

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 8, 2005, from 9 a.m. to 5 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Jeffrey Cooper, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1220, ext. 121, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512523. Please call the information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also discuss and make recommendations regarding general issues related to the premarket requirements for the safe and effective use of hemodialysis equipment labeled for nocturnal hemodialysis therapies. Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 25, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes

at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by May 25, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 240-276-0450, ext. 113, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 28, 2005.

Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

[FR Doc. 05-9008 Filed 5-5-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program; New Discretionary Funding Cycle for Fiscal Year 2006

Funding Opportunity Number: HHS-2006-IHS-TMP-0001.

CFDA Number: 93.228.

Key Dates: Training: May 23-27, 2005; June 15-16, 2005 June 29-30, 2005; and July 13-14, 2005.

Application Receipt Deadline: August 12, 2005.

Application Review Dates: October 3-7, 2005.

Application Notification: Second week of November 2005.

Anticipated Award Start Date: January 1, 2006.

Program Authority: Public Law 93-638, Sections 103(b)(2) and 103(e), Indian Self-Determination and Education Assistance Act, as amended.

I. Funding Opportunity Description

The Tribal Management Grant (TMG) Program is a national competitive

discretionary grant program established to assist Federally-recognized Tribes and Tribally-sanctioned Tribal organizations in assuming all or part of existing Indian Health Service (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. These grants are established under the authority of section 103(b)(2) and section 103(e) of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended.

Funding Priorities: The IHS has established the following funding priorities for TMG awards. 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 applicant. Funds will be distributed until depleted.

- Priority I—Any Indian Tribe that has received Federal recognition (restored, untermiated, funded, or unfunded) within the past 5 years, specifically received during or after April 2000.
- Priority II—All other eligible Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations submitting a competing continuation application or a new application with the sole purpose of addressing audit material weaknesses 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 (NEAR) Center, Department of Health and Human Services (HHS). Please identify by underlining the weakness to be addressed on 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 in the footnotes. The financial statement must also identify specific weaknesses/recommendations that will be implemented 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. See Eligible Project Types.

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

II. Award Information

Type of Instrument: Grant.

Estimated Funds Available: The estimated amount of funds available, based on the Administration's request for the TMG Program, is \$2,430,000 in Fiscal Year (FY) 2006. There will be only one funding cycle in FY 2006.

Anticipated Number of Awards: This estimated amount is anticipated to fund approximately 20–25 new and continuation awards.

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

Estimated Range of Awards: \$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 submitted must be for only one project type. The TMG Program consists of four types of projects: (1) Feasibility studies, (2) planning, (3) evaluation studies, and; (4) health management structure development or improvement. Applications that address more than one project type will be considered ineligible and will be returned to the applicant. The maximum funding level noted below includes both direct and indirect costs. Application budgets which exceed the maximum funding level or project period identified for a project type will not be reviewed. Please refer to Section IV.5. "Funding Restrictions" for further information regarding ineligible activities.

A. 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 necessary plans, approach, training, and resources required to assume Tribal management of the program. The study shall 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 resources 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.

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

A collection of data to establish goals and performance measures for the operation 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/Tribal 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 15250–7945, or (202) 512–1800. You may access this information via the Internet at the following Web site:

<http://www.health.gov/healthypeople/publications/>.

C. 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 programs 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, personal, 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.

D. 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 find is under the Office of Management and Budget (OMB) Circular No. A–133—Revised June 27, 2003, "Audits of States, Local Governments, and Non-Profit Organization." 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 kit. Please see the "Application and Submission Information" section for directions about how to request a copy of the TMG application kit.

III. Eligibility Information

1. Eligible Applicants

Any federally-recognized Indian Tribe or Tribally-sanctioned Tribal organization is eligible to apply for a grant. Eligible applicants include Tribal organizations that operate mature contracts that are designed by a Tribe to

provide technical assistance and/or training. Only one application per Tribe or Tribal organization is allowed.

2. Cost Sharing or Matching

The TMG Program does not require cost sharing or matching to participate in the competitive grant process. However, in accordance with Public Law 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

The following documentation is required (if applicable):

- 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. Draft resolutions are acceptable in lieu of an official resolution. However, an official signed Tribal resolution must be received by the Division of Grants Operations prior to the beginning of the Objective Review (October 3–7, 2005). If an official signed resolution is not received by September 30, 2005, 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 (*i.e.*, 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 April 2000.

- 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 implemented 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.

If a consortium is submitting an application it must:

- Identify all 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 Selection Process” for more information regarding other application submission information and/or requirements.

IV. Application and Submission Information

1. Address to Request Application Package

Interested parties may request a copy of the TMG application kit from either of the following persons: Ms. Deanna J. Dick, Office of Tribal Programs, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, (301) 443–1104. Ms. Patricia Spotted Horse, Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, TMP 100, Rockville, Maryland 20852, (301) 443–5204.

The entire application kit is also available online at: <http://www.ihs.gov/NonMedicalPrograms/tmg/index.asp> and <http://www.grants.gov>.

2. Content and Form of Application Submission

- A. All applications should:
 - Be single-spaced.
 - Be typewritten.
 - Have consecutively numbered pages.
 - Use black type not smaller than 12 characters per one inch.
 - Have one-inch border margins.
 - Be printed on one side only of standard size 8½” x 11” paper.
 - Not be tabbed, glued, or placed in a plastic holder.
 - Contained a narrative that does not exceed 14 typed pages that includes the below listed sections. (The 14-page narrative does not include the workplan, standard forms, Tribal resolution(s), table of contents, budget, budget justifications, multi-year narratives, multi-year budget, multi-year budget justifications, and/or other appendix items.)
 - Introduction and Need for Assistance.
 - Project Objectives(s), Approach, and Results and Benefits.
 - Project Evaluation.
 - Organizational Capabilities and Qualifications.
- Include in the application the following documents in the order presented:
- Application Receipt Record, IHS–815–1A (Rev. 3/05).
 - FY 2006 TMG Application Checklist.
 - FY 2006 General Information Page.
 - Tribal Resolution (final signed or draft unsigned).
 - Documentation for Priority I Participation (if applicable).
 - Documentation for Priority II Participation (if applicable).
 - Documentation of Consortium Participation (if applicable).
 - Standard Form 424, Application for Federal Assistance.
 - Standard Form 424A, Budget Information—Non-Construction Programs (pages 1–2).
 - Standard Form 424B, Assurances—Non-Construction Programs (front and back). The application shall contain assurances to the Secretary that the applicant will comply with program regulations, 42 CFR part 36, subpart H.
 - Certifications (pages 17–19).
 - PHS–5161 Checklist (pages 25–26).
 - Disclosure of Lobbying Activities.
 - Table of Contents with corresponding numbered pages.
 - Project Narrative (not to exceed 14 typewritten pages—should address first year only if project is a multi-year request).
 - Categorical Budget and Budget Justification.

- Multi-year Objectives and Workplan with Multi-year Categorical Budget and Multi-year Budget Justifications (if applicable).
- Appendix Items.

3. Submission Dates and Times

Applications must be received on or before Friday, August 12, 2005. Paper submissions must be received by the IHS by 5 p.m. eastern standard time. Electronic submissions must be received by the Grants.gov Web site by 11:59 p.m. eastern standard time.

The anticipated start date of grants is January 1, 2006.

The IHS is accepting paper and electronic applications for this cycle.

Paper submission—to submit a paper application, include one original and two complete copies of the final proposal with all required signatures and documentation. Mark the original application with a cover sheet that states, "Original Grant Application." Mail or hand-deliver applications to the Division of Grants Operations, Indian Health Service, 801 Thompson Avenue, Rockville, Maryland 20852. Please note: all mailed applications must be received on or before August 12, 2005 by close of business (*i.e.* 5 p.m. eastern standard time).

Hand Delivered Proposals: Hand delivered proposals will be accepted from 8 a.m. to 5 p.m. eastern standard time, Monday through Friday. Applications will be considered to meet the deadline if they are received on or before the deadline, with hand-carried applications received by close of business 5 p.m. For mailed applications, a dated, legible receipt from a commercial carrier or the U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Later applications not accepted for processing will be returned to the applicant and will not be considered for funding.

Applicants are cautioned that express/overnight mail services do not always deliver as agreed. IHS will not accommodate transmission of applications by Fax or E-Mail.

Late application: Applications which do not meet the criteria above will be considered late. Late applications will be returned to the applicant and will not be considered for funding.

Extension of deadlines: IHS may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. Determination to extend or waive deadline requirements rests with the

Chief Grants Management Officer and would appear as an amendment in **Federal Register**.

Acknowledgment of Receipt: Acknowledgment of receipt of applications will be via the Application Receipt Card, IHS 815-1A (Rev. 3/05).

Electronic Submission—To submit an application electronically, please use the Grants.gov "Apply" Web site at <http://www.grants.gov>. The grants.gov Web site will allow applicants to download a copy of the application package, complete it offline, and then upload and submit the application. Electronic submissions must be submitted to and accepted by the Grants.gov Web site by 11:59 p.m.

eastern standard time. Applicants are strongly encouraged to following the instructions exactly for successful submission. As previously noted, the IHS will not accommodate transmission of applications via e-mail.

Applicants planning to submit an electronic application via the grants.gov Web site should note the following:

- Electronic submission is voluntary.
- Applicants entering the grants.gov Web site will find information regarding submitting an application electronically through the site, as well as the hours of operation. The IHS strongly recommends that applicants not wait until the deadline date to begin the application process through grants.gov.
- To use grants.gov, applicants must have a Dun and Broadstreet (DUNS) number and be registered in the Central Contractor Registry (CCR). Applicants should allow a minimum of five days to complete CCR registration. See item 6 of this section, "Other Submission Requirements," for more information regarding the DUNS and CCR registration process.
- Applicants will not receive additional point value for submitting a grant application in the electronic format, nor will the IHS penalize applicants submitting an application in paper format.
- Applicants may submit all documents electronically, including all information typically included on the SF-424 and all necessary assurances and certifications.
- Applications must comply with page limitation requirements described in this program announcement.
- Applications submitted electronically will receive an automatic acknowledgment from the grants.gov Web site that contains a assigned grants.gov tracking number. The IHS will retrieve your application from the grants.gov Web site.

• Applicants may access the electronic application for this program on <http://www.grants.gov>.

• Applicants must search for the downloadable application package by CFDA number—93.228.

4. Intergovernmental Review

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

5. Funding Restrictions

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. Mary Trujillo, 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 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, general, 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

Beginning October 1, 2003, applicants were required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access www.dunandbradstreet.com at <http://www.dunandbradstreet.com> or call 1-866-705-5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

To submit an application electronically, applicants 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 in the appendix of the TMG application kit or on <http://www.grants.gov/CCRRegister>.

More detailed information regarding these registration processes can be found at <http://www.grants.gov>.

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoping the application. Weights assigned to each section are noted in parentheses. The 14-page narrative should include only the first year 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. Criteria

Introduction and Need for Assistance (20 Points)

A. 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.

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

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

D. Identify all previous TMGs received, 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).

E. Identify the eligible project type and priority group of the applicant.

F. 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 Reporting Act reporting requirements, contract reporting requirements, Information Technology (IT) compatibility, etc.).

G. 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 affect of the proposed project on planned/anticipated programs and/or equipment.

H. Address how the proposed project relates to the purpose of the TMG Program by addressing the appropriate description that follows:

- Identify if the Tribe/Tribal organization is a 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 contact (*i.e.*, 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 a 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 organization. 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.
- Outcome 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).

C. Address the extent to which the proposed project will build the local capacity to provide, improve, or expand services that address the need 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 projects 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)

Each proposed project objective should have an evaluation component and the evaluation activities should appear on the work plan.

A. Please address the following for each of proposed objective:

- What data will be collected to evaluate the success of the objective(s).
- How and when the data will be collected.
- Who will collect the data.

B. Explain how the data demonstrates the change brought about by the proposed project objective.

C. Describe any future evaluation efforts for the proposed project that will be conducted after the expiration of the grant.

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 part 900, subpart F, "Standards for Tribal Management Systems". If management systems are already in place, simply note it. (A copy of the 25 CFR part 900, subpart F, is available in the TMG application kit.)

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.

Appendix Items

- Workplan for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant proposed scope of work (if applicable).
- Indirect Cost Agreement.
- Organizational chart (optional).
- Multi-Year Project Requirements (if applicable).

2. Review Selection Process

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

A. Application Submission (Application Deadline: August 12, 2005)

Applications received in advance of or by the deadline and verified by the postmark 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.
- The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an indepth evaluation; otherwise, it may be returned.

B. Competitive Review of Eligible Applications (Objective Review: October 3–7, 2005)

Applications meeting eligibility requirements that are complete, responsible, 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, are forwarded by the Division of Grant Operations to the Area Offices for cost analysis and further recommendation. The program official accepts the Area Office Contract Proposal Liaison Officers' 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 and returned to the applicant. Applications that are approved but not funded will not be carried over into the next cycle for funding consideration.

C. Anticipated Announcement and Award Dates

The IHS anticipates an award start date of January 1, 2006.

VI. Award Administration Information

1. Award Notices

Notification: Second week of November 2005. 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 original 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 which are approved and funded will be notified through the official Notice of Grant Award (NGA) document. The NGA will serve 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 and National Policy requirements

Grants are administered in accordance with the following documents:

- This grant announcement.
- Health and Human Services regulations governing Public Law 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.

- Grants Policy Directives.
- 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 Governments, and Non-Profit Organizations".
- Other Applicable OMB circulars.23. Reporting

- Progress Report—Program progress reports are required semi-annually. 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.

- Financial Status Report—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.

VII. Agency Contact(s)

Interested parties may obtain TMG programmatic information from the TMG Program Coordinator through the information listed under Section IV of this program announcement. Grant-related and business management information may be obtained from the Grants Management Specialist through the information listed 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 four training sessions to assist applicants in preparing their FY 2006 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 application kit or by accessing the TMG Web site at: <http://www.ihs.gov/nonmedicalprograms/tmg/index.asp>. The registration form may be faxed to (301) 443-4666. The training dates are listed below in chronological order and the training sessions will take place in the hotel identified:

- May 23-27, 2005—Oklahoma City, Oklahoma (Limit 26; Registration/Reservation deadline: May 6, 2005), Crowne Plaza, 2945 Northwest Expressway, Oklahoma City, OK 73112, (405) 848-4811—Reference: IHS TMG, Hotel rate: \$66.00/single or double plus 13.875% tax.

- June 15-16, 2005—Albuquerque, New Mexico (Limit 24; Registration/Reservation deadline: May 27, 2005), Courtyard Albuquerque Airport, 1920 Yale Boulevard, Albuquerque, NM 87106, (505) 843-6600—Reference: IHS TMG, Hotel rate: \$68.00/single or double plus 12.0625% tax.

- June 29-30, 2005—Seattle, Washington (Limit 24; Registration/Reservation deadline: June 11, 2005), Holiday Inn Express City Center, 211 Dexter Avenue North, Seattle, WA 98109, (206) 728-8123—Reference: IHS TMG, Hotel rate: \$119.00/single or double plus 15.6% tax.

- July 13-14, 2004—Grand Rapids, Michigan (Limit 24; Registration/Reservation deadline: June 24, 2005), AmeriSuites Grand Rapids/Airport, 5401 28th Street Court SE., Grand Rapids, MI 49546, (616) 940-8100—Reference: IHS TMG, Hotel rate: \$74.00/single or double plus 13% tax.

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, 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 PHS mission to protect and advance the physical and mental health of the American people.

Dated: April 28, 2005.

Phyllis Eddy,

Acting Deputy Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority

Part G—Indian Health Service

Part G, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as amended at 52 FR 47053-47067, December 11, 1987, as amended at 60 FR 56606, November 9, 1995, and most recently amended at 61 FR 67048, December 19, 1996, is hereby amended to reflect a reorganization of the Indian Health Service (IHS) Headquarters (HQ). The goal of the reorganization is to demonstrate increased leadership and advocacy, while improving the Agency's responsibilities for oversight and accountability. We have considered the President's Management Agenda, the Secretary's Workforce Restructuring Plan and recommendations from the Indian Health Design Team and the IHS Restructuring Initiatives Workgroup. Delete the functional statements for the IHS Headquarters in their entirety and replace with the following:

Chapter GA

Office of the Director

Section GA-10, Indian Health Service—Organization

The IHS is an Operating Division within the Department of Health and Human Services (HHS) and is under the leadership and direction of a Director who is directly responsible to the Secretary of Health and Human Services. The IHS Headquarters consists of the following major components:

- Office of the Director (GA)
- Office of Tribal Self-Governance (GAA)
- Office of Tribal Programs (GAB)
- Office of Urban Indian Health Programs (GAC)
- Policy Formulation and Communications Group (GAE)
- Office of Clinical and Preventive Services (GAF)
- Office of Information Technology (GAG)
- Office of Public Health Support (GAH)
- Office of Resource Access and Partnerships (GAJ)

- Office of Finance and Accounting (GAK)
- Office of Management Services (GAL)
- Office of Environmental Health and Engineering (GAM)

Section GA-20, Indian Health Service—Functions

Office of the Director (OD) (GA)

Provides overall direction and leadership for the IHS: (1) Establishes goals and objectives for the IHS consistent with the mission of the IHS; (2) provides for the full participation of Indian Tribes in the programs and services provided by the Federal Government; (3) develops health care policy; (4) ensures the delivery of quality comprehensive health services; (5) advocates for the health needs and concerns of American Indians/Alaska Natives (AI/AN); (6) promotes the IHS programs at the local, State, national, and international levels; (7) develops and demonstrates alternative methods and techniques of health services management and delivery with maximum participation by Indian Tribes and Indian organizations; (8) supports the development of individual and Tribal capacities to participate in Indian health programs through means and modalities that they deem appropriate to their needs and circumstances; (9) ensures the responsibilities of the United States are not waived, modified, or diminished, in any way with respect to Indian Tribes and individual Indians, by any grant, contract, compact, or funding agreement awarded by the IHS under the Indian Self-Determination and Education Assistance Act, Public Law (Pub. L.) 93-638, as amended; (10) affords Indian people an opportunity to enter a career in the IHS by applying Indian preference; and (11) ensures full application of the principles of Equal Employment Opportunity laws and the Civil Rights Act in managing the human resources of the IHS.

Office of Tribal Self-Governance (OTSG) (GAA)

(1) Develops and oversees the implementation of Tribal self-governance legislation and authorities in the IHS, under Title V of the Indian Self-Determination and Education Assistance Act, Pub. L. 93-638, as amended; (2) develops and recommends policies, administrative procedures, and guidelines for IHS Tribal self-governance activities, with maximum input from IHS staff and workgroups, Tribes and Tribal organizations, and the Tribal Self-Governance Advisory Committee; (3) advises the IHS Director on Agency compliance with self-

governance policies, administrative procedures and guidelines and coordinates activities for resolution of problems with appropriate IHS and HHS staff; (4) provides resource and technical assistance to Tribes and Tribal organizations for the implementation of the Tribal Self-Governance Program (TSGP); (5) participates in the reviewing of proposals from Tribes for self-governance planning and negotiation grants and recommends approvals to the IHS Director; (6) determines eligibility for Tribes and Tribal organizations desiring to participate in the TSGP; (7) oversees the negotiation of self-governance compacts and annual funding agreements with participating Tribal governments; (8) identifies the amount of Area Office and Headquarters managed funds necessary to implement the annual funding agreements and prepares annual budgets for available Tribal shares in conjunction with IHS Area and Headquarters components; (9) coordinates semi-annual reconciliation of funding agreements with IHS Headquarters components, Area Offices, and participating Tribes; (10) serves as the principal IHS office for developing, releasing, and presenting information on behalf of the IHS Director related to the IHS Tribal self-governance activities to Tribes, Tribal organizations, HHS officials, IHS officials, and officials from other Federal agencies, State and local governmental agencies, and other agencies and organizations; (11) arranges national self-governance meetings to promote the participation by all AI/AN Tribes in IHS self-governance activities and program direction; (12) participates in meetings for Self-Governance Tribal delegations visiting IHS Headquarters; and (13) participates in cross-cutting issues and processes including, but not limited to emergency preparedness/security, budget formulation, self-determination issues, Tribal shares computations and resolution of audit findings as may be needed and appropriate.

Office of Tribal Programs (OTP) (GAB)

(1) Assures that Indian Tribes and Tribal organizations are informed regarding pertinent health policy and program management issues; (2) assures that consultation and participation by Indian Tribes and organizations occurs during the development of IHS policy and decision making; (3) provides overall Agency leadership concerning functions and responsibilities associated with self-determination contracting (Title I of the Indian Self-Determination Act); (4) advises the IHS Director and senior management on activities and issues related to self-determination