

*Name of Committee:* Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

*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 August 5, 2009, from 8 a.m. to 5 p.m.

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

*Contact Person:* Paul Tran, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [paul.tran@fda.hhs.gov](mailto:paul.tran@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* The committee will: (1) Receive a status update from the Office of Generic Drugs (OGD) on bioequivalence for highly variable drugs (highly variable means that the rate and amount of the drug entering blood varies significantly from one administration to another); (2) receive presentations from the Office of Pharmaceutical Science (OPS) on the scientific and regulatory challenges of Transdermal Drug Delivery Systems (TDDS); (3) receive presentations from OPS and discuss current thinking on "Classifying Pre-Surgical Preparations as Sterile Products" in consideration of how these products are used; and (4) be updated by OPS on the current status of the International Conference on Harmonization (ICH) Quality Topics [i.e., those relating to chemical and pharmaceutical quality assurance (stability testing, impurity testing, etc.)], and outline the role of the ICH Implementation Work Group (Q IWG), its future activities, and any remaining gaps and challenges.

FDA intends to make background material available to the public no later than 2 business days before the meeting.

If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

*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 on or before July 21, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person 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 on or before July 13, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 14, 2009.

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 Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: June 29, 2009.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Office of Clinical and Preventive Services; Division of Behavioral Health; the Methamphetamine & Suicide Prevention Initiative for American Indian and Alaska Native Urban Programs

*Announcement Type:* New.

*Funding Announcement Number:* HHS-2009-IHS-METHU-0002.

*Catalog of Federal Domestic Assistance Number(s):* 93.933.

*Key Dates: Application Deadline Date:* July 31, 2009.

*Review Date:* August 6-7, 2009.

*Earliest Anticipated Start Date:* August 14, 2009.

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#### I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Methamphetamine & Suicide Prevention Initiative (MSPI) for American Indian and Alaska Native (AI/AN) Urban Program communities. This program is authorized under the Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1602(a)(b)(9)(11)(12) of the Indian Health Care Improvement Act (IHCA), as amended. This program is described at 93.933 in the Catalog of Federal Domestic Assistance. The purpose of the MSPI-U is to expand community-level access to effective, Urban AI/AN methamphetamine and/or suicide prevention and treatment programs. Resources will enhance evidence-based or practice-based methamphetamine and/or suicide prevention or treatment programs and/or community mobilization programs. The methamphetamine and suicide prevention or treatment funding will be used to:

- Provide community-focused responses that enhance evidence-based or practice based methamphetamine and/or suicide prevention or treatment services or education programming;

- Coordinate services for communities to respond to their local methamphetamine and/or suicide crises;
- Participate in a nationally coordinated program focusing specifically on increasing access to methamphetamine and/or suicide prevention or treatment related activities among the Federal partners, Areas, Tribes, States, and academic or not-for-profit programs;
- Provide communities with needed resources to develop their own community-focused programs with preference for coordinated programming that maximizes the impact across communities and Tribal groups;
- Establish baseline data information related to methamphetamine abuse/suicides in the local communities;
- Adequately document the level of need for the community; and
- Promote programs that will ensure measureable impact.

Awardees' activities for this program are as follows:

- Develop a three (3) year action plan. Applicants must document how their methamphetamine and/or suicide prevention or treatment activities will be implemented as soon as possible but no later than six (6) months after award. The remainder of Year One, Year Two, and Year Three will focus on implementation. The primary intent of the action plan should be to illustrate how the applicant will enhance community access to or support community delivery of evidence-based or practice-based methamphetamine and/or suicide prevention or treatment services. The action plan should describe the project implementation process. The action plan should include objectives that are specific, measurable, achievable, relevant, and time-phased. Objectives should demonstrate adherence to the Government Performance and Results Act of 1993 (GPRA), where applicable. The implementation process may be guided by a community action organization, collaboration, or a group of partners to plan and implement a community-wide methamphetamine and/or suicide prevention or treatment project. If such partnerships or collaborations are already in place, provide a description of how they intend to expand their scope to include the implementation of the methamphetamine and/or suicide prevention or treatment project. Relevant partnerships working closely with and developing collaborations for the MSPI-U may include smaller urban organizations which combine their resources to implement this project. "Relevant partnerships" can be defined

as developing cooperative agreements and/or Memorandums of Agreement that clearly defines how the collaboration will be conducted.

- Collaborations may also include other partners to share resources and information that could strengthen the program.
- The action plan should focus on developing or enhancing and implementing community-based, evidence or practice-based methamphetamine and/or suicide prevention or treatment strategies. The action plan for the community prevention or treatment program should include the proposed best and promising practices being implemented, identify information sharing processes, and define and identify interactive group activities, data collection (*i.e.* Resource and Patient Management System), evaluation, and ongoing quality assurance improvement processes. The project should include culturally appropriate behavioral, policy, and community approaches to methamphetamine and/or suicide prevention or treatment.

- Applicants must attend one (1) mandatory MSPI-U grantee meeting per year. The budget submitted should reflect travel costs for the project director and the local evaluator to attend this meeting. Location (city/hotel) and time frame for this meeting will be provided after award; however the meeting will generally last two to three days and attendance is mandatory. At these meetings, grantees will present the results of their projects and Federal staff will be available to provide technical assistance.

- Applicants must participate in a national evaluation of this project. Each grantee shall coordinate with their national MSPI project officer. The grantee shall work with the IHS staff and national MSPI project officer to develop a local process to measure specific outcome measures as consistent with national GPRA measures and IHS Division of Behavioral Health (DBH) program requirements.

- Up to a maximum of 20 percent of grant funds may be used to develop or enhance the grantee's local evaluation capacity for the purposes of meeting MSPI data collection requirements. All applicants will be required to employ the use of the Resource and Patient Management System (RPMS) and the RPMS behavioral health module or IHS Electronic Health Record. If applicant is unable to utilize the RPMS as an information management system, the applicant should demonstrate within the application how they will satisfy the data collection requirements.

Applicants will also be required to adhere to any and all GPRA requirements, where applicable.

- Other costs in conjunction with the evaluation of this project may include training (onsite and off-site), conference calls, and information sharing using e-mail and/or faxing materials.

- Applicants are expected to publicize their activities in the affected communities. The action plan may include:

- Identification of one to three environmental issues that community members have stated need to be addressed in order to promote the prevention and/or treatment of methamphetamine abuse and/or suicide. There should be some record that this has been identified as an issue that needs to be addressed. This may include local newspapers, Tribal Council meetings, Town Hall meetings, or radio programs.

- Community programs should inform their community about the program and its goals and the baseline data for the outcome indicators. The program should establish a time frame and setting to share their progress with the community. The settings could include regular programs on the radio station, monthly newspaper reports or newsletter mailings, or one or more graph or 'thermometer' type billboards or centrally placed posters that track progress.

- The action plan should include a community gathering that is held to close out the project with an accounting of the progress by indicators and dialogue about next steps.

## II. Award Information

*Type of Awards:* Grant.

*Estimated Funds Available:* The total amount identified for fiscal year (FY) 2008 is \$1,103,000; FY 2009 is \$1,103,000 Grand total of \$2,206,000. The awards are for 12 months in each budget period. The awards are subject to the availability of funds.

*Anticipated Number of Awards:* An estimated eleven (11) two-year awards will be approved for funding with the amounts identified for FY 2008 and FY 2009. The existing awardees will apply for competing continuation awards for continued funding. Continuation awards will be made based on program performance. Contingent on appropriation of funds, the amount of awards in the third year will continue at the same level as year one and two under this Program Announcement.

*Project Period:* Three (3) Years.

*Award Amount:* \$100,000, per year.

### III. Eligibility Information

#### 1. Eligible applicants are:

• Non-profit Urban Indian Organizations, as defined by 25 U.S.C. 1603(h).

Eligibility is limited to the aforementioned applicants because they have the necessary knowledge of, experience, and capability/capacity to work within the urban AI/AN communities to perform the required activities.

Applicants must provide a letter of support from the board of the urban Indian Organization. If there is insufficient time to procure such a letter of support prior to submitting the application, the letter must be submitted within six months after award. Place this documentation behind the first page of your application form.

2. Cost Sharing or Matching: The Methamphetamine & Suicide Prevention Initiative does not require matching funds or cost sharing.

#### Other Requirements:

A. If application budgets exceed the stated dollar amount that is outlined within this announcement; those applications will not be considered for funding.

B. The budget should include a budget narrative and justification for all cost outlined in the application for the budget period and should explain why each line item is necessary or relevant to the proposed project.

### IV. Application and Submission Information

1. Applicant packages may be found at the Grants.gov Web site (<http://www.grants.gov>), or for a link to the package information go to the Grants Policy Staff Web site at [http://www.ihs.gov/NonMedicalPrograms/gogp/gogp\\_funding.asp](http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp). Information regarding the electronic application process may be directed to Tammy G. Bagley, at (301) 443-6290. The entire application package and detailed application instructions are available at <http://www.grants.gov/index.jsp>.

#### 2. Content and Form of Application Submission

a. You must submit a project narrative with your application package. The project narrative must be submitted in the following format:

- Maximum number of pages: 25. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unspaced.
- Single spaced.
- 8½" x 11" paper.
- Page margin size: One inch.

Your narrative should address activities to be conducted over the entire project period. You must use the sections/headings listed below in developing your project narrative. Be sure to place the required information in the correct section, or it will not be considered.

Your application will be scored according to how well you address the requirements for each section of the project narrative. Your project narrative must include the following items in the order listed:

- Statement of Need
- Describe the target population as well as the geographic area to be served, and justify the selection of both. The target population should include AI/AN youth who are currently residing within a youth regional/residential treatment center or who have been discharged from a residential treatment center within the previous sixty (60) days. Include the numbers to be served and demographic information. Discuss the target population's language, beliefs, norms and values, as well as socioeconomic factors that must be considered in services to this population. Describe a brief history of the youth recidivism issues in the community and responses locally, within the Tribe and in the State.
- Document clearly whether this project will address the transitional/discharge or aftercare problem or decrease the rate of youth recidivism within the YRTC.
- Document the need for a transitional/discharge or aftercare project in the selected community which is experiencing increases in the rate of recidivism. This documentation of need may come from a variety of sources, and applicants are encouraged to provide as much quantifiable data related information about the increases as may be available.
- Show that identified needs are consistent with priorities of the Tribes, State, or county that has primary responsibility for the service delivery system.
- Describe the local resource organizations in the community.
- Depending on the type of project chosen, describe the local transitional/discharge or aftercare resources available to the project.
- Project Plan
- Clearly state the purpose, goals and objectives of your proposed project and how it addresses the target population and the geographic area being served.
- Describe how the project is to be implemented, including the roles of staff to be hired.

• Provide a realistic timeline for the project (chart or graph) showing key activities, milestones, and responsible staff. [Note: The timeline should be part of the project narrative. It should not be placed in an appendix.]

• If you plan to include an advisory body in your project, describe its membership, roles and functions, and frequency of meetings.

• Describe how members of the target population help prepare the application and how they will help plan, implement, and evaluate the project.

• Identify any other organizations that will participate in the proposed project. Describe their roles and responsibilities and demonstrate their commitment to the project. Include letters of commitment from community organizations supporting the project in the appendix.

• Show that the necessary groundwork (e.g., planning, consensus development, development of memoranda of agreement) has been completed or is near completion so that the project can be implemented, and any prevention or treatment interventions can begin as soon as possible but no later than six (6) months after grant award.

• Describe any potential barriers to successful conduct of the proposed project and how you will overcome them.

• Describe your plan to ensure project sustainability when funding for this project ends. Also describe how program continuity will be maintained when there is a change in the operational environment (e.g., staff turnover, change in project leadership) to ensure stability over time.

#### • Organizational Capacity

• Discuss the capability and experience of the applicant organization and other participating organizations with the target population. Provide Memoranda of Understanding or Letters of Agreement specifically for the proposed project from participating organizations in the appendix.

• Describe existing community infrastructure that addresses transitional/discharge or aftercare treatment.

• Provide a list of staff and position descriptions for those who will participate in the project, showing the role of each and their level of effort and qualifications. Include the project director and other key personnel, such as the local evaluator and prevention or treatment personnel.

• Describe the cultural characteristics of key staff and indicate if any are

members of the target population/community.

- Describe the resources available for the proposed project (*e.g.*, facilities, equipment), and provide evidence that services will be provided in a location that is adequate, accessible, compliant with the Americans with Disabilities Act (ADA), and amenable to the target population.

- Describe evidence of successful program management experience (see Criteria for more detail).

- Describe experience with other Federal, state, or private grants.

- Describe data collection experience and capacity for data storage. Clearly describe the project's information management system capabilities and history of its use (if any). Describe any plans to utilize the RPMS information management system with the implementation of this project. If applicant currently utilizes an alternate information management system or is unable to utilize RPMS as an information management system, the applicant should demonstrate within the application how they plan to satisfy the data collection requirements.

#### • Local Evaluation Capacity

- Grantees must evaluate their projects and are required to describe their evaluation plans in their applications. The evaluation should be designed to provide regular feedback to

the project to improve services. The evaluation must include both process and outcome components. Process and outcome evaluations must measure change relating to project goals and objectives over time compared to baseline information. Describe evaluation experience with current or past community projects.

- State willingness to work with IHS evaluation consultant(s) in developing community-specific outcome measures for the local and national evaluation.

- Demonstrate evidence of having secured or plans to secure a qualified local evaluation consultant and/or part-time employee to conduct data collection and data entry (*e.g.*, resume position description).

- Describe plans for data collection, management, analysis, interpretation and reporting. Describe the existing approach to the collection of data, along with any necessary modifications. Be sure to include data collection instruments/interview protocols in an appendix format.

- Demonstrate how the evaluation will be integrated with requirements for collection and reporting of performance data (*e.g.*, RPMS and GPRA indicators, performance measures). Explain: How you will ensure privacy and confidentiality? Where data will be stored? Who will or will not have access to information and how the identity of participants will be kept private, for

example, through the use of a coding system on data records, limiting access to records, or storing identifiers separately from data? Describe adequate consent procedures.

- Applicants must consider their evaluation plans when preparing the project budget. No more than 20% of the total grant award may be used for evaluation and data collection (this is not a research grant).

The evaluation must include both process and outcome components. Process and outcome evaluations must measure change relating to project goals and objectives over time compared to baseline information. Control or comparison groups are not required. Process components should address issues such as:

- How closely did the implementation match the plan?

- What types of deviations from the plan occurred?

- What led to the deviations?

- What effect did the deviations have on the planned intervention and evaluation?

- Who (program, staff) provided what services (modality, type, intensity, duration), to whom (individual characteristics), in what context (system, community), and at what cost (facilities, personnel, dollars)?

Outcome components should address issues such as:

	FY 2008	FY 2009	FY 2010
Outcome measure #1: The proportion of methamphetamine-using patients who enter a methamphetamine treatment program.	N/A .....	Baseline .....	Baseline.
Outcome measure #2: Reduce the incidence of suicidal activities (ideation, attempts) in AI/AN communities through prevention, training, surveillance, & intervention programs.	N/A .....	Baseline .....	Baseline.
Outcome measure #3: Reduce the incidence of methamphetamine abuse in AI/AN communities through prevention, training, surveillance, & intervention programs.	N/A .....	Baseline .....	Baseline.
Outcome measure #4: The proportion of youth who participate in evidence-based and/or promising practice prevention or intervention programs.	N/A .....	Baseline .....	Baseline.
Outcome measure #5: Establishment of trained suicide crisis response teams .....	N/A .....	Baseline .....	Baseline.
Outcome measure #6: Increase tele-behavioral health encounters .....	N/A .....	Baseline .....	Baseline.

- Budget Justification (will not be counted in the stated page limit). You must provide a narrative justification of the items included in your proposed budget, as well as a description of existing resources and other support you expect to receive for the proposed project. Be sure to show that no more than 20% of the total grant award will be used for data collection and evaluation.

Additional information shall be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Position descriptions for key personnel including local evaluator and data collection/data entry employees. If the evaluator will be subcontracted, include a letter of commitment with a current biographical sketch from the

individual(s). Job descriptions should be no longer than one page each.

- Curriculum Vitae/Resume of key personnel (project director, evaluator (if identified). Resumes should be no longer than two (2) pages in length.

- Applicants must provide a letter of support from the board of the urban Indian organization.

You are required to have a Dun and Bradstreet Data Universal Numbering System (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 <http://www.dunandbradstreet.com> or call (866) 705-5711. For more information, see the IHS Web site at: <http://www.ihs.gov/od/pgo/funding/pubcommt.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

### 3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 12 a.m. midnight Eastern Daylight Time (E.D.T.) on the application deadline due date. If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Grants Policy Staff at (301) 443-6290 at least 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 (e-mails 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 Division of Grants Operations (DGO), 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852, (301) 443-5204 by 12 midnight E.D.T. on the application deadline date. Applications not submitted through Grants.gov, without an approved waiver, may be returned to the applicant without review or consideration. Late applications will not be accepted for processing. They will be returned to the applicant 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 allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR part 74 all pre-award costs are incurred at the recipient's risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated.

- The available funds are inclusive of direct and appropriate indirect costs.
- IHS will not acknowledge receipt of applications.

### 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 (800) 518-4726 or [support@grants.gov](mailto:support@grants.gov). The Contact Center hours of operation are Monday–Friday from 7 a.m. to 9 p.m. E.D.T. 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 <http://www.Grants.gov> and select “Apply for Grants” link on the home page. 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 online, please contact Grants.gov Customer Support at: <http://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 (e-mails are acceptable), to [Michelle.Bulls@ihs.gov](mailto: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 DGO, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852 on or before 12 midnight of the application deadline date.

- Upon entering the Grants.gov site, there is information available that outlines 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 could take up to fifteen working days.

- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the CCR. You should allow a minimum of ten working days to complete CCR registration. See below for more information 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.

- Your application must comply with any page limitation 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. DGO will download your application from Grants.gov and provide necessary copies to the cognizant program office. The DGO will not notify applicants that the application has been received.

- You may access the electronic application for this program on <http://www.Grants.gov>.

- You may search for the downloadable application package using 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-2009-IHS-METHU-0002.

E-mailed 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 <http://www.dunandbradstreet.com> or call (866) 705-5711. 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 (888) 227-2423. Please review and complete the CCR Registration Worksheet located 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

### 1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective, qualitative and quantitative, and must measure the intended process and outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

#### Project Plan (30) Points

- Comprehensively describe the proposed three (3) year project—5 Points;
- Comprehensively describe the project's objectives and activities—5 Points;
- Include a timeline of activities. Is the timeline provided comprehensive—5 Points;
- Comprehensively describe and identify potential problem areas or barriers and propose solutions—5 Points;
- Provide community focused responses that enhance evidence-based or practice-based methamphetamine and/or suicide prevention or treatment services or education programming—5 Points;
- Provide communities with needed resources to develop their own community-focused programs with preference for coordinated programming that maximizes the impact across communities and Tribal groups—5 Points.

#### Statement of Need (15) Points

- Provide an adequate baseline picture of the community—5 Points;

- Provide a good description and justification for the identified project target population—10 points.

#### Organizational Capacity (20) Points

- Describe the community infrastructure addressing methamphetamine and/or suicide treatment or prevention—10 Points;
- Comprehensively provide evidence of successful methamphetamine and/or suicide program management capability—5 Points;
- Adequately describe the project staffing, their expected tasks/roles, experience and training, and time commitment—5 Points.

#### Local Evaluation Capacity (25) Points

- Address applicable outcomes/output measures and how they relate to stated activities and objectives—10 Points;
- State a willingness to collaborate and submit data into the MSPI national evaluation process—2 Points;
- Demonstrate evidence of commitment to securing a qualified local evaluation/data collection/entry capacity. Provide documentation—5 Points;
- Demonstrate how the program will use a portion of awarded funds (not to exceed 20 percent) to develop or enhance funding recipients' local evaluation capacity—2 Points;
- Describe how the funding recipients will establish baseline data and information related to methamphetamine abuse/suicides in the local communities—2 Points;
- Demonstrate how the data collection and storage capacity adequately supports the program? If data collected is non-RPMS based, does the proposal describe how such data will be submitted to IHS/HQ—2 Points;
- Describe the local evaluation process in sufficient detail—2 Points.

#### National Evaluation Plan Capacity (10) Points

- State a willingness to participate in a nationally coordinated program focusing on increasing access to methamphetamine and/or suicide prevention or treatment related activities—5 Points;
- State a willingness to attend a minimum of one mandatory MSPI meeting per fiscal year—2 Points;
- State a willingness to participate in monthly/quarterly MSPI awardees conferences—3 Points.

### 2. Review and Selection Process

Each application will be reviewed by the DGO for eligibility, compliance with the announcement, and completeness.

Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that meet eligibility requirements, are complete, and conform to this announcement will be subject to the competitive objective review and evaluation by an Ad Hoc Review Committee of Tribal, IHS, and other Federal or non-Federal reviewers. Applications will be reviewed against criteria. Reviewers will assign a numerical score to each application which will be used to rank applications. The review process will be directed by the DGO staff to ensure compliance with HHS and IHS grant review guidelines.

In addition, the following factors may affect the funding decision:

- Geographic diversity.

IHS will provide justification for any decision to fund out of rank order.

### 3. Anticipated Announcement and Award Dates

Awards will start on August 14, 2009.

## VI. Award Administration Information

### 1. Award Notices

The Notice of Award (NoA) will be initiated by DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer and this is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document. Applicants who are approved but unfunded or disapproved based on their Objective Review score will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted.

### 2. Administrative and National Policy Requirements

Grants are administrated in accordance with the following documents:

- This Program Announcement.
- 45 CFR Part 92, "Uniform

Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments," or 45 CFR part 74, "Uniform Administrative Requirements for Awards to Institutions

of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations.”

- HHS Grants Policy Statement, January 2007.
- OMB Circular A–87, “State, Local, and Indian Tribal Governments,” (Title 2 Part 225) or OMB Circular A–122, “Non-Profit Organizations,” (Title 2 Part 230).
- OMB Circular A–133, “Audits of States, Local Governments, and Non-Profit Organizations.”

### 3. Indirect-Cost Requirements

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to 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 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 DGO at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) <http://rates.psc.gov/> and the Department of the Interior (National Business Center) <http://www.nbc.gov/acquisition/ics/icshome.html>. If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443–5204.

### 4. Reporting

**Progress Report.** Semi-annual and annual report are required. A format will be provided. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. Copies of any materials developed shall be attached. Semi-annual progress reports must be submitted within thirty (30) days of the end of the half year. An annual report must be submitted within thirty (30) days after the end of the 12 month time 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.

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 organization or the individual responsible for preparation of the reports.

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

### VII. Agency Contact(s)

We encourage inquiries concerning this announcement.

For program technical assistance, contact: Bryan E. Wooden, LICSW, LCSW–C, DCSW, Office of Clinical and Preventive Services, Director (Acting), Division of Behavioral Health, 801 Thompson Avenue, Reyes Building, Suite 300, Rockville, Maryland 20852, Telephone: (301) 443–2038, e-mail: [bryan.wooden@ihs.gov](mailto:bryan.wooden@ihs.gov).

For financial, grants management, or budget assistance, contact: Kimberly Pendleton, Senior Grants Management Officer, 801 Thompson Ave, Reyes Bldg, Suite 360, Rockville, MD 20852, Telephone: (301) 443–6290, e-mail: [kimberly.pendleton@ihs.gov](mailto:kimberly.pendleton@ihs.gov).

### VIII. Other Information

This and other IHS funding opportunity announcements can be found on the IHS Web site, Internet address: <http://www.ihs.gov>. Click on “Funding” then “Grants and Cooperative Agreements.”

Dated: June 26, 2009.

**Yvette Roubideaux,**  
Director, Indian Health Service.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Office of Clinical and Preventive Services, Division of Behavioral Health; The Methamphetamine & Suicide Prevention Initiative for American Indian and Alaska Native Youth

*Announcement Type:* New.

*Funding Announcement Number:* HHS–2009–IHS–METHY–0001.

*Catalog of Federal Domestic Assistance Number(s):* 93.933.

**DATES:** *Key Dates:* *Application Deadline Date:* July 31, 2009.

*Review Date:* August 6–7, 2009.

*Earliest Anticipated Start Date:* August 14, 2009.

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### I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Methamphetamine & Suicide Prevention Initiative (MSPI) for American Indian and Alaska Native (AI/AN) Youth (MSPI–Y). This program is authorized under the Snyder Act, 25 U.S.C. 13, and 25 U.S.C. 1602(a) (b)(9)(11)(12); 25 U.S.C. 1621h(m) of the Indian Health Care Improvement Act (IHCIA), as amended. This program is described at 93.933 in the Catalog of Federal Domestic Assistance. The purpose of the MSPI–Y is to expand community-level access to effective methamphetamine and suicide prevention programs through Tribal, youth residential, transitional/discharge, and aftercare services. Resources will enhance existing transitional/discharge and aftercare programs with a specific focus on methamphetamine and suicide prevention. Funding for the MSPIY will be used to:

- Provide community-focused response grants that would allow Tribes and Tribal organizations to utilize the resources to enhance transitional/discharge and aftercare programming focused on methamphetamine and suicide prevention for youth discharged or who have the expectation of discharge from a residential setting to maintain sobriety within their home community.