serving the Tribe/Tribal organization, including Federal administrative functions.

Funding Priorities: The IHS has established the following funding priorities for TMG awards.

- Priority I—Any Indian Tribe that has received Federal recognition (restored, un-terminated, funded, or unfunded) within the past 5 years, specifically received during or after March 2002.
- Priority II—All other eligible Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations submitting a competing continuation application or a new application for the sole purpose of addressing audit material weaknesses. The audit material weaknesses are identified in Attachment A (Summary of Findings and Recommendations) and other attachments, if any, of the transmittal letter received from the Office of the Inspector General (OIG), National External Audit Review Center (NEARC), Department of Health and Human Services (HHS). Please identify the

weakness to be addressed by underlining the item on the Attachment A. Please refer to Section III.3, "Other Requirements" for more information regarding Priority II participation.

Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations not subject to Single Audit Act requirements must provide a financial statement identifying the Federal dollars received in the footnotes. The financial statement must also identify specific weaknesses/recommendations that will be addressed in the TMG proposal and are related to 25 Code of Federal Regulations (CFR) Part 900, "Indian Self-Determination and Education Assistance Act Amendments," Subpart F—"Standards for Tribes and Tribal Organizations."

Priority II participation is only applicable to the Health Management Structure project type. For more information see Section II Eligible Project Types, Maximum Funding and Project Periods.

- Priority III—All other eligible Federally-recognized Indian Tribes or Tribal organizations submitting a competing continuation application or a new application.

The funding of approved Priority I applicants will occur before the funding of approved Priority II applicants. Priority II applicants will be funded before approved Priority III applicants. Funds will be distributed until depleted.

II. Award Information:

Type of Awards: Grant.

Estimated Funds Available: Subject to the availability of funds, the estimated amount available is \$2,529,000 in fiscal year (FY) 2008. There will be only one funding cycle in FY 2008. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: An estimated 20–25 awards will be made under the Program.

Project Periods: Varies from 12 months to 36 months. Please refer to "Eligible Project Types, Maximum Funding and Project Periods" under this section for more detailed information.

Estimated Award Amount: \$50,000/year–\$100,000/year. Please refer to "Eligible Project Types, Maximum Funding and Project Periods" below for more detailed information.

Eligible Project Types, Maximum Funding and Project Periods: Applications may only be submitted for one project type. Applicants must state the project type selected. The TMG Program consists of four project types: (1) Feasibility study; (2) planning; (3) evaluation study; and (4) health

management structure. Applications that address more than one project type will be considered ineligible and will be returned to the applicant. The maximum funding levels noted include both direct and indirect costs. Applicant budgets may not exceed the maximum funding level or project period identified for a project type. Applicants whose budget or project period exceed the maximum funding level or project period will be considered ineligible and will not be reviewed. Please refer to Section IV.5, "Funding Restrictions" for further information regarding ineligible activities.

1. Feasibility Study (Maximum funding/project period: \$ 70,000/12 months)

A study of a specific IHS program or segment of a program to determine if Tribal management of the program is possible. The study shall present the planned approach, training and resources required to assume Tribal management of the program. The study must include the following four components:

- Health needs and health care services assessments that identify existing health care services and delivery system, program divisibility issues, health status indicators, unmet needs, volume projections and demand analysis.
- Management analysis of existing management structures, proposed management structures, implementation plans and requirements, and personnel staffing requirements and recruitment barriers.
- Financial analysis of historical trends data, financial projections and new resource requirements for program management costs and analysis of potential revenues from Federal/non-Federal sources.
- Decision statement/report that incorporates findings, conclusions and recommendations; the presentation of the study and recommendations to the governing body for Tribal determination regarding whether Tribal assumption of program(s) is desirable or warranted.

2. Planning (Maximum funding/project period: \$50,000/12 months)

A collection of data to establish goals and performance measures of current health programs or anticipated PSFAs under a Title I contract. Planning will specify the design of health programs and the management systems (including appropriate policies and procedures) to accomplish the health priorities of the Tribe/organization. For example, planning could include the development of a Tribal Specific Health Plan or a Strategic Health Plan, etc. Please note: The Public Health Service

urges applicants submitting strategic health plans to address specific objectives of Healthy People 2010. Interested applicants may purchase a copy of Healthy People 2010 (Summary Report in print; Stock No. 017–001–00547–9) or CD-ROM (Stock No. 107–001–00549–5) through the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, Pennsylvania 15250–1800. This information is available in electronic form at the following Web site: www.health.gov/healthypeople/publications.

3. Evaluation Study (Maximum funding/project period: \$50,000/12 months)

A systematic collection, analysis and interpretation of data for the purpose of determining the value of a program. The extent of the evaluation study could relate to the goals and objectives, policies and procedures or program regarding targeted groups. The evaluation study could also be used to determine the effectiveness and efficiency of a Tribal program operation (i.e. direct services, financial management, personnel, data collection and analysis, third-party billing, etc.) as well as determine the appropriateness of new components to a Tribal program operation that will assist Tribal efforts to improve the health care delivery systems.

4. Health Management Structure (Average funding/project period: \$100,000/12 months; maximum funding/project period: \$300,000/36 months)

Implementation of systems to manage or organize PSFAs. Management structures include health department organizations, health boards, and financial management systems including systems for accounting, personnel, third-party billing, medical records, management information systems, etc. This includes the design, improvements and correction of management systems that address weaknesses identified through quality control measures, internal control reviews and audit report findings under the Office of Management and Budget (OMB) Circular No. A–133—Revised June 27, 2003, "Audits of States, Local Governments, and non-Profit Organizations." A copy of this circular and 25 Code of Federal Regulations (CFR) Part 900, "Indian Self-Determination and Education Assistance Act Amendments", Subpart F—"Standards for Tribal or Tribal Organization Management Systems" is available in the appendix of the TMG application package. Please see Section IV "Application and Submission

Information” for directions about how to request a copy of the TMG application package.

III. Eligibility Information

1. Indian Tribe or Tribal organization as defined by Pub. L. 93–638, Indian Self-Determination and Education Assistant Act, as amended. Eligible applicants include Tribal organizations that operate mature contracts that are designated by a Tribe to provide technical assistance and/or training. Only one application per Tribe or Tribal organization is allowed. This paragraph should be cross-referenced with Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Applications Submission).

2. Cost Sharing or Matching—The TMG Program does not require matching funds or cost sharing. However, in accordance with Pub. L. 93–638 section 103(c), the TMG funds may be used as matching shares for any other Federal grant programs that develop Tribal capabilities to contract for the administration and operation of health programs.

3. Other Requirements—If application budgets exceed the stated dollar amount that is outlined within this announcement, it will not be considered for funding.

The following documentation is required:

- Tribal Resolution—A resolution of the Indian Tribe served by the project must accompany the application submission. An Indian Tribe that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. 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. A copy of that resolution must be provided for review. If an official Tribal resolution is not available by the application deadline, a draft resolution should be submitted. However, an official signed Tribal resolution must be received by the Division of Grants Operations prior to the beginning of the Objective Review (October 1–5, 2007). If an official signed resolution is not received by the close of business on September 28, 2007, the application will be considered incomplete, ineligible for review and returned to the applicant without consideration. Applicants submitting additional documentation after the initial application submission are required to ensure the information was received by the IHS by obtaining documentation confirming delivery or

receipt (i.e. fax transmittal receipt, FedEx tracking, postal return receipt, etc.).

- Documentation for Priority I Participation—A copy of the **Federal Register** notice or letter from the Bureau of Indian Affairs verifying establishment of Federal Tribal status within the last 5 years. Date must reflect that Federal recognition was received during or after March 2002.

- Documentation for Priority II Participation—A copy of the transmittal letter and Attachment A from the OIG, NEAR Center, HHS. See “Funding Priorities” in Section I for more information. If an applicant is unable to locate a copy of their most recent transmittal letter or needs assistance with audit issues, information or technical assistance may be obtained by contacting the IHS Division of Audit Resolution at (301) 443–7301, or the National External Audit Review Center help line at (816) 374–6714 ext. 108. The auditor may also have the information/documentation required.

Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations not subject to Single Audit Act requirements must provide a financial statement identifying the Federal dollars in the footnotes. The financial statement must also identify specific weaknesses/recommendations that will be addressed in the TMG proposal and are related to 25 CFR Part 900, “Indian Self-Determination and Education Assistance Act Amendments,” Subpart F—“Standards for Tribes and Tribal Organizations.”

- Documentation of Consortium Participation—If an Indian Tribe submitting an application is a member of a consortium, the Tribe must:

- Identify the consortium.
- Indicate if the consortium intends to submit a TMG application.
- Demonstrate that the Tribe’s application does not duplicate or overlap any objectives of the consortium’s application.

- Identify all of the consortium member Tribes.

- Identify if any of the member Tribes intend to submit a TMG application of their own.

- Demonstrate that the consortium’s application does not duplicate or overlap any objectives of the other consortium members who may be submitting their own TMG application.

Please refer to Sections IV.5. “Funding Restrictions” and V.2. “Review and Selection Process” for more information regarding other application submission information and/or requirements.

IV. Application and Submission Information

1. Application package may be found in Grants.gov (www.grants.gov) or at: www.ihs.gov/NonMedicalPrograms/gogp. Information regarding the electronic application process may be obtained from the following persons:

Ms. Patricia Spotted Horse, Program Analyst, Office of Tribal Programs, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, (301) 443–1104 (Telephone), (301) 443–4666 (Fax). E-Mail Address: Patricia.SpottedHorse@IHS.GOV.

Mr. Pallop Chareonvootitam, Grants Management Specialist, Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, TMP 360, Rockville, Maryland 20852, (301) 443–5204 (Telephone), (301) 443–9602 (Fax). E-Mail Address: Pallop.Chareonvootitam@IHS.GOV.

Ms. Michelle G. Bulls, Chief Grants Management Officer, Director, Division of Grants Policy, Indian Health Service, 801 Thompson Avenue, TMP 625, Rockville, Maryland 20852, (301) 443–6528 (Telephone), E-Mail Address: Michelle.Bulls@IHS.GOV.

The entire application package is available at: www.ihs.gov/NonMedicalPrograms/tmg. Detailed application instructions for this announcement are downloadable on Grants.gov.

2. Content and Form of Application Submission

- Be single spaced.
- Be typewritten.
- Have consecutively numbered pages.
- Use black type not smaller than 12 characters per one inch.
- Contain a narrative that does not exceed 14 typed pages that include the other submission requirements below. The 14-page narrative does not include the abstract, the work plan, standard forms, Tribal resolution(s), table of contents, budget, budget justifications, multi-year narratives, multi-year budget, multi-year budget justification, and/or other appendix items.
- Abstract (one page) summarizing the project.
- Introduction and Need for Assistance.
- Project Objective(s), Approach and Results and Benefits.
- Project Evaluation.
- Organizational Capabilities and Qualifications.

Public Policy Requirements: All Federal-wide public policies apply to

IHS grants with exception of Lobbying and Discrimination.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12 midnight Eastern Standard Time (EST) on Friday, August 3, 2007. If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant must contact Michelle G. Bulls, Division of Grants Policy fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (emails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section IV.2. above. Applications not submitted through Grants.gov, without an approved waiver, will be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the application and will not be 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 indirect costs.
- Only one grant will be awarded per applicant.

• Ineligible Project Activities

The TMG may not be used to support recurring operational programs or to replace existing public and private resources. Note: The inclusion of the following projects or activities in an application will render the application ineligible and the application will be returned to the applicant:

- Planning and negotiating activities associated with the intent of a Tribe to enter the IHS Self-Governance Project. A separate grant program is administered by the IHS for this purpose. Prospective applicants interested in this program should contact Ms. Misty Nuttle, Office of Tribal Self-Governance, Indian Health Service, Reyes Building, 801 Thompson Avenue, Suite 240, Rockville, Maryland 20852, (301) 443-7821, and request information concerning the “Tribal Self-Governance Program Planning Cooperative Agreement Announcement” or the “Negotiation

Cooperative Agreement Announcement.”

- Projects related to water, sanitation, and waste management.
- Projects that include long-term care or provision of any direct services.
- Projects that include tuition, fees, or stipends for certification or training of staff to provide direct services.
- Projects that include pre-planning, design, and planning of construction for facilities, including activities relating to Program Justification Documents.
- Projects that propose more than one project type. Please see Section II, “award Information”, specifically “Eligible Project Types, Maximum Funding and Project Periods” for more information. an example of a proposal with more than one project type that would be considered ineligible may include the creation of a strategic health plan (defined by TMG as a planning project type) and improving third-party billing structures (defined by TMG as a health management structure project type).

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

- A grantee may not administer two TMGs at the same time or have overlapping project/budget periods;
- The current project is not progressing in a satisfactory manner; or
- The current project is not in compliance with program and financial reporting requirements.
- Delinquent Federal Debts: No award shall be made to an applicant who has an outstanding delinquent Federal debt until either:
- The delinquent account is paid in full; or
- A negotiated repayment schedule is established and at least one payment is received.

6. Other Submission Requirements

Electronic Submission—The preferred method for receipt of applications is electronic submission through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1-800-518-4726 or support@grants.gov. The Contact Center hours of operation are Monday-Friday from 7 a.m. to 9 p.m. EST. If you require additional assistance, please call (301) 443-6290 and identify the need for assistance regarding your Grants.gov application. Your call will be transferred to the appropriate grants staff member. The applicant must seek

assistance at least fifteen 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 requesting timely assistance with technical issues will not be a candidate for paper applications.

To submit an application electronically, please use the www.Grants.gov apply site. Download a copy of the application package, on the Grants.gov Web site, complete it offline and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to IHS.

Please be reminded of the following:

- Under the new IHS application submission requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, please directly contact Grants.gov Customer Support at: www.Grants.gov/CustomerSupport.
- Upon contacting Grants.gov obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from Grants Policy must be obtained.

• If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (emails are acceptable), to Michelle.Bulls@ihs.gov that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from Grants.gov, and sent directly to the Division of Grants Operations, 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by the due date, August 3, 2007.

• Upon entering the Grants.gov site, there is information available outlining the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation. We strongly encourage all applicants not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov, as the registration process for CCR and Grants.gov could take up to fifteen working days.

• To use Grants.gov, you, as the applicant, must have a Data Universal Numbering System (DUNS) Number and must register in the CCR. You should allow a minimum of ten working days to complete CCR registration. See below on how to apply.

• You must submit all documents electronically, including all information typically included on the SF-424 and

all necessary assurances and certifications.

- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.
- If Tribal resolutions or letters of support are required, please fax to the Grants Management Specialist identified in this announcement.
- Your application must comply with any page limitations requirements described in the program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Indian Health Service, DGO will retrieve your application from Grants.gov. DGO will not notify applicants that the application has been received.
- You may access the electronic application for this program on www.Grants.gov.
- You may search for the downloadable application package by either the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

• The applicant must provide the Funding Opportunity Number: HHS–2008–IHS–TMD–0001.

E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to have a Dun and Bradstreet (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access www.dunandbradstreet.com or call 1–866–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1–888–227–2423. Please review and complete the CCR Registration Worksheet located on www.Grants.gov/CCCRRegister.

More detailed information regarding these registration processes can be found at www.Grants.gov.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The 14-page narrative should include only the first years of activities; information for multi-year projects should be included as an appendix. See “Multi-Year Project Requirements” at the end of this section for more information.

1. Abstract—one page summary

A. Criteria

Introduction and Need for Assistance (20 Points)

(1) Describe the Tribe’s/Tribal organization’s current health operation. Include what programs and services are currently provided (i.e., Federally funded, State funded, etc.), information regarding technologies currently used (i.e., hardware, software, services, etc.), and identify the source(s) of technical support for those technologies (i.e., Tribal staff, Area Office, vendor, etc.). Include information regarding whether the Tribe/Tribal organization has a health department and/or health board and how long it has been operating.

(2) Describe the population to be served by the proposed project. Include a description of the number of IHS eligible beneficiaries who currently use services.

(3) Describe the geographic location of the proposed project including any geographic barriers to the health care users in the area to be served.

(4) Identify all TMGs received since FY 2002, dates of funding and summary of project accomplishments. State how previous TMG funds facilitated the progression of health development relative to the current proposed project. (Copies of reports will not be accepted.)

(5) Identify the eligible project type and priority group of the applicant.

(6) Explain the reason for your proposed project by identifying specific gaps or weaknesses in services or infrastructure that will be addressed by the proposed project. Explain how these gaps/weaknesses were discovered. If proposed project includes information technology (i.e., hardware, software, etc.), provide further information regarding measures taken or to be taken that ensure the proposed project will not create other gaps in services or infrastructure (i.e., IHS interface capability, Government Performance

and Results Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, etc.).

(7) Describe the effect of the proposed project 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 project on planned/anticipated programs and/or equipment.

(8) Addresses how the proposed project relates to the purpose of the TMB Program by addressing the appropriate description that follows:

- Identify if the Tribal/Tribal organization is an IHS Title I contractor. Address if the self-determination contract is a master contract of several programs or if individual contracts are used for each program. Include information regarding whether or not the Tribe participates in a consortium contract (i.e., more than one Tribe participating in a contract). Address what programs are currently provided through those contracts and how the proposed project will enhance the organization’s capacity to manage the contracts currently in place.

- Identify if the Tribe/Tribal organization is an IHS Title V compactor. Address when the Tribe/Tribal organization entered into the compact and how the proposed project will further enhance the organization’s management capabilities.

- Identify if the Tribe/Tribal organization is not a Title I or Title V organizations. Address how the proposed project will enhance the organization’s management capabilities, what programs and services the organization is currently seeking to contract and an anticipated date for contract.

Project Objective(s), Workplan and Consultants (40 Points)

A. Identify the proposed project objective(s) addressing the following:

- Measurable and (if applicable) quantifiable.

- Results oriented.

- Time-limited.

Example: The Tribe will increase the number of bills processed by 15% by installing new software by the end of 12 months.

B. Address how the proposed project will result in change or improvement in program operations or processes for each proposed project objective. Also address what tangible products are expected from the project (i.e., policies and procedures manual, health plan, etc.).

C. Address the extent to which the proposed project will build the local capacity to provide, improve, or expand services that address the needs(s) of the target population.

D. Submit a workplan in the appendix which includes the following information:

- Provide the action steps on a timeline for accomplishing the proposed project objective(s).
- Identify who will perform the action steps.
- Identify who will supervise the action steps taken.
- Identify who will accept and/or approve work products at the end of the proposed project.
- Include any training that will take place during the proposed project and who will be attending the training.
- Include evaluation activities planned.

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 (i.e., revision of policies/procedures, upgrades, technical support, etc.) will be required for the continued success of the proposed project. Include when these updates are anticipated and where funds will come from to conduct the update and/or maintenance.

Project Evaluation (15 Points)

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

A. For outcome evaluation, describe:

- What the criteria will 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 the data will be analyzed.
- How the results will be used.

B. For process evaluation, describe:

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

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

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

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

- How the project will document what is learned throughout the project period.

C. Describe any evaluation efforts that are planned to occur after the grant period ends.

D. Describe the ultimate benefit to the Tribe that is expected to result from this project. An example of this might be the ability of the Tribe to expand preventive health services because of increased billing and third party payments.

Organizational Capabilities and Qualifications (15 Points)

A. Describe the organizational structure of the Tribe/Tribal organization beyond health care activities.

B. Provide information regarding plans to obtain management systems if the Tribe/Tribal organization does not have an established management system currently in place that complies with 25 CFR 900, Subpart F, and "Standards for Tribal Management Systems". If management systems are already in place, simply note it. (A copy of the 25 CFR 900, Subpart F, is available in the TMG announcement.)

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

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

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

information on the proposed position description.

F. If the project requires additional personnel (i.e., IT support, etc.), address how the Tribe/Tribal organization will sustain the position(s) after the grant expires. (If there is no need for additional personnel, simply note it.)

Categorical Budget and Budget Justification (10 Points)

A. Provide a categorical budget for each of the 12-month budget periods requested.

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.)

Multi-Year Project Requirements

Projects requiring a second and/or third year must include a narrative addressing the second and/or third year's project objectives, evaluation components, work plan, categorical budget and budget justification. The same weights and criteria as noted in Section V. Application Review Information that is used to evaluate a one-year project or the first year of a multi-year project will be applied when evaluating the second and third years of a multi-year application. A weak second and/or third year submission could negatively impact the overall score of an application.

Appendix Items

- A. Work plan for proposed objectives.
- B. Position descriptions for key staff.
- C. Resumes of key staff that reflect current duties.
- D. Consultant proposed scope of work (if applicable).
- E. Indirect Cost Agreement.
- F. Organizational chart (optional).
- G. Multi-Year Project Requirements (if applicable).

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

- A. Application Submission (Application Deadline: August 3, 2007). Applications received in advance of or by the deadline and verified by the tracking number will undergo a preliminary review to determine that:
 - The applicant and proposed project type is eligible in accordance with this grant announcement;

- The application is not a duplication of a previously funded project; and
- The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise the application may be returned.

B. Competitive Review of Eligible Applications (Objective Review: October 1–5, 2007). Applications meeting eligibility requirements that are complete, responsive and conform to this program announcement will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of TMG funding is not sufficient to support all approved applications. Applications recommended for approval, having a score of 60 or above by the ORC and scored high enough to be considered for funding will be reviewed by the Division of Grants Operations for cost analysis and further recommendation. The program official accepts the Division of Grants Operations' recommendations for consideration when funding applications. The program official forwards the final approved list to the Director, Office of Tribal Programs, for final review and approval. Applications scoring below 60 points will be disapproved. Applications that are approved but not funded will not be carried over into the next cycle for funding consideration.

3. Anticipated Announcement and Award Dates

The IHS anticipates the earliest award start date will be January 1, 2008.

VI. Award Administration Information

1. Award Notices

ORC Results Notification: November 12, 2007. The Director, Office of Tribal Programs, or program official, will notify the contact person identified on each proposal of the results in writing

via postal mail. Applicants whose applications are declared ineligible will receive written notification of the ineligibility determination and their grant application via postal mail. The ineligible notification will include information regarding the rationale for the ineligible decision citing specific information from the original grant application. Applicants who are approved but unfunded and disapproved will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted. Applicants who are approved and funded will be notified through the official Notice of Award (NoA) document. The NoA will be signed by the Grants Management Officer and is the authorizing document for notifying grant recipients of funding. The NoA serves as the official notification of a grant award and will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period and the budget period. Any other correspondence announcing to the Applicant's Project Director that an application was recommended for approval is not an authorization to begin performance. Pre-award costs are not allowable charges under this program grant.

2. Administrative Requirements

Grants are administered in accordance with the following documents:

- This grant announcement.
- Health and Human Services regulations governing Pub. L. 93–638 grants at 42 CFR 36.101 et seq.
- 45 CFR Part 92, "Department of Health and Human Services, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments Including Indian Tribes," or 45 CFR Part 74, "Administration of Grants to Non-Profit Recipients".
- Public Health Service Grants Policy Statement.
- Appropriate Cost Principles: OMB Circular A–87, "State and Local Governments," or OMB Circular A–122, "Non profit Organizations".
- OMB Circular A–133, "Audits of States, Local Government and Non-Profit Organizations".
- Other Applicable OMB circulars.

3. Indirect Costs

This section applies to all grant recipients that request indirect cost in their application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to have a current indirect cost rate agreement in

place 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 means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the awarding office, the award shall funds for reimbursement of indirect costs. However, the indirect cost portion will remain restricted until the current rate is provided to DGO.

Generally, indirect costs rates for IHS Tribal organization grantees are negotiated with the Division of Cost Allocation (DCA) <http://rates.psc.gov> and indirect cost rates that are for IHS funded Federally recognized Tribes are negotiated with the Department of Interior. If your organization has questions regarding the indirect cost policy, please contact the Division of Grants Operations (DGO) at 301–443–5204.

4. Reporting

A. Progress Report. Program progress reports are required either semi-annually or annually. [Semi-annual] program progress reports must be submitted within 30 days at the end of the half year. These reports will include a brief comparison of actual accomplishments to the goals established for the period, reasons for slippage (if applicable), and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Reports. Financial status reports are required either semi-annually or annually. [Semi-annual] financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

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

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment.

Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organizations or the individual responsible for preparation of the reports.

VII. Agency Contact(s)

Interested parties may obtain TMG programmatic information from the TMG Program Coordinator listed under Section IV of this program announcement.

Grant related and business management information may be obtained from the Grants Management Specialist listed under Section IV of this program announcement. Grants.gov concerns submission and waiver requests may be addressed by Ms. Michelle Bulls, Division of Grants Policy. Contact information is noted under Section IV of this program announcement. Please note that the telephone numbers provided are not toll-free.

VIII. Other Information

The IHS will have three training sessions to assist applicants in preparing their FY 2008 TMG application. There will be one 5-day training session and three 2-day training sessions. The 5-day training session will provide participants with basic grant writing skills, information regarding where to search for funding opportunities, and the opportunity to begin writing a TMG grant proposal. The 2-day training sessions will focus specifically on the TMG requirements providing participants with information contained in this announcement, clarifying any issues/questions applicants may have and critiquing project ideas. In an effort to make the 2-day training sessions productive, participants are expected to bring draft proposals to these meetings.

Priority will be given to groups eligible to apply for the TMG Program. Participation is limited to two personnel from each Tribe or Tribal organization. All sessions are first-come first-serve with the above limitations noted. All participants are responsible for making and paying for their own travel arrangements. Interested parties should register with the TMG staff prior to making travel arrangements to ensure space is available in selected session.

There is no registration fee to attend the training session(s). The registration form may be obtained from the TMG Web site at: www.ihs.gov/NonMedicalPrograms/tmg. The registration form may be faxed to (301) 443-4666. The anticipated training dates and locations are listed below in chronological order:

- May 8–9, 2007—Oklahoma City, Oklahoma (Limit 25)
- May 23–24, 2007—Portland, Oregon (Limit 25)
- June 4–8, 2007—Minneapolis, Minnesota (Limit 25) (TGCI Grantsmanship Training)
- June 13–14, 2007—Billings, Montana (Limit 25)

IHS Checklist

The following IHS Checklist is included to assist applicants in proposal preparation and follow-up. Applicants are highly encouraged to employ this checklist for their benefit and to submit it as part of their proposal. This checklist will be utilized by the Office of Tribal Programs during their initial programmatic review of the application to ensure required items requested are submitted and the application is eligible for further review via the Objective Review Committee. This checklist is available on the TMG Web site at www.ihs.gov/nonmedicalprograms/tmg.

IHS FY 2008 TRIBAL MANAGEMENT GRANT APPLICATION CHECKLIST

Applicant Name: _____			
Application Tracing Number: _____			
Electronic Submission: _____		Waiver Obtained: _____	
Title I: _____	Title V: _____	Project Type: _____	

Item	Applicant	Grants	Programs
1. Eligibility: (circle) Tribe Tribal Organization	_____	_____	_____
2. 501c(3) Non-Profit Organization	_____	_____	_____
3. Tribal Resolution:			
a. Final signed resolution	_____	_____	_____
b. Draft unsigned resolution	_____	_____	_____
4. Priority I Documentation (if applicable)	_____	_____	_____
5. Priority II Documentation (if applicable)	_____	_____	_____
6. Consortium Participation Documentation (if applic.)	_____	_____	_____
7. SF 424 Application for Federal Assistance	_____	_____	_____
8. SF 424A Budget—Non Construction	_____	_____	_____
9. SF 424B Assurances	_____	_____	_____
10. Disclosure of Lobbying Activities	_____	_____	_____
11. Abstract	_____	_____	_____
Project Narrative (14 Pages Maximum):			
a. Introduction and Need for Assistance	_____	_____	_____
b. Project Objective(s), Workplan & Consultants	_____	_____	_____
c. Project Evaluation	_____	_____	_____
d. Organizational Capabilities and Qualifications	_____	_____	_____
13. Categorical Budget & Budget Justification	_____	_____	_____
14. Multi-year Summary & Budget Justification:			
Year 1 Year 2 Year 3	_____	_____	_____
15. Appendices:			
a. Workplan	_____	_____	_____
b. Resumes	_____	_____	_____
c. Position Descriptions	_____	_____	_____
d. Consultant Scope of Work	_____	_____	_____
e. Indirect Cost Rate Agreement	_____	_____	_____

Item	Applicant	Grants	Programs
f. Organizational Chart (optional)			
g. FY 2008 TMG Checklist			
Applicant signature/Date: _____			
IHS Grants Management Signature/Date: _____			
IHS Program Office Signature/Date: _____			

The Public Health Service (PHS) strongly encourages all grant 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.

Dated: March 7, 2007.

Robert G. McSwain,
Deputy Director, Indian Health Service.
[FR Doc. 07-2389 Filed 5-15-07; 8:45 am]
BILLING CODE 4165-16-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5144-N-01]

Notice of Competition Advocate Designation Under the HUD Acquisition Regulation

AGENCY: Office of the Chief Procurement Officer, HUD.

ACTION: Notice of competition advocate designation.

SUMMARY: In accordance with HUD's acquisition regulations (HUDAR), this notice announces HUD's designation of a competition advocate. Under the Federal Acquisition Regulations (FAR), each agency designates a competition advocate whose responsibilities include, but are not limited to: Promoting the acquisition of commercial items, promoting full and open competition, challenging requirements that are not stated in terms of functions to be performed, performance required or essential physical characteristics, and challenging barriers to the acquisition of commercial items and full and open competition such as unnecessarily restrictive statements of work, unnecessarily detailed specifications, and unnecessarily burdensome contract clauses.

DATES: *Effective Date:* January 31, 2007.

FOR FURTHER INFORMATION CONTACT:
Gloria Sochon, Assistant Chief

Procurement Officer for Policy and Systems, Office of the Chief Procurement Officer, 451 Seventh Street, SW., Room 5276, Washington, DC 20410-3000, telephone (202) 708-0294. Persons with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

SUPPLEMENTARY INFORMATION: The uniform regulation for the procurement of supplies and services by federal departments and agencies, the FAR, was promulgated on September 19, 1983 (48 FR 42102). The FAR is codified in title 48, chapter 1, of the Code of Federal Regulations. HUD promulgated its regulation to implement the FAR on March 1, 1984 (49 FR 7696). The HUDAR (title 48, chapter 24 of the Code of Federal Regulations) is prescribed by the Chief Procurement Officer under section 7(d) of the Department of HUD Act (42 U.S.C. 3535(d)); section 205(c) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 486(c)); the Secretary's delegation of authority effective October 6, 1998 (63 FR 54723) and the general authorization in FAR 1.301.

Under 48 CFR 2401.601-70, the Chief Procurement Officer is HUD's Senior Procurement Executive. In accordance with 48 CFR 2406.501, HUD's Senior Procurement Executive shall designate the Department's competition advocate by notice in the **Federal Register**. Therefore, the Chief Procurement Officer designates a Special Assistant to the Chief Procurement Officer as HUD's competition advocate.

This designation supersedes the previous designation of competition advocate published in the **Federal Register** on August 23, 1999 (64 FR 46109).

Dated: May 11, 2007.

Joseph A. Neurauter,
Chief Procurement Officer.
[FR Doc. E7-9434 Filed 5-15-07; 8:45 am]
BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Bayou Sauvage National Wildlife Refuge in South Louisiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent to prepare a comprehensive conservation plan and environmental assessment; request for comments.

SUMMARY: We, the Fish and Wildlife Service, intend to gather information necessary to prepare a comprehensive conservation plan and associated environmental documents for Bayou Sauvage National Wildlife Refuge. We furnish this notice in compliance with our comprehensive conservation planning policy to advise other agencies and the public of our intentions, and to obtain suggestions and information on the scope of issues to be considered in the planning process.

DATES: To ensure consideration, we must receive your written comments by June 15, 2007.

ADDRESSES: Send your comments or requests for more information to: Charlotte Parker, Natural Resource Planner, Southeast Louisiana National Wildlife Refuge Complex, 61389 Highway 434, Lacombe, Louisiana 70445; Telephone: 985/882-2000; or electronically to: Charlotte_Parker@fws.gov.

SUPPLEMENTARY INFORMATION: With this notice, we initiate the process for developing a comprehensive conservation plan for Bayou Sauvage National Wildlife Refuge in New Orleans, Louisiana.

The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd-668ee), requires the Service to develop a comprehensive conservation plan for each national wildlife refuge. The purpose in developing a comprehensive conservation plan is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In